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Advancing process evaluation oresearch within the filed of neurological rehabilitation

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Advancing process evaluation research within the field of neurological rehabilitation

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Abbreviations

ABI – Acquired brain injury

ADL – Activities of daily living

ANOVA – Analysis of variance

ASSIA – Applied Social Sciences Index and Abstracts

CENTRAL – Cochrane Controlled Trials Register

CFIF – Consolidated framework for implementation fidelity

CFIR – Consolidated framework for implementation research

CINAHL – Cumulative Index to Nursing and Allied Health Literature

CIR – Critical incident report

CMO – Context - Mechanism - Outcome configuration

COPM – Canadian Occupational Performance Measure

COTiD – Community Occupational Therapy in Dementia study

CP – Cerebral palsy

CRD – Centre for Research and Dissemination (York, UK)

DORIS – Database of Research Into Stroke

EBP – Evidence based practice

EPPI-Centre – The Evidence for Policy and Practice Information and Co-ordinating Centre

HTA – Health Technology Assessment

ICF – International Classification of Functioning, Disability and Health

iCMO – Initial Context-Mechanism-Outcome configuration

JBI – Joanna Briggs Institute

MeSH – Medical Subject Headings

MRC – Medical Research Council

MS – Multiple sclerosis

NGT – Nominal group technique

NHS – National Health Service

OPERA – Older People's Exercise intervention in Residential and nursing Accommodation study

OT – Occupational therapist/occupational therapy

OTCH – Occupational therapy in care homes study

PD – Parkinson's disease

PEDro – Physiotherapy Evidence Database

RCT – Randomized controlled trial

SSCI – Social Sciences Citation Index

TA – Thematic analysis

TBI – Traumatic brain injury

TRACS – RCT study looking at the benefits of a structured programme for caregivers of inpatients after stroke

WHO – World Health Organization

Outputs

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Abstract

There is a pressing need for rehabilitation researchers to further develop their understanding around the complex interventions they deal with on a daily basis. Prevailing methodological approaches, such as pragmatic RCTs, often fail to address the challenges resulting from the complexity of these neurological rehabilitation interventions, specifically in relation to fidelity. Furthermore, the need for an evidence-based client centred approach has inevitably led to an impact on the fidelity of trialled rehabilitation interventions and therefore a potential impact on trial outcomes. Process evaluations are regarded as effective at investigating why and how does an intervention work or fail. To date, there is very limited guidance to help rehabilitation researchers design and conduct one. Thus, there is a strong need to advance the development of process evaluation research within the field of neurological rehabilitation.

Study aim

The aim of this study is to advance thinking and practice in process evaluation and clinical trial methodology within the field of neurological rehabilitation.

Methods

Realist evaluation principles were used to carry out the process evaluation of a complex occupational therapy intervention within stroke rehabilitation. Data comprised in depth interviews (n=17), critical incident reports (n=20) and 'Intervention Log' records. In addition to this a systematic review that applies a two stream (research evidence and methodological evidence) mixed evidence synthesis was completed in order to investigate how process evaluations are currently being carried out alongside neurological rehabilitation research. Finally, a formal consensus development process, based on a modified Nominal Group Technique involving an expert panel (n=10) was chosen to produce a process evaluation methodological guidance.

Findings:

Results from this work have contributed to the body of evidence in a number of ways. Firstly, by providing evidence to support the need for the modification of the Consolidated Framework for Implementation Fidelity (CFIF) in order to include a 'learning over time' component. Secondly, by advancing programme theory of fidelity to inform process evaluation research and design. The proposed programme theory, comprising four areas (balancing act, building rapport, re-engineering of the environment and learning over time) are new in that they meld hypotheses embedded within the therapeutic components of the intervention and from its broader implementation. This refined programme theory is transferable and can be applied by other rehabilitation researchers embarking in the design and conduct of a process evaluation. Thirdly, the results presented here contribute to the realist evaluation body of knowledge by providing new evidence of its successful and fruitful application to inform rehabilitation process evaluation research. Finally, this thesis includes a new guidance to assist researchers at the time of designing and conducting process evaluations alongside trials of complex rehabilitation interventions.

Recommendations:

A number of recommendations for research and policy have been identified: (1) Rehabilitation researchers should pay close attention to the potential impact that learning over time, intervention tailoring, staff level of experience and training can have on trial process and outcomes. (2) More research is necessary in order to further investigate and support the potential role and applications of realist evaluation principles to RCT rehabilitation research. (3) Future government and research funding policies produced to inform the investigation of complex interventions should address their inherent multi-component nature; Funding agencies should include process evaluations as one of the eligibility criterion that researchers have to fulfil in order to be able to apply for funding.

CHAPTER 1:

Setting the scene

1.1 Introduction to this thesis

This thesis provides an important contribution to the field of neurological rehabilitation research. Current neurological rehabilitation research is under pressure to produce high quality evidence on how and why complex rehabilitation interventions work (or fail). The investigation of implementation fidelity has been identified as an important component of implementation which needs to be addressed. However to date there is little evidence on how to assess it when dealing with the challenges inherent to complex rehabilitation interventions. The results presented in this thesis are an attempt to bridge this gap. This thesis provides a new methodological lens and it reports on a new conceptualization of fidelity and its impact on process evaluation in the context of neurological rehabilitation research.

This chapter provides an overview of the main issues that are currently shaping the development of rehabilitation research. It aims at providing a detailed illustration of the inherent complexity of rehabilitation interventions and how this complexity impacts on the ways in which researchers make decisions about how they design their evaluations. In line with this, this chapter provides a brief overview and reviews current frameworks for the investigation of implementation and implementation fidelity. Finally, a review of the concept of process evaluation and how it can contribute to fidelity research is provided. This chapter concludes with the study's main aims and objectives and a brief summary of the content of each chapter.

1.2 The evidence-based context of healthcare research

Healthcare professionals have a responsibility to provide best possible care for every patient and thus they need to have a good understanding of conditions and their prognosis in order to make a diagnosis and decide on the

appropriate therapy plan (Hush and Alison 2011). Until the 1990s these decisions were primarily based on knowledge from practice, clinical intuition and experience (Gibson and Martin 2003). In the 1990's healthcare research disciplines moved towards the 'evidence-based' healthcare paradigm (Hush and Alison 2011). This meant that decision-making underpinned by evidence became imperative; healthcare disciplines then increasingly adopted a philosophy that the choices for patient care should be based on the best available and most up to date evidence (Rycroft-Malone 2001, Gibson and Martin 2003).

Upshur (2001, p.7) defines evidence as: "*an observation, fact, or organised body of information offered to support or justify inferences or beliefs in the demonstration of some proposition or matter at issue"*. A number of limitations to this evidence based approach have been reported. Upshur (2002) criticized evidence based practice (EBP) for excluding intuition or experience as 'ways of knowing'. Baumann (2010) discusses that for example EBP guidelines fail to adequately represent the true complexity of clinical situations and therefore their usefulness is limited when professionals have to make decisions about specific individuals. In regards to the availability of evidence, Saver and Kalafut (2001) argue that evidence is likely to lag behind evolving health conditions impacting on a diverse and changing population. Regardless of these opinions, very few would argue strongly against it. It is widely considered the best available practice model to follow, primarily because as it is founded on clinical research evidence it is likely to be the least biased (Herbert et al. 2001, Rycroft-Malone et al. 2004, Hush and Alison 2011). This is also the case for rehabilitation professions where a number of authors have stated that the quality of patient care is better when evidence is used to inform decisions (Iles and Davidson 2006, Heiwe et al. 2011).

The progression of healthcare research towards evidence based practice is inevitably shaped by what is counted as evidence. The question at hand is what the different forms of knowledge are and what is considered valid evidence (Gibson and Martin 2003). Sackett et al. (1996) propose a model where evidence-based practice should aim to integrate research evidence and

knowledge from clinical practice experience (expertise) and patients' perceptions and preferences. In other words, their model states that evidence-based practice should not replace clinical experience and judgment, it should build on it. Despite this model, evidence-based practice is commonly critiqued as being a 'cookbook approach' which devalues clinical experience and ignores patients' preferences (Straus and McAlister 2000, Hush and Alison 2011). Furthermore it is often accused of following a very strict hierarchy of best evidence, placing randomized controlled trials (RCTs) at the top and relegating other evidence to a secondary role. These criticisms have embraced a need for a broader definition of evidence-base in healthcare research (Upshur 2001, Rycroft-Malone et al. 2004) and rehabilitation research (Bennett and Bennett 2000, Herbert et al. 2001).

Current healthcare research faces a number of challenges such as increasing patient expectations, financial constraints, a strong risk-aware culture and a high degree of managerialism (Rycroft-Malone et al. 2004). As a result the traditional approaches to evidence-based practice are being challenged. In answer to this, Rycroft-Malone et al. (2004) proposed a definition of evidence which not only included external sources such as research evidence but also internal sources such as clinical experience, patients' experience and finally an understanding of the local context. In line with this, several authors are moving towards an approach which considers that evidence-based practice should be an interaction of both, contextual and purely mathematical evidence (Gibson and Martin 2003, Hush and Alison 2011). As Roberts (1997) puts it: "*Not everything that counts can be counted"*. This, has led to an active debate, currently taking place in healthcare research and more specifically in rehabilitation research, on what are the most appropriate and efficient ways of producing high quality evidence to show the effects of interventions which are often complex and multi-layered. A review and critique regarding current rehabilitation research follows.

1.3 Rehabilitation research

1.3.1 The purpose of rehabilitation - brief historical overview

The word rehabilitation has its origin in the Latin words 'to make fit again'. Whilst the idea of rehabilitation has been around for centuries, going back to ancient Greece, it was the struggle against polio around 1916 coupled with the two World Wars that led to its acknowledgement as playing a role in re-establishing people with disabilities and injured soldiers (Rusk 1958). The 1950's was a critical time for the development of rehabilitation disciplines in terms of gaining independence and autonomy. Since then and during the next 50 years rehabilitation professionals (initially considered physiotherapists, occupational therapists and speech and language therapists) found new opportunities and more options to improve patient function with fast developments in interventions (Gritzer and Arluke 1985).

Rehabilitation was traditionally defined as a secondary intervention which aimed at 'restoring' patients as far as possible to their previous condition after injury or disease (Tunbridge 1972). This definition was based on a medical model approach and assumed that disability was permanent and rehabilitation aimed at helping the patient adapt or compensate for it. In this traditional model rehabilitation was separated and distinct from medical treatment (Waddell and Burton 2004) and a patient was seen as "*a passive subject to whom treatment is applied by a doctor or therapist"* (Ward and McIntosh 2003, p.17).

Since the early 1970s there has been wide recognition that rehabilitation is not simply a medical matter and its model has shifted from being 'disability focussed' to being firmly set on the promotion of participation with a strong emphasis on the individuals' unique needs and their surrounding social contextual systems (Barnes 1991, Levin et al. 2009). This shift has been supported by the World Health Organization (WHO) in its published *International Classification of Functioning, Disability and Health* (ICF) (2001) and its more recent *World Report on Disability* (2011). These publications draw attention to environmental factors as a vital dimension of disablement (Ward and McIntosh 2003).

To date there is no generally accepted definition of rehabilitation. Ward and McIntosh 2003 (p.15) define it as: "*the active participation of a disabled person and others to reduce the impact of disease and disability on daily life"*.

Hammell (2006, p.8) further addresses the aims of rehabilitation by defining it as:

> "*a process of enabling someone to live well with an impairment in the context of his or her own environment and, as such, requires a complex, individually tailored approach".*

In summary current rehabilitation's core objective is to restore and recover, to the maximum degree possible, not only function and premorbid movement patterns but also the individual's role in society (social participation) (Nocon and Baldwin 1998). In this way, it requires both therapeutic and social interventions which address clinical problems but also individual's physical and social environment (Waddell and Burton 2004). As a consequence rehabilitation can be described as a 'mixed field' with some professionals and researchers working at reducing impairment and others focussing on promoting participation. This, amongst other aspects linked to rehabilitation interventions constitutes a challenge in itself.

1.3.2 Current challenges in rehabilitation research

Rehabilitation research shares the challenges currently being addressed in healthcare research. However, this chapter will now review a number of specific characteristics inherent to rehabilitation interventions which make their research particularly demanding.

1.3.2.1 Rehabilitation interventions are complex

Rehabilitation interventions are often complex (Robinson et al. 2005, Redfern et al. 2006). Complex interventions can be defined as those made up of a number of components or *active ingredients* that interact with each other and with outside factors to bring about changes to outcomes (MRC 2008). Complex interventions are regarded as having inherent heterogeneity (Horner et al. 2006). They will often be offered multiple times to multiple participants, the location and site of delivery can change as well and they can be delivered to individuals, families, combinations, etc. (Santacroce et al. 2004). Similarly, they are designed in a number of sessions to allow time for individuals to learn

and comprehend their content (Kern and Prinz 2002). As a consequence it can be extremely difficult to know why a complex intervention worked (or not) without examining all underlying components (Grant et al. 2013).

In the year 2000 the Medical Research Council (MRC) published a *Framework for the Development and Evaluation of RCTs for Complex Interventions* (MRC 2000). This publication was considered ground-breaking since it acknowledged the fact that many innovative health interventions in areas such as social policy, education and public health practice amongst others were made up of more than one singular element (Cohn et al. 2013). As Cohn et al. (2013, p.41) reported, "*the framework presented an analytical problem requiring fresh thought from the research community"*. The MRC reported in their initial framework and in more recent guidelines (MRC 2008) that these interventions with several interacting components aiming to target a number of different outcomes present a number of additional problems and challenges which the evaluator must overcome.

The proposed MRC framework and guidelines (2000, 2001, and 2008) suggest a number of phases that define the complex intervention research process. They state that evidence is ultimately embedded within an RCT design. The first three phases are preparatory and aim at developing the intervention prior to conducting the RCT. During the pre-clinical stage the theoretical basis of the intervention is established, stage I involves modelling and inclusion of service users' views and opinions into the theoretical framework. Stage II is the feasibility study and stages III and IV are the trial and long term implementation respectively. The framework does not provide details as to which research methods should be used but it does explain what the research should be asking at each stage in order to make sure the chosen method is appropriate to find the answer. This framework has already been applied to a number of research projects belonging to a wide variety of disciplines such as stroke research (Tilling et al. 2005, Robinson et al. 2005). According to Craig and Petticrew (2013) the guidance has been strongly influential. They reported that by mid-2012 the MRC 2008 guideline had been cited almost 230 times and the original 2000 guidance nearly 700 times.

How to evaluate and describe complex intervention components (described as active ingredients) is the target of an ongoing debate (Campbell et al. 2007, Craig et al. 2008 and Clark 2013). A wide community of authors openly defends the MRC's approach of identifying and describing intervention components as a feasible way of evaluating a rehabilitation intervention without compromising its complex nature (Robinson et al. 2005). However, some authors (Hawe et al. 2004a, Anderson 2008, Cohn et al. 2013, Richards 2015) explain that reducing a complex system into simply the sum of its parts might 'make it lose its essence' since it solves the problem of complexity in a mechanical way. They argue that it is the properties of the interactions between these components that create complexity. Following Glouberman and Zimmerman's (2002) work, Marchal et al. (2013) argue that whilst complicated problems are formed of a number of parts, that can be solved using identified formulae and instructions, complex problems however rarely benefit from these tools, since they are uncertain. Complex problems are therefore solved allowing time for learning about each component and for making sense of events taking place (Marchal et al. 2013). Thus, the evaluation of complex interventions represents a great challenge since the path that these interventions follow to success is variable and cannot be accurately predicted (Rogers 2008). Rogers (2008) suggests, as a vital early step, identifying intervention components and classifying them as either complicated or complex. Byng et al. (2008) further explain that amongst these components, those that are key or essential will need to be addressed since it will be them that will most likely vary and manifest themselves in different ways depending on the context.

Furthermore, interactions between components and their impact on outcomes need to be understood in the context of a research trial; failure to do this may inevitably lead to uncertainty at the time of implementation (Byng et al. 2008). Authors such as Clark (2013) discuss, that to date, issues around complexity and its components are often present in the literature but they are often identified and described 'ambiguously or vaguely'. He further explains that this can lead to "*theoretical and ontological ambiguities, lack of methodological transparency and potentially, resistance to the wider movements towards*

complex interventions" (p.185). In his work he explains that it is necessary to theorize the chosen approach to the components in terms of their individual and combined power and their relation with the power of the intervention as a whole.

Regardless of ongoing debates there is consensus in the fact that it is the multi-component nature of complex rehabilitation interventions that makes defining what it is about the intervention that works, and how, very challenging, even when the intervention leads to successful outcomes and significant responses (Redfern et al. 2006).

1.3.2.2 Limited theory development in rehabilitation

"Rehabilitation has long lacked a unifying conceptual framework" (WHO 2011, p.95). Hammell (2006) describes how rehabilitation professionals share a number of assumptions regarding the nature of their work (e.g. needs to be apolitical, relevant and useful), the nature of their goals (e.g. to increase function, independence and quality of life) and the nature of the relationship with the client (e.g. must to be holistic and client-centred). Whyte et al. (2009) point out that contrary to basic assumptions a rehabilitation theory would be highly valuable in terms of describing and identifying not only hypothesized active ingredients of an intervention but also the mechanisms through which each of these active ingredients will have an impact (Nixon and Creek 2006). Hence, it can inform researchers' choices of exclusion/inclusion criteria and outcome measures. Despite all this, it is widely accepted across rehabilitation researchers that many areas of rehabilitation are theoretically underdeveloped (Carpenter and Suto 2008) and as a result there is a growing need for a comprehensive theory of rehabilitation (Forsyth et al. 2005, Graham and Cameron 2011, Reinhardt 2011). According to some authors the rehabilitation field should invest the same level of energy and resources in developing well-articulated theories and consequent theoretical models that it invests in empirical research (Whyte 2008). However, this is not the case; authors such as Forsyth et al. (2005, p.261) explain that rehabilitation professionals have been distracted by the idea that "*practical action flows naturally from basic knowledge"* and not theories. Carpenter and Suto (2008), further argue that,

in order for professionals to choose to apply and use theories to guide their decisions, these would need to be more ‘real’ and more grounded in clients’ lives and experiences.

In the year 2001 the ICF was published (WHO 2001). Its aim was to provide an international and interprofessional basis for studying and understanding health which could be used to compare data across countries for, amongst others, the purpose of research and development of health policy. Work on the ICF was a response to the disability rights movement which put forward the social model of disability. This model showed the environment as the true cause of disability (Barnes et al. 2000). Emerging from this movement the ICF increased its emphasis on environmental factors and shifted its focus from the cause of the disease to its impact on functioning (Alford et al. 2013). The ICF is 300 pages long and covers 484 body functions, 294 body structures, 382 activities and participation items and 253 environmental factors. It is organized in two parts, one covers contextual factors (environmental and personal) and the other functioning and disability. The concept of participation plays an important role in the ICF classification as well as in rehabilitation (Hemmingsson and Jonsson 2005) and is defined as the individuals’ involvement in everyday life situations. The ICF is considered to provide a shared understanding of disability that can support, amongst others, rehabilitation researchers since it is in line with the views of the disability rights movement (Hurst 2003).

The ICF has not been free of criticism. Rehabilitation researchers have argued that its theoretical underpinnings are not clear enough and need further development (Imrie 2004). Also, authors such as Barnes et al. (2000) criticized the ‘classification’ component of the ICF since they consider that it is the practice of ‘classifying’ people that leads to stigmatization of people with disabilities. Regardless of the criticisms, its contribution to rehabilitation, looking beyond the physical impairments towards a participatory approach aware of the interaction between the health condition and social, personal and environmental factors, is widely agreed (Quintas et al. 2012, Alford et al. 2013). Furthermore, it has been a successful tool for conceptualizing the

characteristics and the experiences of people with a wide range of health conditions (Alford et al. 2013).

Since rehabilitation is a very broad discipline, the question of how many theories, if more than one, are needed to guide its research and practice has been presented (Whyte 2008). According to Whyte (2008), the ICF model of human functioning (WHO 2001) is far from being a theoretical model and further points out that it would be very difficult to come up with a single theoretical model of the enablement and disablement process. The solution he proposes involves different research groups 'building' specific pieces which can then be united in the form of an overall model or larger framework of enablement and disablement. As he puts it:

> "*It is self-evident that no single theoretical framework can account for changes in organ structure and function, changes in activity performance, and changes in the social and physical enforcement. Rather, we will need to seek different tools for change in these different domains"* (p.208).

Finally, Whyte says that there are many well developed theories that would be relevant to rehabilitation such as learning theories on procedural memory or practice-based skill learning, theories of goal setting and self-management or theories of diffusion of innovation (Rogers 2003).

1.3.2.3 Limited evidence based research

As Groah et al. (2009, p.943) state when discussing rehabilitation there is "*a gradual change in emphasis, in part led by the EBP movement, toward greater quality and value of health care and the research that drives it"*. In line with this, a challenge facing rehabilitation research is that to date, the assumptions underpinning rehabilitation professionals' decisions lack in evidence base support (Carpenter 2004, Groah et al. 2009). As the population is aging, and advances in medicine are improving survival rates and life expectancy, the need for rehabilitation services as part of a health care system has increased and will continue to do so (Whyte et al. 2009). As a result, rehabilitation treatments can be expected to become more critical (Institute of Medicine 2007) and the push towards evidence based decision making more

accentuated. In regards to how the field of rehabilitation has embraced EBP, Cicerone (2012, p.188) points out that:

> *"The notion of an evidence-based approach to rehabilitation has not always been accepted, and is not always so readily accepted today, but it has assumed a more central role in how we think – and maybe how we provide treatment".*

Rehabilitation accomplishments are difficult to evaluate and despite their importance there is sparse evidence to support the efficacy and efficiency of treatments (Whyte et al 2009). As a consequence the development of innovative interventions and programmes is being slowed down (Tate 2006). As Grabois (2007, p.409) puts it, there is a "*lack of evidence-based research to prove what we do really works"*. Several reasons for this, such as inadequate funding and not enough trained researchers, have been identified (Tate 2006, WHO 2011). However, the inherent complexity of rehabilitation interventions which makes their evaluation highly challenging has been considered the main reason behind the lack of available evidence (Whyte 1997). In summary:

- ✓ Rehabilitation research often involves complex behavioural treatments in contrast to passive or surgical treatments (Hart and Bagiella 2012).
- ✓ It is often very difficult to define the rehabilitation intervention in detail in terms of what are its 'active ingredients'.
- ✓ Rehabilitation interventions are often delivered face to face, where interactions therapist/patient play a vital role
- ✓ Rehabilitation interventions and linked treatment plans will need to be tailored to patients' needs.
- ✓ Rehabilitation research is often context specific and defined as the interaction between the individual and the environment (Townsend 2002). In other words, identifying contextual processes (physical, psychological, social, etc.) and acknowledging that researchers bring their values into situations is of great importance when thinking about the science of rehabilitation.

- ✓ Rehabilitation outcome measures are varied and complex, there is no agreed taxonomy (Dejong et al. 2004). Rehabilitation research will often use several measures and will involve a multidisciplinary team.
- ✓ Samples sizes are often too small (WHO 2011) since the range of disabilities is very extensive and diversity of conditions is high. Thus, rehabilitation research is often highly individualized to a small homogeneous group of people.

1.3.3 Evidence in rehabilitation research

The following section in this chapter will explore how rehabilitation researchers have 'gone about' obtaining evidence. A critique on the development of health research, and rehabilitation research in particular, from the early start of clinical trials to the worldwide recognition of RCTs as 'gold standard' follows.

In 1983 Pocock explained that *"properly conducted clinical trials, which follow the principles of scientific experimentation, provide the only reliable basis for evaluating the efficacy and safety of new treatments" (p.1).* His definition of what is meant by 'clinical trial' was:

> *"The term may be applied to any form of planned experiment which involves patients and is designed to elucidate the most appropriate treatment for future patients with a given medical condition"* (p.1)

As Pocock (1983) wrote, one of the essential characteristics of a clinical trial should be the use of a sample of patients to make generalizations regarding the treatment of the general population. Although originally a large majority of clinical trials evaluated drug therapy, they now are the means to evaluate a multitude of other aspects in health research such as surgical procedures, patient management, alternative therapies etc.

A clinical trial will start off with a 'good idea' which proposes the use of an innovative therapy or treatment that not only looks like it has a chance to work but is also realistic (Pocock 1983). Secondly, the researcher will then need to compare a group of patients receiving the proposed innovative treatment with

a control group that is receiving standard care (or alternatively remains untreated). Finally, patients will need to be assigned to one group or the other randomly. Clinical trials are considered to follow the steps of *the scientific method*. In his book Pocock (1983) illustrates how this takes places: the clinical trial must describe a starting hypothesis to be tested, exactly the type of patient it is targeting, the proposed treatments and finally how potential effects are going to be evaluated avoiding bias. Statistical methods should then be applied to test the hypothesis and assess the strength of the evidence regarding 'response to treatment'. The final step will involve interpreting findings from the data, drawing conclusions and arguing their relevance to the wider field.

1.3.3.1 From clinical trials to RCTs

Although it is possible to go back to prehistoric times and identify human attempts to assess the efficiency of therapies and treatments (Bull 1959), it is only since the 1950s that the great development and the acceptance of clinical trials, as we know them, has taken place, partly due to the pioneering work of the MRC during the 20th century.

The Bible describes the first record of a clinical trial (Bhatt 2010). It was carried out by a military leader during his rule in Babylon. It happened as a result of him making his troops eat only meat and drink only wine. Because some objected, he decided to allow this group to eat vegetables and water for ten days. Those in this last group appeared healthier and better nourished, thus he permitted them to continue with this diet. It was the first ever recorded uncontrolled human experiment which resulted in changes in public health (Collier 2009).

It was Dr Lind (1716-1794) in the 18th century who was the first physician to conduct a controlled clinical trial in the modern era. He treated twelve patients with scurvy on board the Salisbury at sea. A number of different diets were offered to the different treatment groups. His results showed clear benefits of a diet including lemons and oranges (Twyman 2004). Although his results appeared conclusive it took another fifty years for the British navy to take it on

board and supply lemon juice to its sailors. This delay has remained a feature to the present date.

Most pre-20th century experiments had no base in the scientific method. Louis (1834) was one of the first researchers to use the 'numerical method' to assess the efficacy of treatments. He also described the need for accurate observations of impact of treatments on patients, the need to understand well the progress of the illness in untreated groups and the need to have a detailed description of the characteristics of the disease prior to treatment (baseline observations). Finally he argued the need to observe any changes or deviations from the intended treatment under study. Louis' work (1834) on the value of bleeding as a treatment for pneumonia found no positive effect, and contradicted current practice at that time in France. His work greatly influenced clinical practice and he can be considered a founding figure in regards to laying the basis of the application of the scientific method to clinical trials.

The first double blind controlled trial was carried out by the MRC in the UK in 1943 to investigate the treatment of common cold using patulin (Hart 1999). It was one of the last trials that carried out non-randomized allocation of participants. It enrolled over a thousand British office and factory workers suffering from colds and it was very efficiently controlled to make sure the physician and the patient were blinded to the treatment. The results of the trial didn't show any significant effective impact of patulin (Hart 1999).

It is widely accepted that the first randomized controlled group clinical trial was carried out by the MRC in 1946, investigating the use of streptomycin in pulmonary tuberculosis (MRC 1948). As Hart (1999) explains, it was the very limited amount of streptomycin available from the USA at that time that made the decision to not treat the control group ethically justifiable. Dr Hill (the trial's statistician) instituted randomization and described it in detail in the landmark publication by the MRC (1948). This trial was a turning point and Hill's reports and published work on fundamental concepts such as concurrent controls, randomization, patient eligibility, treatment protocol etc. (Hill 1962) have become a pillar for the conduct of clinical trials as we now know them (Pocock 1983).

Although RCT research has radically influenced public health decision making, the importance placed on replication has stopped single trials with unexpected findings changing medical opinion and clinical practice. For example, in 1961, a randomized multi-centre trial testing the use of tolbutamide, variable dose insulin, standard dose insulin and placebo for the treatment of diabetes led to the testing with tolbutamide to stop due to highly significant differences in cardiovascular mortality between tolbutamide and placebo groups (Bhatt 2010). The trial results reported evidence that the risk of taking tolbutamide was moderately strong. However, tolbutamide is used to date for the treatment of diabetes, although not routinely due to a higher incidence of adverse effects compared to newer drugs.

Clinical trials looking at aspects of patient management have also been carried out during the last 30 years. Work by Rawles and Kenmure (1980) looked at the benefits of immediately admitting patients with myocardial infarction to a coronary care unit or treating the patients at home. Although their results showed no significant difference in patient mortality they did identify the need for improving the speed in which a patient is admitted to hospital. In this way RCTs have been extremely valuable in providing objective evidence to inform the implementation of new policies.

1.3.3.2 Explanatory and pragmatic trials

As already explained clinical trials are to date the main tool used to test and evaluate interventions. It is important to dedicate some time to explain the differences between the two broad categories into which these fall: pragmatic trials and explanatory trials. This distinction was already established by Schwartz and Lellouch (1967) forty years ago when they discussed the applicability of trial results beyond the ‘artificial environment of the trial’.

Explanatory trials have been defined as those that aim to evaluate an intervention in a controlled, well defined setting; they aim to test whether an intervention works (or does not work) under optimal situations. The whole experiment is designed in a way that controls for all possible confounders so that the potential impact of the intervention is maximised (Patsopoulos 2011).

However, realistically healthcare interventions can seldom be controlled (Lee et al. 2001). A pragmatic trial, on the other hand, aims at testing interventions in 'real life' context, in other words, using everyday clinical settings, making it essential that all levels of context factors be described to understand changes in outcomes (Kaplan et al. 2010, Krist et al. 2013). This is believed to maximize its applicability and generalizability (Patsopoulos 2011). Pragmatic trials are aimed at informing heath and policy decisions (Treeweek and Zwarenstein 2009). This need for applicability has been voiced not only by those interested in the efficiency of clinical problems (Rothwell 2006) but also those involved in health policy (Tunis et al. 2003).

Drawing a line between an explanatory and a pragmatic trial is not an easy task since most trials will have aspects of both (Patsopoulos 2011). Thus there is no clear line, but a *continium*. Thorpe et al. (2009) published the pragmatic-explanatory continuum indicator summary (PRECIS). This tool has 10 dimensions that help researchers designing trials do it in a way that is in line with the purpose of the trial. Patsopoulos (2011) carried out a MEDLINE search with the words 'pragmatic' and 'naturalistic' along with the word 'trial'. This search showed a vast increase in hits since the 1970 up to 2011 and this can be seen as a clear indication that the field of healthcare research is moving towards a pragmatic approach. However, several authors have reported that there is still a role for explanatory trials and that although a trial can be designed to have some components that are more pragmatic than explanatory, and vice versa, there are trials that must lean towards the explanatory end of the explanatory-pragmatic *continium* (Treeweek and Zwarenstein 2009, Patsopoulos 2011). Such is the case of most new interventions when they are first trialled and cause-effect relationships have been identified. Thus, it can be understood that pragmatic trials are not meant to replace explanatory trials but complement them. Treeweek and Zwarenstein (2009) explain that a more pragmatic trial might be the most appropriate starting point when the researchers are investigating an intervention that is not well understood. If subgroup analysis shows a significantly interesting impact in a particular group of patients, then a more explanatory trial within this particular group could follow.

Although there is a need for more trials with a pragmatic attitude, authors such as Treeweek and Zwarenstein (2009) state that there is a further need to summarize existing evidence on the applicability of trials, not only in their own context, but also their relevance to other contexts. Thus, there is a need to work on developing a methodology to address contextual factors and their potential impact on the applicability of trial results. This is in line with the scope and aims of this thesis which will be described at the end of this chapter.

1.3.3.3 Rehabilitation research RCTs

As already mentioned there is a growing expectation for rehabilitation professionals to develop and use evidence-based treatment methods. In order to do this rehabilitation researchers need to understand how to design and carry out high quality clinical trials (Hart and Bagiella 2012, Behrman et al. 2013). The number of rehabilitation research RCTs carried out rose dramatically from 2000 to 2005. During this period, this field published half of what had been published since 1950 (Tate 2006). Neurological rehabilitation RCTs on brain injury and multiple sclerosis made up 24% and 14% respectively of all rehabilitation RCTs (Tate 2006). Although there is wide variability in rehabilitation research designs, at present RCTs are considered the 'gold standard' in order to test the efficacy of a treatment (Blackwood et al. 2010, Friedman et al. 2010). As a consequence many other study designs, which could potentially be more advantageous at proving the effectiveness of a treatment, are being rejected, in order for example to, increase the chances of success when applying for funding (Whyte et al. 2009, Whyte and Barrett 2012).

The debate as to whether healthcare complex interventions can and should be tested using RCTs is an ongoing one (Wells et al. 2012). Several authors have considered that evaluating what in the complex intervention worked, what interactions took place and how these outcomes have been influenced is a challenging task which RCTs can fail to achieve (Campbell et al. 2000, Langhorne and Dennis 2004, Grossman and McKenzie 2005, Byng et al 2008). As Byng et al. (2008) argue, contextual factors play a major role in shaping impacts on outcomes. The implementation of complex interventions

will inevitably require different doses and structures in place and as a result will not be ‘set in stone’. To the contrary, it is likely they will be constantly developing, just as health services are. Thus, RCTs might not be the answer (Hawe et al. 2004a). In line with this, Whyte et al. (2009) report that the rigor and the tight focus on efficacy which comes hand in hand with designing an RCT, can be of disadvantage to the research of complex rehabilitation interventions. These interventions are often delivered during periods which can last weeks or months and this can challenge, for example, guidelines for implementation amongst other things (Cheeran et al. 2009).

During the last decade a number of rehabilitation RCTs have failed to prove the effectiveness of promising rehabilitation interventions. Logan et al. (2003) found no evidence of the benefit of OT leisure interventions for community stroke patients. More recently another RCT looking at the impact of a community exercise programme for people with long term neurological conditions failed to increase levels of activity or have a significant impact on health and well-being measures (Elsworth et al. 2011). Finally, Forster et al. (2013) carried out a pragmatic cluster RCT looking at the benefits of a structured programme for caregivers of inpatients after stroke (TRACS study) which failed to show any significant difference in any of the assessed outcomes.

A number of factors have been reported as contributing to the difficulty in evaluating complex rehabilitation interventions via RCT methods:

Participant recruitment and retention: rehabilitation practice lacks nationally standardized sets of outcome measures and as a result researchers recruiting participants into an RCT have to use individually designed screening tools (Bherman et al. 2013). Following a recruitment criteria that is therapeutically based (Wolf et al. 2008) is a more complex, expensive and time consuming procedure than the one followed in most medical trials, which often utilise a simple chart review. Furthermore, due to the nature of the patients recruited into rehabilitation trials, researchers will need to allocate extra resources (e.g. transportation to and from research base, reminders such as phone calls, etc.) in order to maximize participant retention (Sullivan et al. 2007).

In terms of recruiting intervention staff, rehabilitation RCTs face further challenges. The skill, previous experience and knowledge of those administering the intervention can influence intervention impacts (Hart and Bagiella 2012). Similarly, the inevitable heterogeneity of trial participants in regards to previous experiences, attitudes towards the intervention or personal and demographic characteristics may further influence RCT outcomes as well (Grossman and Mackenzie 2005).

Control groups, placebos and blinding: Most RCTs require a control and a comparison treatment group. Designing a control group that is appropriate for rehabilitation research and specifically for behavioural based treatments is a complex issue which has been widely discussed in the literature (Barkauskas et al. 2005, Hart et al. 2008, Hart and Bagiella 2012). A way to define control conditions that is often used in RCTs is as 'care as usual'. This presents two main problems when designing rehabilitation RCTs (Hart and Bagiella 2012). Firstly, there might not be any 'usual' care organized for that problem and secondly it might be that there is an available 'usual care' but it is 'too broad and variable' and therefore cannot be well defined for the purpose of the trial.

By definition a 'placebo treatment' has to be 'inert', has to do no good and no harm and it has to be identical to the experimental group so it can contribute to the double blinding. This, unlike in medical trials, is very difficult to achieve in most rehabilitation RCTs (Hart and Bagiella 2012). This type of trial evaluates interventions which normally involve practicing and acquiring knowledge, not just ingesting a drug. Having a control group that receives a 'placebo' that is totally passive is virtually impossible. As suggested in the literature, if rehabilitation researchers want to create a placebo it is necessary for them to analyse the complex intervention in detail in order to identify which of its components are integral to the treatment (or integral, or essential, or active) and which are merely incidental (Patterson and Diepe 2009). This is not free of challenges because what is incidental in one treatment could be integral for another.

Treatment differentiation is vital and needs to be clearly defined *a priori* by the rehabilitation researcher. In other words, the experimental intervention and the

control intervention have to be different in the way that the trial planned it. The contents and procedures for both groups need to be clearly established which includes, as explained above, a clear identification of the active ingredients that will define the experimental intervention group. Furthermore it is very important to describe two treatment groups that are equally credible and equally delivered. Failure to achieve this will decrease the chances of achieving treatment blinding and also might impact on staff and participants who will feel more or less enthusiastic depending on what group they are allocated. This could ultimately introduce bias to the results (Whitehead 2004).

Blinding of participants and practitioners involved in a rehabilitation RCT is also very challenging. Participants recruited into a rehabilitation RCT will most likely know the intervention they are receiving and staff will need to act the same in both intervention and control groups in regards to verbal instructions, feedback, enthusiasm, contact time whilst making sure the control group are not exposed to the essential components of the complex intervention. This can be extremely difficult. However, since most rehabilitation trials do not use objective outcome measures it is critically important to have strategies in place for the blinding of the evaluator. It is possible to achieve this in rehabilitation trials by following basic precautions in terms of how to control communication between the intervention staff and the evaluators (Wood et al. 2008).

1.3.4 The case of neurological rehabilitation

The neurorehabilitation clinician, just like other rehabilitation professionals, relies on his/her judgement, communication and partnership with the patient and evidence from the scientific literature in his daily decision making (Tilson et al. 2008). An increase in research evidence regarding the plasticity of the neuromuscular system through appropriate intense training (Edgerton et al. 2004, Nudo 2006) has impacted on the work of neurorehabilitation professionals who not only work on restoring function but also on altering neuromuscular system function to achieve a therapeutic effect (Levin et al. 2009). This adds further complexity to neurological rehabilitation interventions. Regardless of the fact that there are ample examples of quality studies evaluating neurological rehabilitation interventions such as the EXCITE study

(Wolf et al. 2008), the SCILT study (Dobkin et al. 2006) the STEPS study (Sullivan et al. 2007), the ReMiND study (das Nair and Lincoln 2012) and the LEAPS study (Duncan et al. 2007) there is a need for more comprehensive and clearly designed neurological rehabilitation studies (Thompson 2000). Thompson (2000) reports that it is possible, although extremely difficult, to demonstrate the effectiveness of complex neurorehabilitation interventions providing that the methodology is well thought through and the choice of outcome measures is adequate. He further identifies a number of challenges that neurological rehabilitation studies often fail to overcome. He explains that firstly, neurological rehabilitation interventions are often not described in detail. Secondly, that standardization is likely to be compromised since locations and duration of interventions often vary. Thirdly that control groups are in many cases nearly impossible to find and blinding is rarely guaranteed. Finally he explains that reaching consensus or agreement on the most appropriate outcome measures is extremely challenging. According to Thompson (2000), outcome measures must aim at identifying the impact of the rehabilitation process as a whole, considering not only impacts on disability but also on quality of life, independence or coping skills. In order to do this, many studies evaluating neurological rehabilitation interventions have chosen to use generic measures of disability and quality of life. However, since these are not disease specific, they can fail to accurately identify changes directly linked to the intervention under study (Van der Putten et al. 1999). As stated above, the challenges faced by rehabilitation research are in line with those that apply to the neurological rehabilitation field. Thus, the researcher considers that this thesis, although focussed on advancing methodologies in order to design and conduct process evaluations in neurological rehabilitation research, can further contribute to inform the wider field of rehabilitation.

1.3.5 The OTCH trial – case study for this thesis research

This chapter continues by explaining the OTCH study (Occupational Therapy in Care Homes). This rehabilitation research trial was chosen as a case study for this thesis research work as the OTCH intervention is a clear example of a complex neurological rehabilitation intervention.

The OTCH trial is a pragmatic cluster randomised controlled trial aimed at assessing the impact of a targeted course of occupational therapy on people living in nursing and residential homes after suffering from a stroke (Sackley et al. 2004). This Health Technology Assessment (HTA) funded cluster trial compared the level of independence on activities of daily living achieved by stroke patients at control care homes with the level of independence of patients living at care homes that have had active occupational therapy input. To date this study is the largest cluster RCT looking at occupational therapy in care homes and provided information not only on the impact that occupational therapy had on promoting independence in activities of daily living but also on other aspects such as depression and quality of life.

The OTCH intervention was focused on mobility, transfers and seating assessments, task related interventions on self-care activities, and the provision of adaptive equipment and environmental adaptations (Sackley et al. 2006) (Please see Table 1.1 for more information). The intervention also included a training package for care home staff working in participating care homes, which covered the principles underpinning occupational therapy interventions and decision making.

Table 1.1 OTCH trial information (Sackley et al. 2006)

Setting	Older people care homes from around the UK were included. Care homes were included regardless of their funding models. Homes for people with learning disabilities or drug addiction were excluded.
Recruitment	Care homes were provided with information on the trial both orally and through information sheets. Care home managers had to provide written consent for the care home to be included in the study. Once care homes were recruited participant recruitment started with the assistance of care home managers. Residents of the care home that had had a stroke or transient ischaemic attack (TIA) were included in the study. Participants were excluded if they were receiving end of life care (life expectancy < 6 months). A senior member of the care home staff, general practitioner, research nurse or therapist approached identified potential participants (or their family) to explain what the study was about and ask if they were interested in participating in the study. Interested residents (or a family member – consultee) were asked to sign a consent form.

Randomisation	Homes were grouped and randomised (50:50) to receive either OT intervention or control (usual care). The study coordinator was the one assigning the clusters to either OT intervention or control arm and contacting care home managers to make arrangements for OTs to visit the care home and start the intervention. Allocation was done using blocked randomisation within strata (type of home: residential, nursing). Although independent assessors were blinded to the treatment allocation it was not possible to blind therapists and residents.
The intervention	Provided by qualified OTs, it aimed at improving participants' independence in activities of daily living (ADLs) such as feeding, toileting, bathing, transferring and mobilising. Adaptive equipment was provided when necessary and residents' environment was also adapted as needed (e.g. raised toilet seat or grab rails). Demonstration on how to use adaptive equipment was provided by the OTs. The OT intervention lasted a maximum of 3 months, however, the frequency and duration of OT sessions was dependant on patients' needs and agreed goals in the treatment plan. A client centred approach was followed and therefore included continuous assessment, treatment and reassessment. OTs were asked to keep a treatment log to report the dose and the focus of interventions. The intervention was delivered in three month waves. The control group intervention meant that care homes would continue providing their usual care. The intervention further involved a training package for care home staff. This training included education on principles driving OT interventions and decision making. The control group received similar training but only after the 12 month follow up assessment.
Outcome measures	Demographic data including age, gender, current medication intake and date, type and side of stroke was collected from all participants. The primary outcome measure was the Barthel Activity of Daily Living Index (Mahoney and Barthel 1965), where a change of two points was accepted as being clinically meaningful (Lang et al. 2008). Secondary outcome measures such as the Rivermead mobility index, geriatric depression scale and EQ-5D (to measure quality of life) were also used.
Data analysis	A mixed model analysis was used to compare Barthel index scores between the intervention and control groups. Secondary analysis was carried out to evaluate any longer term effects, a repeated measures mixed model analysis of primary outcome was carried out, comparing groups across all time points.

Results from the OTCH trial

A pilot study (Sackley and Dewey 2001) showed that a relatively small level of occupational therapy may have detectable impact on morbidity in stroke patients living in care homes. The OTCH cluster randomised controlled trial intervention was delivered over different phases of recruitment, across 114 care homes in England and Wales, by a team of trial occupational therapists to a sample of people with stroke and other co-morbidities. A total of 2538 occupational therapy visits were made to 498 participants in the intervention group (Sackley et al. 2015). Results showed no significant difference between intervention and control group in the primary and secondary outcome measures. The study therefore provided no evidence at any observational time points of the benefits of occupational therapy for all care home residents suffering from stroke related disabilities in terms of level of functional capacity as measured by the Barthel index. The research also found no evidence of any impact of the programme on the secondary measures such as mobility, mood or health related quality of life (Sackley et al. 2015). The research team reported, as one of the results that deserved attention following the trial, the fact that whilst in the pilot trial the mean baseline Barthel score was in the moderate range, in the larger trial it was within the severe range, with 47% of the participants rated as very severe. Recruitment for the trial was reported as high with a large number of care homes expressing interest and receptive to interventions that could potentially benefit residents. Finally, no adverse events were reported and there were high completion rates for all assessments at each endpoint. Potential limitations were identified. Firstly, the percentage of incidence of stroke in the study care homes was 16% which was lower than expected and resulted in a large number of small clusters. Secondly, engagement in the intervention plans proposed by the occupational therapist was reported as potentially being limited due to the high proportion of participants suffering from moderate to severe depression and cognitive impairment. Finally, as mentioned above, more than 70% of the residents were categorized as severe or very severe using the Barthel index at baseline, a fact which could have further hindered participants' ability to follow therapy plans. The authors considered that there is a need for further scrutiny and

development of alternative strategies when investigating programmes targeted at a clinically complex population whilst remaining client centred and goal orientated.

1.3.6 The role of qualitative methods in rehabilitation research

Qualitative research is historically associated with anthropology, sociology, education and psychology. Contrary to quantitative driven research which is interested in identifying cause-effect relationships, qualitative research is more interested in identifying 'how' and 'what' has taken place (Carpenter and Suto 2008). In broad terms, qualitative research often follows an interpretivist paradigm (for more information please refer to Chapter 2) which embraces the existence of 'multiple realities'. Qualitative research can be defined as following an inductive process (which can result in non-linear paths) which strives to be carried out underpinned by the unavoidable contextual framework. It aims at generating descriptive data which welcomes the interaction between participant and researcher.

It was not until the 1980s that there was a general move away from the positivist paradigm and the use of quantitative methods. Healthcare researchers searched for new ways to define the 'truth'. This led to a lively debate on issues of objectivity and generalizability (Denzin and Lincoln 2005, Carpenter and Suto 2008). It was during this period that qualitative research was welcomed in mainstream research and recognized in the health profession journals. Today, in the 21st century the debate regarding trustworthiness and credibility of qualitative research is an ongoing one (Denzin and Lincoln 2005, Miller and Crabtree 2005).

As previously discussed the strong push towards EBP has further developed the debate between qualitative and quantitative researchers. Two bastions of EBP have in recent years, embraced research which no longer assumes the epistemological hegemony of RCTs and is moving towards the acceptance of qualitative research. Firstly, as already explained, the MRC guidelines (2000, 2008) formally recommend the use of qualitative research during the initial exploratory phases of the research, in order for example to identify the

underlying mechanisms that will influence outcomes. Also, they promote its use in the final phase of the research to assess effective implementation in uncontrolled settings. Secondly, Cochrane Collaboration has recently tentatively accepted qualitative methods (Noyes et al. 2008, Noyes 2010). A number of authors (Creswell 1998, Gibson and Martin 2003, Miller and Crabtree 2005, Carpenter and Suto 2008) strongly believe that qualitative research is now widely accepted in health care and rehabilitation research. According to them, there is no 'best approach' to healthcare research; it is the issue under investigation and the research questions which will determine the choice of approaches. Despite all this, authors such as Denzin and Lincoln (2005) feel that qualitative evidence is still being relegated to a secondary and auxiliary role in generating evidence which highlights a 'narrow view' of what should be regarded as evidence.

As Miller and Crabtree (2000, p.613) explain: "*the new gold standard, if there should be any at all, needs to include qualitative methods along with the randomised controlled trial"*. The use of qualitative research prior to, alongside or following RCTs is becoming a popular approach to current complex intervention research, due to, amongst other reasons, its accepted use in identifying the role that contextual factors play at the time of testing the intervention (Campbell et al. 2000, Craig et al. 2008, and O'Cathain et al. 2013). Qualitative research can further contribute to complex intervention research by providing explanations to variation in outcomes, identifying how recruitment procedures developed, or explaining the perception that patients and intervention staff had regarding the intervention (Donovan et al. 2002, O'Cathain et al. 2014). Finally, qualitative research alongside RCTs has proven useful in order to identify which changes to the feasibility trial (e.g. regarding recruitment procedures) needed to be done prior to the main trial (Donovan et al. 2002).

In 2013 O'Cathain et al. carried out a review of current healthcare research practice. This review was aimed at identifying what aspects of research trials were being addressed via qualitative research and what was their potential contribution to the generation of evidence. They found that whilst a majority

(71%) of qualitative studies focussed on the intervention being trialled, only 15% focussed on the design, process and conduct, 1% on the outcomes of the trial and 3% on the outcome measures used in the trial. The minority of the qualitative research was undertaken at the pre-trial stage (28%). The authors reported that the value of the qualitative results and contribution to the trial results was not always made explicit. However a number of benefits linked to the use of qualitative research were identified. Qualitative research was found to optimize the trialled intervention and its implementation, to facilitate interpretation of trial results and to inform researchers on how to account for human expectations. Also, qualitative research provided useful evidence that informed choices regarding which interventions were more likely to be effective. This ultimately led to the avoidance of the unnecessary costs of carrying out RCTs on ineffective interventions. In a similar study Lewin et al. (2009) found that 30% of healthcare trials had associated qualitative research. However, they concluded that on average, this qualitative component was methodologically weak, and not clearly integrated into the main trial.

In terms of timing, there is no consensus to date as to when, during the research process, qualitative research should be carried out (Lewin et al. 2009). O'Cathain et al. (2013) found that only 28% of the studies they identified in their systematic review had undertaken qualitative research at the pre-trial stage. In regards to this they argue that more qualitative research would need to be carried out during the pre-trial phases in order to reduce the chance of 'unwanted surprises'.

The question is then, can qualitative approaches play a role in addressing some of the challenges that rehabilitation researchers face? Until recently, rehabilitation research evidence has been associated with RCTs as the 'gold standard' and it is argued that this has restricted the sorts of questions and issues that rehabilitation research has investigated (Hyde 2004). More recently EBP has embraced the importance of client centeredness (Miller and Crabtree 2005, Holm 2005 and Hammell 2006). In order to address and accomplish client-centeredness, rehabilitation research studies have had to adapt and include greater methodological diversity and qualitative approaches

(Gibson and Martin 2003, and Carpenter 2004). As expressed by Carpenter and Suto (2008, p.21) when describing the role that qualitative research plays in rehabilitation research:

> "*Qualitative research has role to play in identifying the concepts that help us understand people's lives, contributing evidence to support rehabilitation theories that emerge from and are relevant to the social, political, economic and cultural contexts in which clients live"*.

They continue:

> "*Qualitative research, in using an inductive and contextualized inquiry approach focused on research participants' accounts, is well suited to explore how ideologies privilege one group over another and influence disabled people's lives"* (Carpenter and Suto 2008, p.26).

Despite this opinion, rehabilitation professionals, who up until recently were primarily educated in the positivist paradigm and quantitative methods, have found it hard to adapt to the resurgence of qualitative research (Dyck 2000). Rehabilitation researchers have had to start to understand that the researcher is no longer an outsider ('blank page') but an active character in the research process, free to bring his/hers orientations and personal experiences into the research study (Dyck 2000).

To sum up, qualitative approaches are considered to enrich rehabilitation research in four ways (Carpenter and Suto 2008):

- Through carrying out qualitative research it is possible to understand how professional knowledge is developed and transmitted in order to generate clinical reasoning.
- Qualitative approaches can contribute to the research into developing new outcome measures that are client centred and focus on individual goals and priorities (e.g. COPM, Law et al. 2005)
- Qualitative approaches are very well suited to explore clients experiences regarding health related experiences and their perceptions

of complexity of rehabilitation practice and the therapeutic relationship (Cooper et al. 2005, Grypdonck 2006). There is a wide number of authors who agree that the patient's subjective experience and beliefs should be at the centre of the rehabilitation process (Diller 2005, Rath et al. 2011, and Cicerone 2012). Consequently, Diller (2005) argues that rehabilitation frames of reference need to be further developed to acknowledge patients subjective experience and meanings of illness.

- Qualitative research can be used to achieve a better understanding of the rehabilitation context (Heckman and Cott 2005).

1.4 Summary

Up to this point this chapter has provided an overview of the current challenges inherent to rehabilitation research. Furthermore, it has discussed the different approaches taken by researchers in order to obtain evidence that proves the effectiveness of their proposed interventions. Finally, the OTCH study has been described in detail, as an example of a trial looking at the impacts of a complex rehabilitation intervention. This chapter will now discuss current approaches that researchers are using in order to understand intervention implementation, its barriers and its enablers and the role that these play in shaping potential outcomes.

1.5 The evaluation of complex interventions and their implementation

1.5.1 Thinking about implementation

As Damschroder et al. (2009, p.50) identified "*many interventions found to be effective in health services research studies fail to translate into meaningful patient care outcomes across multiple contexts"*. In other words, their implementation fails. So then, what is implementation? Rabin et al. (2008, p.118) define it as: "*the process of putting to use or integrating evidence-based interventions within a setting"*. Researchers investigating implementation are

interested in evaluating firstly, whether the original intervention, including all its components, is faithfully transported to the chosen setting (implementation fidelity) and secondly the role of context as a set of circumstances that surround the particular implementation effort and adapt it accordingly (Damschroder et al. 2009). Implementation theory emphasises the importance of the organisational context within which practitioners operate in shaping the implementation of health care interventions (McCormack et al. 2002, McNulty and Ferlie 2002, Greenhalgh et al. 2009). There is recognition of the "*dynamic interplay between individuals and the organisations in which they work, and how that interplay influences individual and organisational behaviour change*" (Damschroder et al. 2009, p.5). As described in the literature, the implementation of healthcare interventions, such as the OTCH intervention, can face barriers at multiple levels of the delivery such as the provider level, the patient level or the policy and organizational level (Ferlie and Shortell 2001). In view of this, healthcare researchers are increasingly recognizing the vital role of implementation theories as a path, not only to evaluate the extent to which implementation is effective at optimizing intervention outcomes in a particular context, but also in terms of expanding findings into other contexts (Greenhalgh et al. 2009).

To date, many implementation theories related to dissemination, innovation, organizational change, knowledge translation and research uptake amongst others have been published, all using different terminology and definitions. These often overlap and often fail to address all key constructs (Damschroder et al. 2009). A number of conceptual and theoretical frameworks which have been developed within the implementation literature were recently synthesised in the Consolidated Framework for Implementation Research (CFIR) (Damschroder et al. 2009). This framework highlights additional factors relating to the intervention itself, the people involved in it and the available support towards implementation which, cumulatively, may explain the success or failure of implementation (Damschroder et al. 2009). It further explores the challenges that can be associated with bringing a complex intervention into practice with high fidelity (quality of implementation) which must be addressed if the intervention is to improve outcomes. The CFIR framework includes the

following domains which, cumulatively, explain the success (or not) of implementation: *Intervention characteristics*, including core elements, and peripheral elements which are adapted to ensure 'fit' within a particular organization; *Inner context*, such as the structural characteristics, networks and communications, culture climate and readiness for change; *Outer context*, or the economic, political and cultural contexts within which an organisation sits; *The Individuals* involved with implementation (in the case of the OTCH study, predominantly OTs and care home staff) and the *Implementation Process* itself. These constructs identify and investigate, in detail, complex interventions and how their implementation fidelity can be maximized.

1.5.2 What is fidelity and why investigate it?

Implementation fidelity has been described as a key component in a number of frameworks for guiding research and practice of implementation science (Breitenstein et al. 2010). Dusenbury et al. (2003, p.240) define fidelity of implementation as: "*the degree to which teachers and other program providers implement programs as intended by the program developers"*. Regardless of the fact that this definition is widely recognized (Mihalic 2004, Carroll et al. 2007, Breitenstein et al. 2010, Cross and West 2011 and Proctor et al. 2011), definitions vary across disciplines and to date no consensus has been reached (Dusenbury et al. 2003, Cross et al. 2011). This has led to a lack of clarity at the time of researchers making decisions on how to best investigate and address fidelity (de Vos et al. 2013).

A number of benefits linked to the investigation of implementation fidelity have been proposed in the literature:

- Firstly, it is considered to help avoid type III errors (Dobson and Cook 1980). Without measuring a program's adherence to a protocol or planned model the researcher cannot know if the intervention had unsuccessful outcomes because it did not work or because it was not implemented as planned (and for example some components were omitted) (Mihalic 2004, Chen 2005). Yeaton and Sechrest (1981) point out that when an intervention is not

implemented with fidelity then the lack of an effect is of no interest. In essence, the data is no longer interesting.

- Secondly, it helps identify what changes were made in a program and how these programs impacted outcomes. Dumas et al. (2001) explain that fidelity wants to answer two questions: Are the providers doing what the protocol says? And if they are, are they doing it the same with all participants? In other words, fidelity assessments are a way to ensure that the proposed intervention is being delivered the same across sites and that differences are being documented (Paulson et al. 2002, Mowbray et al. 2003). With this information the researcher can then make informed decisions in regards to excluding data from the sites that deviate too far from the protocol (Teague et al. 1995). Thus, fidelity also plays a role in enhancing statistical power to help explain variance in outcomes (Teague et al. 1995).
- Thirdly, investigating implementation fidelity can provide information about the feasibility of the intervention. If the right level of fidelity is difficult to achieve it can be inferred that the feasibility of the innovative intervention is likely to be low (Dusenbury et al. 2003).
- Finally, but not least important, information on fidelity can help explain negative or ambiguous findings (Hohmann and Shear 2002).

Fidelity has been described as being constituted by the following components (Dane and Schneider 1998):

- Adherence: it measures to what extent the delivery was similar to the design or plan and if all the intervention components were delivered in the right context to the appropriate population, using the right protocols and materials.
- Exposure or dose: how much of the intervention did participants receive, how many sessions were implemented for how long and how frequently.
- Quality of delivery: appropriateness of the delivery process by staff members (skills, enthusiasm, preparedness).

- Participant responsiveness: how much did participants engage and respond to the intervention and how did the participants judge the outcome and relevance of the intervention.
- Program differentiation: presence or absence of the critical (essential) components of the intervention; which elements are essential to the intervention for its success. It is 'differentiation' that determines which elements are essential for the success of the intervention and will therefore impact on outcome results and which elements are redundant. Essential components of interventions should be identified so that strategies to increase programme tailoring can be developed accordingly (Altman 1995, de Vos 2013).

Dane and Schneider (1998) argued that in order to achieve a 'holistic picture' of implementation fidelity all five components needed to be evaluated and monitored. They carried out a literature review to examine the extent to which fidelity (programme integrity) was verified in evaluation of early secondary prevention programmes. They concluded that most authors had focussed on one or two of these components of fidelity ignoring the rest. In line with this Dusenbury et al. (2003) adopted Dane and Schneider's model and reported that by focusing only on measuring for example adherence it was unlikely that the researcher would be able to explain which factors had an impact on intervention implementation. However, not everyone agrees that each of these five elements should be included in the evaluation of fidelity (Elliot and Mihalic 2004)

Based on previous models new frameworks and ways of assessing fidelity have been published recently. For example, Dariotis et al. (2008) had a simple approach and used a 4-point scale, completed by implementers, to compare program delivery to the intended implementation plan. In 2007 Carroll et al. carried out a critical review of conceptualizations of fidelity and as a result proposed *the consolidated framework for implementation fidelity* (CFIF); it was generated by drawing broadly from the implementation literature and from the work by Greenhalgh et al. (2004) which looked at how complexity could become a barrier to 'diffusion of innovations'. The CFIF framework became a

novel contribution by addressing intervention complexity in depth. In the CFIF all components of implementation fidelity, represented as adherence (content, coverage, frequency and duration), are presented as interacting with 'moderating factors' which are those that can potentially impact on the degree of fidelity. Moderating factors are described as having complex relationships amongst each other and also with the degree of implementation fidelity. These moderating factors are: intervention complexity, facilitation strategies, quality of delivery, and participant responsiveness. Facilitation strategies such as training, manuals or supervision are described as serving two purposes: firstly they can improve the intervention implementation and secondly they can help standardize it. The authors (Carroll et al. 2007) explain that in the case of complex interventions it is not the number of facilitation strategies in place but their careful and informed choice which can lead to a higher degree of implementation success.

The *participant responsiveness* component of the CFIF refers to the level of enthusiasm shown by intervention providers and how much patients are engaging in the process. The authors draw from Rogers' diffusion of innovation theory (Rogers 2003) which argues that the successful uptake of an intervention depends largely on how the intervention is accepted by both those providing it, and those receiving it. This is true at both an individual and organizational level where if an organization does not embrace and commit to an intervention then responsiveness of individuals will be negatively affected (Dane and Schneider 1998).

1.5.2.1 Modifications to Carroll's framework

In recent years there has been a growing interest in the study of context within implementation research (McCormack et al. 2002, Robert and Fulop 2014) (a detailed review on the concept of context is available in Chapter 2). As a result, since the publication of the CFIF in 2007 authors such as Hasson (2010) have proposed modifications such as the addition of two extra moderating factors: *recruitment* and *context*. The authors describe the c*ontext* as the 'surrounding social systems' that include aspects of the intervention such as the culture of organizations, social behaviour/interactions amongst members, social

structures etc. The second modification of the CFIF consisted of the inclusion of recruitment as a moderating factor. The authors, in line with other researchers (Baranoswki and Stables 2000, Steckler and Linnan 2002) believe that strategies to recruit patients at individual and organizational level play a vital role in shaping implementation fidelity.

In this thesis fidelity is defined as a reflection of 'high quality implementation' and as a thread that pulls together implementation processes within a clinical trial along with the theories embedded in a complex intervention. The researcher understands that by investigating fidelity the chances of being able to unpin and understand implementation processes are maximised. The researcher agrees with Dusenbury et al. (2003) and several other authors when they argue that in order to understand and investigate implementation fidelity all moderating factors should be evaluated and that to date most research has been almost exclusively made up of adherence measurements (Mihalic 2004, Faw et al. 2005, Herzog and Wright 2005, Carroll et al. 2009).

1.5.2.2 Fidelity research in rehabilitation

The top priority of rehabilitation researchers, policymakers and practitioners should be to develop, support and implement, with the highest possible degree of fidelity, programs that will produce positive vocational health and psychological outcomes for people with disabilities (Rubin and Roessler 2000). To date, very little attention has been given to the investigation of fidelity in rehabilitation research studies, such as OTCH, despite the complex, multicomponent and contextually driven interventions that this research deals with (Whyte and Hart 2003, Resnick et al. 2011, Poltawski et al. 2014) and despite researchers calls on the need to address it (Hart and Bagiella 2012, Murphy and Gutman 2012)

In terms of assessing implementation fidelity, a number of challenges which are inherent to rehabilitation research studies, such as OTCH, have been identified:

- *Maturation* (Bellini and Rumrill 1999): is when, with time, participants mature, grow and learn and are stronger as a result of a developmental

process; this in itself can impact on implementation fidelity and ultimately influence outcomes independently of the trialled intervention.

- High variability of staff delivering the intervention both, in terms of expertise or personality and also in terms of the discipline they belong to.
- Variability amongst the functional levels and disability types among participants.

A number of rehabilitation research studies have specifically addressed implementation fidelity (Leeuw et al. 2009, Resnick et al. 2011, Hildebrand et al. 2012, Di Rezze et al. 2013, and Poltawski et al. 2014). Poltawski et al. (2014) in their study of an exercise-based rehabilitation intervention for long term stroke survivors called Action for Rehabilitation from Neurological Injury (ARNI) tested the use of the framework for fidelity developed by the US NIH Behaviour Change Consortium (Bellg et al. 2004). This framework considers both, the evaluation of the therapist behaviours and patients' experiences (Bellg et al. 2004, Di Rezze et al. 2013). It identifies five areas to be addressed when investigating implementation fidelity: study design, the training of intervention provider, treatment delivery, receipt of intervention and enactment. Poltawski et al. (2004) reported that the model had proven to be useful once it was adapted and modified more broadly to the characteristics of rehabilitation research. They proposed a modified model which included three faces: intervention and study design, resourcing and implementation. Their model describes an approach where researchers are mainly focussed on investigating the principles underpinning the intervention and whether these are being implemented as planned rather than focussing solely on the content and delivery (Hawe et al. 2004b).

In summary, the evaluation of fidelity in rehabilitation research has, up to now, not been based on conceptual models of fidelity and has largely evaluated components of the intervention at a program level (e.g. whether or not intervention was conducted). Di Rezze (2012) reported the possible application of the CFIF (Carroll et al. 2007) to rehabilitation research and further stated that there is a strong need for researchers to develop rehabilitation-specific frameworks and measures for the evaluation of

implementation fidelity. The overall aim of this thesis is directly in line with this identified need.

1.5.3 Investigating fidelity in the context of process evaluations

According to Richards (2015, p.12) the purpose of a process evaluation is "*to understand the mechanisms by which the intervention exerts its effects, getting into the 'black box' of the intervention*". Although, as Hasson (2010) points out, there is a degree of overlap in the terms process evaluation and fidelity (Hulscher and Laurant 2003, de Vos et al. 2013), both share a common aim, amongst others: identifying variations across intervention sessions. These can occur as the provider makes adjustments to the protocol based on assessment of earlier sessions or, conversely, monitoring unplanned changes that take place as the provider "drifts" from the protocol and identifying their impact on outcomes (Nigg et al. 2002, Bellg et al. 2004). Both work on identifying the underpinning characteristics of intervention components and how these impact on its delivery to a set standard (Rossi et al. 2004). On the one hand authors such as Mihalic (2004, p.83) have stated that "*fidelity is assessed by conducting process evaluations*". On the same lines Craig et al. (2008, p.12) state that "*process evaluations nested within a trial can also be used to assess fidelity and quality of implementation*". However, on the other hand, process evaluations have been described as being capable of 'measuring' a number of implementation fidelity components (Steckler and Linnan 2002). This thesis is in line with Steckler and Linnan's (2002) approach. Thus the OTCH process evaluation attempts to assess and bring clarity regarding some aspects of the 'quality of implementation' of the OTCH intervention.

The concept of process evaluation is not new. Even as early as 1960 Suchman (1967) defined the concept and ideas behind it when writing about program evaluation although did not use the term 'process evaluation'. The core of these first definitions remains. However, it was not until the 1980s that the concept of process evaluation experienced a great development. Thus, the debate regarding its components and how to accurately define them was initiated (Corbetta 2003). For example, Basch et al. (1985) made the first

reference to process evaluations being a tool to avoid Type III errors. They explained that measuring implementation processes was critical to avoid drawing incorrect conclusions about the effectiveness of an intervention. Questions such as: "*was the intervention delivered as planned?"* became paramount to process evaluation research. Researchers who found a negative answer to this question would then be required to identify in which ways the intervention was not delivered as intended (Steckler and Linnan 2002). Additionally researchers then started to realize that it was equally vital to know how much of the intervention was actually received by participants. This was defined by Steckler and Linnan (2002) as 'dose received'. As Steckler and Linnan (2002) explained, 'dose received' is important because, even if the researcher is clear about the degree to which the intervention was delivered as planned, it might be that nobody actually received it.

In the late 1990s and in early 2000 there was a vast increase in the number of research articles that included research into process evaluation components (Hasson et al. 2012). This was due, amongst other things, to the fact that during that period the complexity of healthcare interventions and their multicomponent nature was being widely addressed (MRC 2000). Researchers identified a great need for process evaluations in order to understand how these newly defined complex interventions were being carried out both at a component level and as a whole. This realisation of the need for process evaluations was further exacerbated by the fact that many trials of complex interventions were multi-site; it became clear that understanding how interventions were implemented across sites was essential (Wells et al. 2012, Hoekstra et al. 2014).

As an example of these early developments in process evaluation research is the process evaluation of the Child and Adolescent Trial for Cardiovascular Health (CATCH) study (Perry et al. 1997). This process evaluation (McGraw et al. 1994) was novel in that it specified four areas to investigate: *participation* (did targeted staff attend the training sessions?), *dose* (were the CATCH components implemented?), *fidelity* (were the components implemented according to protocol?) and *compatibility* (did the study fit the context of the

school as well as the need of the teachers and staff?). Additionally it acknowledged the role of the environment in which the intervention took place which had rarely been done before (Elder et al. 1994).

A number of reasons for carrying out process evaluations in healthcare research have been discussed in the literature:

1. *To understand results from trials*: when interventions produce significant results it is important to understand which components are working and contributing the most to this success. Similarly, when interventions show no significant effect there is a need to understand why (Mihalic 2004). One reason for this, amongst others, is the need to justify the use of 'tax payers' money'.
2. *To understand and improve theory-informed interventions:* a process evaluation can help understand if the theoretical constructs that were considered vital at the time of developing the intervention were actually so in impacting on outcomes.
3. *To inform improvements to intervention design and choice of methods.*
4. *To investigate program implementation*, assessing for example, the quality and accuracy in the delivery of the intervention to participants (Lipsey and Cordray 2000, Fixsen et al. 2005). Process evaluations can improve the validity of the intervention and help identify and avoid type III errors (Dobson and Cook 1980).
5. *To potentially help increase transferability of interventions* to different settings and locations (Bradley et al. 1999).

1.5.3.1 Frameworks for process evaluations

In 2000, Baranoswki and Stables published a framework to inform process evaluation research. In this framework they listed eleven components of process evaluation: *recruitment, maintenance, context, resources, implementation, reach, barriers, exposure, initial use, continued use and contamination.* However, a few years later a number of gaps and limitations of this framework were identified by Steckler and Linnan (2002). The first gap they identified was a lack of clear definitions of the proposed process

evaluation components. They identified that there was an overlap in what each component was addressing and this could minimize the chances of comparing findings from one process evaluation to another. They further pointed out that unclear definitions could lead to unmanageable, simple, 'nice to have' amounts of data being collected, which would represent a waste of effort and resources (Steckler and Linnan 2002). The second gap they identified was a lack of systematic approaches to guide process evaluations which according to them, meant that each researcher would find themselves reinventing the procedure. Finally, they identified a lack of theory behind the development of proposed trialled interventions, which would limit the power of process evaluations to contribute to the development of the mechanisms of change taking place.

In 2002, Steckler and Linnan, in their work '*Process evaluation for public health interventions and research*', proposed an approach to process evaluations that would assist researchers to identify intervention components, how these were delivered and to what standard. Table 1.2 provides a brief description of their proposed components of a process evaluation.

Table 1.2 Process evaluation components according to Steckler and Linnan (2002)

PE component	Definition
context	The social, political, physical environment that could have an impact on implementation
reach	The proportion of patients that participated in the intervention
dose delivered	How much of the intervention was provided
dose received	How much of the delivered intervention was assimilated by participants who were engaged
fidelity	To what extent was the intervention delivered as had been intended by the researchers, what was the quality of implementation
Implementation	A combination of reach, dose delivered, dose received and fidelity. Steckler and Linnan (2002) explain that it is difficult to assess (calculate). They suggest a number of methods (e.g. average of the four, product of the four, etc.)
Recruitment	How were participants attracted at individual and organizational level

1.5.3.2 Methods in process evaluation

The way in which process evaluations are designed and carried out in current healthcare research is highly varied (Grant et al. 2013) and, as Richards (2015) argues, it will strongly depend on the research question that needs to be answered. In line with the previously discussed developments taking place in primary health research, process evaluations often involve the use of both qualitative (e.g. observation, interviews, focus groups, and content analysis) and quantitative approaches (e.g. surveys, checklists, attendance logs). This combination is considered to yield a level of detail that neither method on their own could achieve (Tashakkori and Teddlie 1998). Steckler and Linnan (2002) point out that researchers need to be realistic and consider available resources (e.g. time, funding, staff) in order to make informed decisions on the choice of methods. Although in recent years there has been a strong increase in published research on theories and frameworks driving and guiding process evaluations for complex interventions, there is limited guidance to help researchers design process evaluations (Grant et al. 2013). Only one guidance to date has been published in this matter, by the MRC (Moore et al. 2014a), which provides a framework to inform process evaluations of public health interventions that is highly relevant to complex interventions. This guidance together with other approaches to process evaluation will be further discussed in subsequent chapters.

1.6 Rationale for this study

This far, the context in which this thesis is set has been presented. This study has been designed to elicit further development of the approaches currently used to investigate implementation fidelity (via process evaluation) of complex rehabilitation interventions. The challenges inherent to the investigation of complex rehabilitation interventions, which are known to influence and impact on the quality of the evidence it produces, have been outlined. The current need for high quality evidence on the effectiveness of rehabilitation interventions has been reported, together with the need to further develop process evaluation methodologies. The rationale for this study is strongly

based on this need, coupled with the fact that process evaluations help increase the quality of evidence obtained from research trials. This study has been designed to investigate the usefulness of applying new methodologies to rehabilitation research process evaluations and to provide new guidance to design and conduct them.

1.7 Study aim and objectives

Study aim: Drawing on a case study, evidence synthesis and consensus development work, this thesis aims to advance thinking and practice in process evaluation and clinical trial methodology within the field of neurological rehabilitation.

Study objectives:

- To report an overview of the development of fidelity research and process evaluation methodology within research into complex interventions in health and social care.
- To conduct a realist, process evaluation of a complex occupational therapy intervention within stroke rehabilitation.
- To complete a methodological review of process evaluation design and conduct within neurological rehabilitation.
- To construct methodological guidance about how to best design and conduct process evaluations alongside trials of complex rehabilitation interventions.

1.8 Thesis overview

Chapter 1. This chapter provides the background to the study and presents a review on the challenges faced by rehabilitation researchers at the time of assessing the impact of complex rehabilitation interventions and designing trials. This chapter further discusses the importance of understanding the fidelity of complex interventions, particularly via the use of process

evaluations. The concept of process evaluation is presented and current frameworks described. The study aims and objectives have been set out.

Chapter 2. The methodological approach employed for this study is discussed. A brief review and critique of current healthcare paradigms and their application to rehabilitation research is presented. The epistemology and ontology underpinning the thesis study is discussed. Finally the justification for the choice to apply realist evaluation to address one of the objectives of this thesis is provided via an in depth exploration of its underpinnings.

Chapter 3. This chapter reports on the research methodology and design of the process evaluation of the OTCH study. A justification for the choice of realist evaluation is presented and data collection methods are described in terms of their suitability to address the study's aims and objectives. The realist cycle followed by the researcher in order to undertake this process evaluation is outlined in detail.

Chapter 4. This chapter is a report of the findings from the OTCH process evaluation. The results from each of the steps of the realist cycle which the process followed are presented. An initial programme theory and the results from the process that led to a refined programme theory are described. Finally the four refined programme theory CMOs are presented and the implications for fidelity research are discussed.

Chapter 5. This chapter reports on a mixed-evidence systematic review looking at the current state of process evaluation research alongside neurological rehabilitation research trials. The chosen methodology to undertake this mixed-evidence review is discussed. Two evidence streams are described. The process of carrying out the individual synthesis of each of the streams followed by a combined third synthesis providing a number of statements informing process evaluation research is explained.

Chapter 6. This chapter is a report of the consensus work carried out in order to develop best practice guidance for carrying out process evaluations alongside rehabilitation research trials. The nominal group technique chosen

to carry out the work is discussed and its usefulness is reviewed. The chapter finally presents a proposed completed guideline.

Chapter 7. This final chapter concludes the thesis. It presents a discussion which considers the main findings of the study and its contribution to current existing evidence. Emergent findings are considered and the aims and objectives of the study are revisited. The implications of the new findings for policy and research are presented. Recommendations for future research are suggested. The strengths and limitations of the study are discussed and finally a section on reflexivity is included in this chapter in order to show how the researchers' thinking and learning skills evolved throughout the PhD process.

1.9 Conclusion

In summary, this chapter has provided an overview of the current state of rehabilitation research and its developing focus on investigating complex interventions. More specifically this chapter has reviewed how rehabilitation researchers have identified the need to further develop their understanding in regards to the complex interventions they deal with on a daily basis. A number of challenges have been identified as impacting on the way today's rehabilitation researchers approach the investigation of implementation fidelity within process evaluation research. The need for an evidence-based client centred approach has inevitably led to an impact on the fidelity of trialled interventions. The way in which today's rehabilitation researchers address fidelity issues and the impact that it can have on trial outcomes remains a challenge that needs further development. This study provides a new contribution to what is already known about how to address this phenomenon. Assessing implementation fidelity of rehabilitation interventions via high quality process evaluations is likely to increase the researchers understanding on why a complex intervention works or fails. Improving process evaluation evidence base and further developing guidelines and frameworks to inform it is of vital relevance to today's rehabilitation research.

A realist evaluation approach was chosen to carry out the process evaluation

of the OTCH trial in order to develop and test context-mechanism-outcome propositions to show what works. Choosing realist evaluation was important to seek the ways in which the trialled intervention worked, for whom and under what circumstances. This thesis advances understanding of the use of realist evaluation as a methodological approach to guide the undertaking of process evaluations.

In this first chapter the intention was to set the scene and guide the reader as to the contents of the thesis. The study's rationale, aims and objectives have been presented. Increasingly, there are calls for research to show and provide evidence on how and why complex rehabilitation interventions work (or fail). Investigating fidelity within process evaluations has been identified as a vital step in order to achieve this. To date there is scarce research evidence on how to design and carry out process evaluations within this challenging rehabilitation field. This thesis is presented as an attempt to bridge this gap.

CHAPTER 2:

Philosophical and methodological underpinnings

2.1 Introduction

The epistemological and ontological positions of this study are presented in this chapter in order to explain the theoretical underpinnings informing the study's design. This chapter starts by exploring the paradigms that currently guide rehabilitation research. Positivism, interpretivism and critical realism are discussed and critiqued and their role in shaping this study is stated. This chapter will then briefly review and critique mixed method approaches. Justification for the choice of realist evaluation will then follow. The strengths of this methodology will be reviewed and its suitability to address the study's aims and objectives will be argued. A detailed review of realist evaluation principles will be provided and this will include in depth discussion regarding its underlying assumptions. The concept of context will be discussed as will its place within realist evaluation.

2.2 Epistemology and ontology of healthcare rehabilitation research

A wide variety of research methodologies and related methods are used in health research and rehabilitation research. It is of vital importance for the researcher to embed these methodologies in a particular position and understanding of the world (Denzin and Lincoln 1998). The researcher will need firstly to define the ontological views of his research by establishing what he/she considers to be the nature of reality (Hudson and Ozanne 1988). In other words, what 'things', if any, really exist, or to the contrary, are a product of the person's mind and individual perceptions (Burrell and Morgan 1979). How the researcher views reality is a vital corner stone for all following assumptions and research decisions taken from there on (Guba and Lincoln

1994, Everest 2014). Secondly, researchers will need to clarify what is the epistemological stance of their research. In line with its etymological origin (the Greek word epistêmê which means 'knowledge') epistemology focusses on studying where the basis of knowledge lies (Hall 1990). The epistemological position of research describes the assumptions to be followed in terms of the sources and the nature of knowledge and questions where true knowledge comes from and how can reality be known (Guba and Lincoln 1994, Carson et al. 2001). Furthermore, epistemology will define how new knowledge can be produced and how a researcher can go about acquiring scientific knowledge (Broom and Willis 2007, Ashatu 2009). As Everest (2014, p.8) argues:

> "*In the context of healthcare research, knowledge of epistemology enables the researcher to epitomize various aspects of the phenomenon under investigation and then proceed to ascertain the kind of knowledge he/she intends to acquire about it"*.

It is vital for rehabilitation researchers to clearly distinguish between their epistemological stance and chosen methodology. These two terms are intimately related but whilst epistemology involves the philosophy of how we come to know, methodology is more practical in nature. Its focus is on specific ways that researchers can use to try to understand their surrounding systems (Guba and Lincoln 1994).

In terms of ontological perspectives or views on social reality, two predominant positions have been described in health research. The first one assumes that social reality exists independent of what the researcher thinks or perceives. This reality is objective and unique; it can be investigated using 'scientific' methods of enquiry (Bitter and Parker 1997, Gallagher 2008) which epistemologically are believed to provide truthful and objective facts and knowledge about social and human behaviour (Lee-Kelley 1929) but only once contextual factors are controlled. The second one believes that social reality is constructed by individuals and their understanding of the world around them. Realities are therefore individually generated (Guba and Lincoln 1994). From an epistemological perspective, knowledge is not unique and can be generated via understanding the world that surrounds the person and her/his

own individual experiences in it. Human behaviours are determined to a large extent by external factors surrounding them, and as a consequence 'looking for the truth' can only be achieved by investigating people's experiences in depth (Graue and Walsh 1998, Byrne-Armstrong et al. 2001).

2.3 Paradigms underpinning rehabilitation research

2.3.1 What is a paradigm?

The term paradigm has been defined in a number of ways (Guba and Lincoln 1994). It can be defined as an overarching philosophical or ideological stance, a system of beliefs about the nature of the world. When applied to a health research setting, it is the base and fundamental assumptions that are followed when producing knowledge (Rubin and Rubin 2005, Broom and Willis 2007). Burrell and Morgan in 1979 explained that '*to be located in a particular paradigm is to view the world in a particular way'* (Burrell and Morgan 1979, p.24). Morgan (2007, p.50) describes paradigms as *"shared belief systems that influence the kinds of knowledge researchers seek and how they interpret the evidence they collect"*. He explains that paradigms are not only worldviews but also shared beliefs by a 'community of scholars' in a particular research field.

A paradigm will take a position in terms of the nature of reality (ontology) and knowledge (epistemology) (Kalof et al. 2008 and Saunders et al. 2009) and it will guide and inform decisions made in terms of how research is carried out. Simply said by Guba (1990, p.17) a paradigm is a "*basic set of beliefs that guide action".*

Current rehabilitation research varies greatly in terms of researches' epistemological and ontological positions. As mentioned above, these positions and chosen paradigms will serve as a thinking framework and thus will greatly influence studies in terms of objectives, design and ultimately type of knowledge they produce (Jonker and Pennink 2010, Wahyuni 2012). In regards to this Guba and Lincoln (1994 p.116) argue that: "*paradigm issues are crucial; no inquirer ought to go about the business of inquiry without being*

clear about just what paradigm informs and guides his or her approach". The chapter continues by discussing research paradigms and their role in today's rehabilitation research.

2.3.2 Positivist paradigms

The concept of 'positivism' has been pivotal in the debate over the philosophy of science since the beginning of the 19th century (1844) when Comte introduced the term (Comte 1974). Although positivism had been a theme in the history of western thought for a while, it is widely accepted that it was Auguste Comte who coined the actual notion of positivism and developed this approach in the 19th century (Macionis 2012). Comte sought to take the rules and laws of natural sciences (that at that time followed Newtonian mechanics), physics, astronomy and chemistry and apply them in order to investigate society (social theory) and human behaviour. Comte's work was very important in consolidating positivisms into sociology by "*transforming society on the basis of science*" (Giddens 1987). Society was seen as an organism that followed the same evolutionary principles as biological organisms.

Although Comte is seen as the 'father' of positivism, his work was mainly rhetorical. It was Emile Durkheim (1858-1917) who was labelled the first 'sociologist' and did the first empirical work to investigate society (Corbetta 2003). He examined social phenomena by measuring a set of independent variables in order to identify causal links. During the 1920s logical positivist thought was developed, rejecting Comte's positivism. Logical positivists considered physical evidence as paramount: "*The stated aim of the logical positivist is to cleanse scientific knowledge of speculative thinking, for it is not tied in a direct and demonstrable way to experience"* (Smith 1998 p. 97). Logical positivists such as Schlick, who began the movement in 1922 at the University of Vienna, believed that Comte's attempts to apply natural science techniques to society had not gone far enough. Thus, they developed statistical and analytical tools to analyse social behaviour. Current social science positivists who focus on statistical analysis are situated in between these two positions. They believe that theory can be created as a result of

data, but the theoretical propositions are less systematized than the logical positivist would accept as universally valid (Corbetta 2003).

2.3.2.1 The positivist reality and its application to rehabilitation research

Ontologically, positivism understands reality as concrete. Positivism lies on 'realism' which assumes that there is a reality which can be subject to discovery and analysis; only what can be observed is real. In realist ontology, a 'real' world exists independent of our interpretations. As Westhorp et al. (2011, p.3) explain, for realists "*things are considered real if they can have a real effect in the world"*.

Epistemologically, positivism assumes that knowledge is gained through observation. The researcher can report on the reality that is discovered through observation (Everest 2014). He/she can be an objective observer (objectivism) or, in other words, the researcher and the subject are independent from each other and exist independently (dualism). Positivism assumes that truths can be explained and predicted and that society, like the physical world, operates according to general law (Broom and Willis 2007). Thus, positivist rehabilitation researchers identify a research topic and define a series of research questions and hypotheses to be tested empirically via structured experiments. Statistical mechanisms will find relationships between variables and this will produce broad generalisations regarding the rehabilitation intervention under investigation. In terms of methodology, positivist enquiry strategies often rely on quantitative methods which have hugely developed in the last century. A positivist rehabilitation researcher will consider that impacts of interventions can be successfully replicated by other researchers attempting to implement the same rehabilitation intervention. Lack of reliability is a consequence of biases, errors in measurements, lack of consistency in the research process or contextual differences (Weber 2004).

Under a positivist paradigm, researchers, including those working in rehabilitation, must remain detached from the participants at all times. Only by doing this can context-free generalizations be described (Hudson and Ozanne 1988). As Giddens (1987) explains, positivism assumes reality is constant and

it can be measured regardless of the researchers' believes. Positivists believe that methods and strategies used in natural sciences can therefore be applied to social sciences. However, rather than imposing natural science models on to the social world, positivism should follow the premises of the scientific method/enquiry (Bryman 2001). Thus, the researcher will need to be objective when collecting and interpreting social data and work to generate neutral and unbiased laws and models from it (Bryman 2001, Rubin and Rubin 2005).

Although the philosophical ideas of positivism have evolved considerably since Comte's time they still form the basis for much rehabilitation research today (Petty et al. 2012). As Broom and Willis (2007, p.21) state: "*the basic premise of a reality that can be objectively measured, given the right instruments and conditions, still dominates health research in the clinical and social sciences".*

Since the end of the 1960s positivism has been the target of strong criticism (Weber 2004). As put by Roberts (1997) '*not everything that counts can be counted*'. Patomäki and Wight (2000, p.213) wrote about positivism: "*it is epistemologically and ontologically flawed; it is also co-responsible for many of the social ills and political catastrophes of the modern world".* Detractors of positivism consider that reducing research to what is observable (or even measurable) is not justified in social research and, that by doing so, researchers miss out on all hidden patterns and their underlying explanatory rules which are legitimate components of the research (Broom and Willis 2007).

Although positivist thinking can offer a lot to health research (Weber 2004) and rehabilitation research (Carpenter 2004), over the last century several authors have argued quantitative methods which dominate positivist thought cannot answer 'why'; The epistemological standpoint of positivist methods gives insufficient weight or no attention to the person's individual life experience (Rubin and Rubin 2005). As Petty et al. argued in 2012 when discussing the use of quantitative methods to investigate manual therapy, they provide "*a narrow understanding of our practice"*. Authors such as de Vaus (1995) rejected the need to search for objectivity and the desire for generalizability

that positivist researchers strive for. They argued that it is not possible to produce completely objective data, that all knowledge will be subjective and interrelated with the social and cultural context of the trial and its researchers. More recently, Bracken (2010) argued that, by trivializing human factors, positivist approaches to social sciences do not account for the human side of reality. He states that positivism tends to "*minimize the complexity of social interactions and fails to capture the lived socio cultural nature of humanity"* (p.4). In regards to knowledge produced by positivist research using quantitative methods, Johnson and Onwuegbuzie (2004, p.19) explain that "*it may be too abstract and general for direct application to specific local situations, context and individuals"*. This is particularly true in rehabilitation where the focus of care is often outside the scope of the biological body and more concerned with the surrounding contextual systems (Gibson and Martin 2003). Carpenter (2004) argues that the uncritical adoption by rehabilitation researchers of a positivist paradigm, has limited the power of this research to take into account patients' perspectives and to address the complexities of clinical practice.

2.3.3 Interpretivist paradigms

In 1883 Dilthey published his first critique of positivism which triggered the philosophical debate on the differences between understanding human thought and explaining nature (Rickman 1960). He refuted the fact that humans could not be investigated in cause-effect terms. It was at the beginning of the 20th century when Max Weber was the first to propose an alternative paradigm to positivism, called interpretivism. Thus, in the 1920s and 1930s the Chicago School started a movement that rebelled against positivist paradigms to be applied to social sciences. Its aim was to refocus social science, to consider meanings to be constructed and interpreted by individuals and groups embedded in a social and historical context. It emerged in order to challenge the positivist notion of a single 'truth' and defended the concept of 'multiple realities' (Schutz 1970). A strong interpretivist tradition emerged in the social sciences, gathering momentum in the 1960s and 1970s (Broom and Willis 2007). Authors such as Glaser and Strauss (1967), Berger

and Luckmann (1967) and more recently Rubin and Rubin (2005) have led its development.

Over the past decade there has been intense theoretical discussion in terms of how interpretivist led research can contribute to advance the body of evidence in rehabilitation (Carpenter and Suto 2008). Whilst OT practice has embraced theoretical discussion and debate over the richness of interpretivist approaches (Ballinger 2004), physiotherapy practice has been slower to recognize how these can contribute to the understanding of rehabilitation practice (Johnson and Waterfield 2004).

2.3.3.1 Interpretivist paradigms in rehabilitation research

Interpretivism can be defined as *"an approach in social science based on an assumption that human beings construct their social reality, and that the social world cannot exist independently of human beings"* (Holloway 2005 p.290). This paradigm assumes a relativist ontology in which realities are multiple, constructed and holistic and individuals play a role in creating meaning (Cohen et al. 2000). Knowledge is 'constructed'; there is not 'the one and only' 'universal' reality but individual ones which are generated as a result of the person's immersion in different cultural, historical and social contexts (Schutz 1970, Guba and Lincoln 2005, Broom and Willis 2007, Merriam 2009, Scammell 2010). Each individual will construct their own reality drawing, from the meaning that they assign to actions and events (Hudson and Ozanne 1988, Bryman 2001). The impact of context is considered unavoidable, a fact which Dervin (1997, p.32) simply explains by writing: "*context is something you swim in like a fish"*. Interpretive research is about subjectivity and complexity and therefore it allows acknowledgement of conflict, struggles and subjectivity (Rubin and Rubin 2005).

The epistemological stance of an interpretivist is subjectivism. In other words, what is known and who knows it are influencing each other, all descriptions are time and context bound. Thus, it is impossible to separate cause and effect as they are simultaneously shaping each other and therefore changing (Guba and Lincoln 1994). A rehabilitation researcher following an interpretivist

paradigm will believe that "*what we observe is not nature itself but nature exposed to our method of questioning"* (Heisenberg, 1958, p.288). This means that the chosen methodology and methods will impact on the subject and this will therefore impact on the results. Reality is sought by stablishing and understanding people's lived experiences and subjective feelings which leads to decision making. This subject aspect of meaning is what interpretivist researchers should strive for (Ezzy 2002).

In interpretivist rehabilitation research, the researcher should be involved with the participants in a given context, interact with them and remain open to changes and new ideas throughout the study (Gibson and Martin 2003, Petty et al. 2012). The main goal is not to come out with generalizations but to interpret human behaviour and predict the causes of it and its effects. Qualitative methods which follow an interpretivist approach have provided a useful tool to investigate this new understanding of reality (Everest 2014), since they are aimed, not at looking for patterns in group behaviour, but patterns in subjective experiences (Rubin and Rubin 2005). As Everest (2014, p.10) states: "*interpretivism is the father of qualitative research".* These qualitative approaches are focussed on identifying what events mean to individuals and how "*what has happened to them and around them"* has influenced this meaning. Furthermore, these approaches have been described as being philosophically compatible with client-centred practices which are embraced by rehabilitation professionals; they provide the tools for researchers to identify how therapy interventions can be tailored to the needs of patients (Carpenter 2004). They can also help understand how function impacts on peoples' roles in the community, which is another of the main concerns of rehabilitation professions such as physiotherapy (Gibson and Martin 2003). Finally, because interpretivist approaches focus on 'why' things happen, they are likely to provide a better understanding of theories that underpin rehabilitation professionals practice and their interactions with patients (Carpenter 2004, Kroll et al. 2005).

Terms such as credibility, transferability, dependability and validity are used in interpretivist research (Denzin and Lincoln 1998). The transferability of

findings is based on contextual applicability. Interpretivists, such as Erlandson et al. (1993, p.33) argue that *"the researcher collects sufficiently detailed descriptions of data in context and roots them with sufficient detail and precision to allow judgement about transferability"*. They believe that generalization, in the scientific sense of the word, is impossible (Dervin, 1997). In terms of reliability, for an interpretivist a piece of research is reliable if the research team can prove that at the time of interpreting findings they showed an awareness and acknowledgment of the subjectivity they could have brought to the research and made the necessary steps to reduce its implications (Denzin and Lincoln 1998). When discussing validity, interpretivists are concerned with showing that the claims they make in their findings are justifiable (Carpenter 2004). Researchers are expected to examine the evidence and where 'it comes from', check the research process, any possible biases or contextual factors, etc. in order to come to the conclusion that the results are reasonable or plausible.

Interpretivism hasn't been free of criticism, especially regarding research methods. It has often been described as 'soft' and 'unscientific' (Petty et al. 2012). Detractors of interpretivism argue that, there is still a lack of consensus as to which are the best methods and tools for data collection when carrying out qualitative research (Carpenter 2004). Authors such as Silverman (2001) have expressed doubts as to whether participants' accounts investigated through unstructured interviews or focus groups (often used by interpretivist researchers) are really generated by them or they are prompted and driven by the researcher. In the same manner, qualitative data analysis methods have often not been clearly explained, thus producing generalizations that are based on a small sample size (Bryman 2001). Finally, some researchers argue that whilst some health research areas under investigation might be strongly subjective and determined by experiences and context, others are purely physiological and physical and therefore are not suitable for interpretivist analysis (Carpenter 2004, Weber 2004).

Several authors have reported how overall interpretivist research in rehabilitation is under-represented (Gibson and Martin 2003, Johnson and

Waterfield 2004). Gibson and Martin (2003) found that out of 584 research articles published in four physiotherapy journals from Canada, Britain, USA and Australia from 1996 to 2001 only 25 were qualitative studies (4.3%). The same search in OT found that qualitative studies represented 29.7% of the total. Petty et al. (2012) reported that in the last 16 years, out of the 475 original articles published on manual therapy, only ten used a qualitative research approach. The first of these was published in 2007.

2.3.3.2 The long standing debate between positivism and interpretivism

The debate of positivist versus interpretivist approaches is a long standing one (Weber 2004) and it is highly relevant to rehabilitation research. However, as stated by Everest (2014, p.11) "*neither interpretivism nor positivism offers panacea to challenges of validity and reliability of findings in healthcare research*". Originally, and particularly in fields such as rehabilitation research, the debate has been considered useful since it contributed to unsettling the hegemony of positivist approaches and it gave the opportunity for interpretivist ones to grow and develop (Carpenter 2004). However, in recent years, researchers both from a positivist and interpretivist stance have stated their wish for the debate to end, since according to them "*it no longer serves a useful purpose"*, to the contrary, it contributes to generate a 'bigger schism' between researchers (Weber 2004, Johnson and Onwuegbuzie 2004). As Weber (2004, p.10) says regarding the differences between both approaches, "*we should understand them, but they should not divide us"*. The aim of researchers should be to produce relevant knowledge and a very strict separation of ontological and epistemological positions can be artificial and forced (Golafshani 2003). It is the excellence of the research that matters and in order to achieve it researchers, including those working on rehabilitation, have the responsibility to be aware of, and understand, the tools they have at hand (Bryman 2001). The question is then, why does the debate continue? Two main reasons have been proposed. The first one is linked to the fact that the language which researchers use to describe their research is often 'arcane' and does not help communication. Weber (2004) proposes the use of simpler language which would facilitate critique and debate and will mitigate

misunderstandings between researchers using either approach. The second reason could be that interpretivist researchers could still feel as if they are being discriminated or negatively affected by biases (for example at the time of submitting work for funding). In answer to this Weber (2004) argues that researchers need to 'deal with this' and accept that avoiding all types of biases is impossible. All researchers can do is aim to mitigate the impacts of the bias.

2.3.4 Critical realism

Previously known by terms such as post-positivism, critical realism emerged as a reaction to the failings of positivism, and a shift of the natural sciences (mainly physics) from a Newtonian mechanistic approach to a more 'relative' one that had place for 'uncertainty'. Einstein and Heisenberg were the drivers of this shift towards probability and uncertainty; if the natural world could no longer be studied in a mechanistic way, neither could the social facts (Alvesson 2010).

Critical realists emphasize that since all measurements are fallible, and have a degree of error, it is necessary to use multiple data collection approaches. All data will then need to be triangulated in an attempt to achieve the best possible observation of reality (Patomäki and Wight 2000). Critical realists believe that all 'scientists' are inherently affected (biased) by their beliefs, perceptions and the way they see the world around them and interpret it (Alvesson 2010). As a result, it is not possible to see the world perfectly as it really is. Our best hope of achieving objectivity is triangulating across multiple perspectives, all of them biased. However a critical realist rejects the relativist idea of incommensurability of different perceptions and perspectives, the idea that it is impossible for two different people to understand each other because of their different backgrounds. Critical realism believes that people can hope to understand and translate each other's experiences (Alvesson 2010). They believe reality exists (ontology) but can only be known imperfectly and in terms of probabilities (Tashakkori and Teddlie 2003).

A critical realist understands that there is a reality independent of the person's thinking and that this reality can be studied by science. In broad terms

positivists are realists, the difference is that a critical realist understands and recognizes that all observations of the real world have a degree of error and that all theories are subject to be revised, not set in stone (Archer et al. 1998). In this way critical realism challenged the positivist stance that only the observable could be associated with reality (Spencer 1995). As the term implies, a critical realist is critical about human's ability to identify and understand reality completely and with all certainty. For critical realists, reality exists outside any description of it and what you learn about it is confined to the here and now (Stickley 2006).

Originating in the writings by the English philosopher, Roy Bhaskar (1975), critical realism considers that both, positivism and interpretivism, are not realistic enough. It considers both of these paradigms as too superficial and non-theoretical. Critical realism is based on the realist perspective, which challenges the belief that what we know about the world is real (Oltmann and Boughey 2011). The premise of critical realism is to identify underlying mechanisms that lead to observable phenomena. These are the focus of knowledge (Wand et al. 2010). Critical realism focusses on ontological matters (Patomäki and Wight 2000). Bhaskar (1975) describes a shift from epistemology to ontology and explains that these should remain separated due to what he calls the 'epistemic fallacy'. Coupling both will lead to confusing what exists with what we know about it (the knowledge we have of it – what we believe). Bhaskar (1975) defines reality as consisting of three domains:

- *The empirical*: what we can observe
- *The actual*: is the domain that includes all that transpires independently of the researcher or whoever records it.
- *The real*: mechanisms. Something is real if it has a causal effect, if it affects behaviour and causes a difference in it. Reality does not always represent material objects since ideas and discourses are real and can produce effects.

According to Bhaskar (1989), the process begins with the generation of hypothetical mechanisms which are postulated would account for the

phenomenon under investigation. These mechanisms are then studied empirically in order to develop explanations of the structures and processes. These allow for the development of theories linked to these structures and processes which can then be tested (McEvoy and Richards 2006). Bhaskar (1989) defines this stage as 'explaining the explanations'. It is this process that makes critical realism expand beyond positivism and interpretivism (Syed et al. 2009).

Critical realism shares with positivism the interest in the objective world, patterns, generalizations and causality. However, it also argues that studying only what can be observed is a superficial approach that disregards the mechanisms that produce the phenomena, which are often unobservable (Archer et al. 1998). Thus, the world cannot be reduced to observable facts. Unlike positivism, critical realism doesn't understand causality in terms of universal, predictable patterns, it is interested in complex networks of theoretical and observable elements embedded in context and changeable societies (Archer et al. 1998). Although critical realism shares an interest in synthesis and context with a number of qualitative approaches, it also emphasizes the objective nature of reality and assumes that a reality made up of social constructions is unclear and misleading. Reality, as such, is different from the person's conception of it, it exists independently of researchers' ideas or descriptions of it (Patomäki and Wight 2000). Whilst not accepting statistical regularity and predictability, critical realists do define demi-regularities as "*the occasional, but less than universal actualization of a mechanism or tendency, over definite region of time-space"* (Archer et al. 1998, p.149).

2.3.5 Mixed methods – the paradigm debate and its use in rehabilitation research

Critical realism has been considered a paradigm within which mixed methods of both quantitative and qualitative data can be achieved (Downward and Mearman 2004). Mixed methods research studies are defined as those studies that involve both, quantitative and qualitative methods for the same study and they then involve the integration of the data in the research process (Denzin 1970, Steckler et al. 1992, Creswell et al. 2003). Mixed method research is

currently gathering momentum and growing in healthcare sciences research (Creswell 2003, Tashakkori and Teddlie 2003, Borglin 2015). Unsurprisingly this has led to the rise of criticism and debates regarding its meaning, dominant paradigm and other philosophical issues which have surfaced, both from within (Morse 2005) and outside (Denzin and Lincoln 2005). However, in regards to rehabilitation studies, such as this one, Smith et al. (2012) argue that there is a need for more critical discussion in order to generate a clear understanding of what mixed methods entitles. They argue that the choice for mixed methods should be based on critical research reasoning rather than linked to the "*elevation of quantitative methods above qualitative methods"* (p.375). This resonates with the researcher's justification for the choice of using mixed method approaches to data collection in this thesis.

There is currently an ongoing debate regarding which paradigm best suits mixed methods research (Creswell 2011, Creswell and Plano Clark 2011). Different stances have been proposed, the 'purist stance' talks about the 'incompatibility thesis' (Howe 2004) which states that mixed methods are not possible because paradigms cannot be mixed. As Holmes (2006) explains, it is not possible to have one part of the research following one view on reality mixed with a different one in another part of the research. In this stance, paradigms are seen as impermeable, with impermeable boundaries. However, several health research authors have worked to bring down these boundaries (Guba and Lincoln 2005, Creswell 2011). They explain that different elements of different paradigms can be blended together and therefore paradigms do not dictate data collection methods (Johnson and Onwuegbuzie 2004). This is in line with the researcher's stance at the time of designing and conducting this research study.

A number of authors have expressed how, by using simultaneously qualitative and quantitative methods, rehabilitation researchers will be able to address all aspects and concerns of current practice and its inherent complexity (Rauscher and Greenfield 2009, Shaw et al. 2010). Thus, in line with the research presented in this study, they conclude that mixed methods research is well suited for rehabilitation research by broadening the scope of enquiry in

order to better understand patients' illness and rehabilitation process. However, several authors (Bryman 2007, Coleman et al. 2007) have raised their concerns regarding the paucity of evidence showing genuine integration of quantitative and qualitative findings carried out by researchers claiming to follow a mixed methods approach; qualitative research methods and findings are often positioned 'second' and as servicing the needs of quantitative methods (Hesse-Biber 2010). Authors such a Borglin (2015) and Kroll et al. (2005) have argued that rehabilitation researchers embracing mixed methods research should pay attention and justify decisions in regards to the level of method integration, the timing, the priority assigned to each type of method and the theoretical framework informing the research.

The second current discussion is in relation to the use of the terms 'qualitative and quantitative'. In the 1970s and 1980s the terms qualitative and quantitative became descriptors for paradigms (Giddings 2006). More recently a strong case has been made by the research community explaining that the terms qualitative and quantitative should refer to methods and that these should be separated from philosophical issues and paradigms (Denzin and Lincoln 2005, Creswell 2011). Authors have been advised to therefore refrain from mixing and using both interchangeably (Greene 2007). Vogt (2008, p.1) summarizes the discussion by saying "*to think in terms of quantitative and qualitative designs is a category mistake*".

The 'war' between quantitative and qualitative approaches has been affected by the development of mixed method research. In line with this study's stance, Johnson and Onwuegbuzie (2004, p.14) state that:

> "*The goal of mixed methods research is not to replace either of these approaches but rather to draw from the strengths and minimize the weaknesses of both in single research studies and across studies".*

They agree with Howe (2004) in that they believe the links between paradigms and research methods should not be set in stone or even necessary. A qualitative researcher should be free to use quantitative methods and so a quantitative researcher use qualitative ones. They say that there is no

entailment between epistemology, methodology and methods (Johnson et al. 2004, Phillips 2004). Thus, a chosen epistemological view should not mean that the qualitative researcher for example is forced to avoid using quantitative data collection methods or the other way around. This view is shared by the researcher in this study.

2.3.5.1 A critique of mixed methods approaches

Mixed methods research has been criticized for favouring critical realist thinking over more interpretive approaches (Giddings 2006, Creswell 2011). Authors such as Lincoln and Canella (2004) or Howe (2004) argue that funding organizations are still assigning a prominent role to quantitative research in mixed methods when they ask a researcher to produce findings that can be replicated, generalized and disseminated via empirically tested methods. This, as Howe (2004) explains, places qualitative methods in second place and gives them the auxiliary role of providing more knowledge (accumulating knowledge). Also, as Creswell (2011) says, mixed methods have given the opportunity to qualitative inquiry to advance in research fields that were traditionally positivist led. Furthermore many studies' designs in mixed methods give priority to qualitative methods (Creswell 2011) although what is needed is 'mixed methods interpretivism' in which quantitative methods are relegated to a secondary or auxiliary role within a qualitative research (Howe 2004).

Finally, the methodological sophistication that mixed methods studies often involve, demands the researchers to greatly develop their research skills (Curry et al. 2009). Most researchers will be highly experienced in the use and application of qualitative or quantitative methods but rarely both. Unless this changes and researchers involved in mixed methods research work at developing a balanced set of skills, the validity and reliability of their findings will be compromised (Bryman 1992). Researchers need to understand that as today's research world is growing in complexity and is becoming more dynamic and interdisciplinary they will be required to understand a broad array of methods used by them and other colleagues in order to be able to engage in positive and productive collaborations (Johnson and Onwuegbuzie 2004).

2.3.6 Implications for this study

As already discussed at the beginning of this chapter, it is of vital importance for the researcher to clearly define ontological and epistemological views regarding his/her research. The underpinnings of critical realism and its ontological view of reality which have been described above align themselves with the overall aims and objectives of this study.

As Mackenzie and Knipe (2006, p.8) explain, the use of the term paradigm in this thesis is reserved for "*the philosophical intent or underlying theoretical framework and motivation of the researcher with regards to the research"*. The author of this thesis agrees with Johnson et al. (2007, p.117) when they explain that in regards to paradigms "*the dividing lines are much fuzzier than typically suggested in the literature'' and 'positions are not nearly as 'logical' and as distinct as is frequently suggested in the literature".* However, the research presented in this thesis will address a number of the methodological challenges and debates that are currently taking place in healthcare and rehabilitation research which have been previously described in this chapter. Furthermore this research remains flexible at the time of choosing methodologies and data collection methods, whilst remaining focused in finding answers for proposed research questions. As discussed above the author of this thesis agrees with those authors who argue that the ontological and epistemological views underpinning a piece of research should not disregard data collection methods, they should be independent of them. The researcher believes that rigorous and systematic synthesis of both qualitative and quantitative research can be a successful approach to addressing complex rehabilitation interventions and justifying decisions behind practice issues, theory development etc. In regards to the very often referred to 'gold standard' of research the author of this thesis is in agreement with what Miller and Crabtree suggested in 2000 (p.613): "*the new gold standard, if there should be any at all, needs to include qualitative methods along with the randomized controlled trial"*. Furthermore, the researcher considers that it is the research question and what is being studied that will justify the chosen approach.

Whilst aligned to critical realism, by taking a flexible stance the researcher has had the chance to mix approaches to data collection and methodologies and consequently challenge the dualistic views (quantitative/qualitative) that, as previously discussed in this chapter, she considered unproductive. The researcher believes that neither quantitative nor qualitative methods alone could provide an in depth enough answer to the research questions proposed in this study.

This research aims to solve practical problems taking place in the real world. As discussed above, the identified research questions presented in this thesis have been answered using a variety of approaches and data collection methods which have at times been quantitative in nature and at other times qualitative. In other words, the researcher has used 'different lenses' in order to address the proposed aims and objectives of this study.

Closely linked to critical realism the researcher chose 'realist evaluation' as the methodology to inform the OTCH process evaluation. The place of realist evaluation within the critical realism paradigm is now explored.

2.4 Realist evaluation

2.4.1 Philosophical underpinnings and principles of realist evaluation

One of the methodological approaches used in this thesis is realist evaluation which addresses the importance of context in shaping the theories of how interventions work (Greenhalgh et al. 2009, Marchal et al. 2012, Rycroft-Malone et al. 2012). Realist evaluation is underpinned by the philosophy of critical realism (Wand et al. 2010) and draws from Pawson and Tilley's seminal work (Pawson and Tilley 1997). They explain that realist evaluation is an approach which is grounded in scientific realism which considers that both the social and the material world are 'real' and both can have a real effect and can cause change. Realism has its roots in 'critical realism' (previously discussed in this chapter) (Bhaskar 1989). Scientific realists consider that reality exists independently of people's perception of it (Pawson and Tilley 1997, Wand et al. 2010, Tang 2011) and that it is possible to work towards understanding

what causes the changes. Realism brought a different way to account for the nature of reality. It sits between positivism and interpretivism in its epistemological believe that although there is no final truth it is possible to accumulate knowledge and improve our understanding of reality (Westhorp et al. 2011).

The key goal of a realist evaluation is to uncover middle range theories which are defined by Merton (1967, p.39) as:

> "*Theories that lie between the minor but necessary working hypotheses that evolve in abundance during day-to-day research and the all-inclusive systematic efforts to develop a unified theory that will explain all the observed uniformities of social behaviour, social organization and social change".*

For realism these middle range theories lie between the 'big policy ideas' and the day to day problems and challenges of implementation.

2.4.2 How do interventions work according to realist evaluation?

From a realist perspective, an evaluation cannot lead to universal findings. What it can do is help the research to identify, through cumulation of knowledge rather than replication, which specific aspects of the intervention work and how (Pawson and Tilley 1997). Thus, investigating the nature of interventions (programmes), such as OTCH, and understanding how they work and how they bring about change is of vital importance in a realist evaluation.

The most fundamental realist claim about interventions is firstly, that they are 'theories incarnate'. Realist evaluations are always based on a hypothesis that considers that the delivery of the intervention will generate a particular improved outcome. In order to be formulated, these hypotheses should be grounded on assumptions and therefore they are theories (Pawson 2006, Westhorp et al. 2011). Thus, the author of this thesis considers that the delivery of the OTCH intervention will generate impacts on outcomes and it is these hypotheses that will require further testing.

Secondly, for scientists carrying out a realist evaluation, interventions are 'embedded' into social systems and these social systems will underpin and will explain the reasons for current problems or situations (Pawson and Tilley 1997). As a consequence, realist evaluation acknowledges and needs to identify the different layers of social reality (contextual factors) which form and surround interventions. Not only will the characteristics of the participants have to be researched but also additional contextual factors such as their relationships, their individual capacities, the institutional setting, economic situation, etc. (Pawson et al. 2004). In line with this the researcher, by applying realist evaluation principles will need to pay close attention to the context in which the OTCH intervention is embedded.

Thirdly, interventions are 'active'. That is, they generally bring about change via the active input of individuals. As Pawson et al. (2011, p.519) argue: *"Programmes are active, not passive. Interventions do not work in and of themselves; they only have affect through the reasoning and reactions of their recipients".*

Whilst in other research approaches random allocation and blinding are normally used to reduce all human intentionality from the research, realist evaluation assumes that active participation and understanding of the reasoning of stakeholders is paramount in order to evaluate the outcomes of an intervention (programme) (Rycroft-Malone et al. 2010).

Finally, interventions are open systems. They cannot be isolated or kept constant. There is always going to be the chance of events taking place (political changes, practitioner learning, management innovations etc.) that will make interventions, such as OTCH, be flexible and variable. In line with this, the study reported here considers that the delivery and the implementation of an intervention like OTCH will be subject to change and will not remain constant (Pawson et al. 2004, Pawson 2006).

2.4.3 Realist evaluation in practice

According to realist evaluation, changes in outcomes are the consequences of interventions, and researchers should not just investigate a single fixed and measurable outcome measure. To the contrary, in realist evaluation the identification of outcomes should be addressed in a range of forms and strategies (Tolson et al. 2007, Salter and Kothari 2014). Realist evaluation is not a method and doesn't provide a standardized formula or methodological rules or steps that need to be rigorously followed (Rycroft-Malone et al. 2010, Salter and Kothari 2014). Accordingly, realist evaluation has no preference for qualitative or quantitative methods. It is methodologically neutral and does not reject any experimental methods (Marchal et al. 2012, Salter and Kothari 2014). It acknowledges the richness in mixed methods to investigate programme processes as long as the balance of selected methods is in line with the realist hypothesis that is being tested and with the possibilities of data collection. However, Pawson and Tilley (1999) explain that a realist evaluation will need to follow a set of principles. These are explained below.

Firstly, as previously mentioned realist inquiry will start with the formulation of an initial programme theory (middle range theory). According to theory-driven evaluation schools a middle range theory is a set of tangible assumptions that explain how researchers envisage the intervention to reach its expected outcomes (Marchal et al. 2012). Once the programme theory is generated it can be used to guide the collection, analysis and synthesis of data that will lead to the development of a tested theoretical account of intervention implementation and impacts (Marchal et al. 2012). As a consequence, the programme theory will be refined across cycles of evaluation which will lead to a refined middle range theory which then may lead, or kick off, a new study (Marchal et al. 2012).

Secondly, investigations should be presented in the form of linked configurations of context, mechanism and outcome (CMOs) which will be refined via the evaluation process (Pawson and Tilley 1999). These CMOs may form patterns or demi-regularities and will help uncover explanatory, contingent theories of what works, for who, under what conditions and why, in

order to generate changes. In the case of the OTCH process evaluation this CMO framework would provide a structured approach to understanding how the OTCH intervention worked, what was it about it that worked and in which contexts.

Finally, the realist understands causality in terms of underlying causal mechanisms generating regularities (Pawson and Tilley 1997). This generative theory of causality assumes that interventions will bring about different outcomes because the responsible mechanisms are not necessarily or equally activated in all contexts. Pawson and Tilley (1997) explain that mechanisms are the combination of reasoning (e.g. values, beliefs and attitudes) and available resources (e.g. skills, funding, support) that will enable a suite of interventions (i.e. programme) to work and bring about change. Mechanisms "*describe what is about programmes and interventions that bring about any effects"* (Pawson and Tilley 1999, p.156). These underlying causal mechanisms will often not be apparent, they will be hidden and can be described as the building blocks of middle range theories. Furthermore, these mechanisms will only be activated if the conditions are right for them. Realist evaluation applies this to social programmes (exactly the same as in natural sciences experiments where for example objects fall because of gravity even though the researcher does not *see* it) and wants to know and understand the causal mechanisms and the conditions that are necessary to trigger them in order to produce outcomes (Pawson and Tilley 1999). As already mentioned, realist evaluation doesn't ask 'does this intervention work?' but instead what is it that works, for whom, under what circumstances and how. This resonates with the aims and objectives of the OTCH process evaluation, interested in identifying which are the conditions under which mechanisms are fired. The concept of 'context' within realist evaluation is now explored in more detail.

2.4.4 Thinking about context

Etymologically the term 'context' has its roots in the term '*contextus*' which means 'joining together'. Health care research often involves 'joining together' new interventions or guidelines with an organization and its staff and trying to understand what are the impacts and what changes are taking place (Dixon-

Woods 2014). Researchers therefore face two main challenges. Firstly, trying to understand the interactions between contexts and interventions and secondly identifying ways to deal with the impact that contextual factors have on implementation (Dixon-Woods 2014). Regardless of the fact that even back in 1955 Gouldner already pointed out that 'context is everything' and more recently authors such as Bate (2014, p.3) have argued that "*nothing exists, and therefore can be understood, in isolation from its context, for it is context that gives meaning to what we think and do",* much of today's healthcare research and practice remains 'acontextual'. Context is often regarded as a nuisance that interferes with the researcher's purposes.

To date, there is neither an explicit or well-articulated theory of context nor a consensual definition which enhances the difficulties researchers face when attempting to investigate it (van Dijk 2009, Bate 2014). It is "*an overworked word in everyday dialogue but a massively understudied and misunderstood concept"* (Bate 2014, p.4). Metaphors such as "*a garden or fertile soil"* (Simmel 1921) have been used to define context. This is risky and can lead to thinking of context as a physical fixed space, ignoring the 'temporal context' which is, as research has shown, equally important (Bate et al. 2008). Context has also been seen as 'noise' which researchers strive to interpret and make sense of (Montgomery 2006). Conceptualizing context, either as 'concrete and measurable' or 'socially constructed' has been regarded as a priority in current research, since by doing so there is a higher chance of ensuring that it is taken into account at the time of implementation (Bate 2014).

As mentioned above, context was traditionally perceived, in line with positivist thinking, as an objective phenomenon, as something 'real' that was tangible, had a measurable impact and could be manipulated and shaped. More recently, this position has been challenged and researchers are assuming a more subjectivist, interpretivist notion of context. What is important is not just measuring what is 'out there', it is understanding the role of context in the interpretation of events and societal interactions (van Dijk 2009). In line with this, 'context' is therefore 'individual' and there is no such thing as a 'universal' context or set of interpretations shared by everyone. Accordingly, researchers

looking at context are now expected to immerse themselves into the participants (actors) point of view – an 'insider's perspective'.

The importance of context in the social sciences world has been recognized for some time. Petticrew et al. (1992) carried out studies in the 1980s looking at it but even earlier, in the 1970s, Meyers and Goes (1988) assessed context when they investigated how 12 innovations were introduced to US community hospitals. They reported that out of the three identified factors impacting on assimilation (environment, organisational context and leaderships, the attributes of the innovation and the interactions between these), contextual factors were responsible for only the 11% of the variation. More recently Bate et al. (2002) evaluated the first Institute for Healthcare Improvement (IHI) Breakthrough Collaboratives in the NHS and identified contextual aspects which impacted on the effectiveness of the collaborative. These were leadership, power and cultural contexts. In this study the effect of context was included in the researched hypothesis: the effectiveness of collaboratives would be affected not only by the method but also the way it was implemented and the context in which the implementation took place.

Although Greenhalgh et al. (2004) in their review reported that there has been an increase in studies with an interest in how context impacts and enhances or inhibits the diffusion of an innovation in an organisation, studies that declare to examine context as an objective are still rare (Bacharach and Baumbeger 2007). Øvretveit et al. (2011) in their review paper looking at how context affected interventions to improve patient safety, found a number of studies that commented on the role of context but did not provide empirical data to address its possible impact. Before that, work by Rycroft-Malone et al. (2002) on the PARIHS (Promoting Action on Research implementation in Health Services) framework proposed that evidence, context and facilitation were the three interactive elements that successful implementation of evidence into practice was a function of. Greenhalgh et al. (2005) worked on 'receptive contexts' in organizational innovations. They identified four features of organizational context that made an organization be receptive: leadership and vision, risk-taking climate, clear goals and priorities and high quality data capture systems.

According to several authors (Bacharach and Baumbeger 2007, Krein et al. 2010, Robert et al. 2010, Robert and Fulop 2014, Øvretveit 2014) context has been studied from a stratified point of view, dividing it in factors and sections, ignoring its *continium* and cumulative impact. The conceptualization of context as a 'process' that needs to be monitored, and its impacts longitudinally acknowledged, is becoming popular amongst researchers (Dopson and Fitzgerald 2005, Bates 2014). Thus, the question of which methodologies are most effective in researching context is of vital importance in today's healthcare research.

2.4.4.1 Using realist evaluation to understand the role of context

For implementation research, 'context' is the "*set of circumstances or unique factors that surround a particular implementation effort"* (Damschroder et al. 2009, p.53). However, under a realist evaluation approach, context are pre-existing structures that may or may not activate a mechanism (Pawson and Tilley 1997). Mechanisms will only be active under particular circumstances, in other words, different contexts. Through investigating the context embedded in the OTCH intervention, realist evaluation can find answers to the 'for whom' and 'in what circumstances' the intervention will or will not work. Pawson and Tilley (1997) argue that whilst experimental approaches are reduced to describing outcomes neglecting the significance of context, realist evaluation can provide explanation on why programmes work. Pawson and Tilley (1997) further explain that the causation generative theory that realist evaluation assumes, assigns context a major role since outcomes are considered to be determined by interactions between context and mechanism. As Westhorp et al. (2011, p.8) explain, in realist evaluation, context

> *"Refers to features of participants, organisation, staffing, history, culture, beliefs, etc. that are required to 'fire' the mechanism (or which prevent intended mechanisms from firing)*".

Pawson and Tilley (1999) state that "*context must not be confused with locality"*. It could also relate to systems of social and personal relationships, economic conditions, etc. What is necessary for realist evaluation is to assess

which factors in the context affect how programs work, but in order to do this a detailed account of context has to be addressed at the time of designing the evaluation (Westhorp et al. 2011).

Realist evaluation has been highly recommended as an approach that successfully acknowledges and accounts for context as a process (Robert and Fulop 2014). It has been described as a useful framework to understand an intervention and its relationship with the context (Byng et al. 2008, Marchal et al. 2012). By choosing a realist evaluation methodology to carry out the OTCH process evaluation, the researcher aims to generate data which is contextually focussed and longitudinal (context as a process). As Bate et al. (2008) explain, carrying out a realist process evaluation can help avoid the tendency, or often preference, of looking at context in terms of cause-effect, which would ignore the process explanations and theories of the 'how'. Accordingly, realist evaluation aims to identify interactions, and, over time, dynamism of contextual factors at different levels (Robert and Fulop 2014).

2.4.5 A critique of today's realist evaluation research

Realist evaluation has been successfully applied in a number of health care settings representing a range of interventions and has proven to be a useful methodology (Marchal et al. 2012, Salter and Kothari 2014). Two reviews have been published presenting data investigating how the concepts of realist evaluation have been applied in health systems (Marchal et al. 2012) and implementation research (Salter and Kothari 2014) and what methodological limitations were identified. Both reviews concluded that the literature is still 'small and young'. Marchal et al. (2012) reported on only 18 papers mostly published between 2008 and 2010, and Salter and Kothari 2014 reported on 14 studies published between 2007 and 2013. Despite these observations, realist evaluation has been applied in an array of fields within health research in a variety of healthcare settings involving a range of interventions. Overall, these authors (Marchal et al. 2012, Salter and Kothari 2014) found that different approaches were being used by researchers at the time of applying realist evaluation principles. This proved challenging in practice. Also, these reviews found great diversity in the depth of the application of the philosophical

concepts, the chosen terminology and the scope of application in the research process. Marchal et al. (2012) argue that this diversity could have impacted on the way mechanisms were analysed.

To date, there are two main reasons which researchers present in order to justify the choice of a realist evaluation methodology. The first one is that realist evaluation provides a valid way to investigate how context and mechanisms bring change in outcomes (it helps 'open the black box') (Clark et al. 2005, Greenhalgh et al. 2009, Ogrinc and Batalden 2009). The second one is that realist evaluation is well suited to investigate complex interventions with complex pathways which represent a high proportion of interventions under study by today's researchers (Byng et al. 2008, Mackenzie et al. 2009, Rycroft-Malone et al. 2010 and Maluka et al. 2011). Porter and O'Halloran (2012) discuss the rapidly developing contribution of realist evaluation to evidence-based practice. They explain that realist evaluation can address the main weaknesses of evidence-based practice by dealing with complex healthcare interventions and moving on from the 'exclusive and authoritarian' use of RCT as 'the only thing that counts as evidence'.

A number of applications of realist evaluation have been reported during the last decade. For example, realist evaluation has proven useful to assess the application of policies and legislative measures against personal drug consumption through the implementation of a pilot programme (Leone 2008). In this study, Leone (2008) found the construct of CMOs to be helpful to inform the evaluation design; using the concept of mechanisms she was able to explain how different contexts affected how individuals reacted to a similar intervention. Other areas in which the use of realist evaluation has proven successful are, for example, informing study protocols (Douglas et al. 2010), as a tool to evaluate educational interventions (Ogrinc and Batalden 2009) or as a framework for carrying out process evaluations (for more detail please refer to chapter 4) (Byng et al. 2005, Byng et al. 2008). It has also been applied successfully to evaluate the management of health care institutions or services (Marchal et al. 2010) or the implementation of 'protocol based care', looking at how, if at all, it had impacted on service delivery (Rycroft-Malone et al. 2010).

Rycroft-Malone et al. (2010) reported that realist evaluation was especially useful (although also challenging to operationalise) because of the emphasis it places on both, understanding how context influences practice and developing explanatory theory of how implementation works.

In summary, as Marchal et al. (2012) explain there has been a relatively small uptake of this methodology considering the long period since Pawson and Tilley published their work (1997). A number of reasons for this have been identified. Firstly, the lack of methodological guidance remains an issue which has led to several authors reporting facing difficulties at the time of identifying and distinguishing between mechanisms and context and generating CMOs (Byng et al. 2008, Marchal et al. 2010, Rycroft-Malone et al. 2012, Salter and Kothari 2014). However, authors such as Byng et al. (2008) argue that they solved the problem by returning to the philosophical basis of realism, and its application to implementation science, which leans towards more interpretive approaches rather than deductive ones. They conclude that although challenging, the idea of CMOs makes sense to implementation science because of its "*notion that one cannot separate out outcome from mechanism of action and operationalization within particular contexts that are in constant state of flux"* (Byng et al. 2008, p.12). Secondly, the application of a realist evaluation methodology has been described as time consuming (Redfern et al. 2003, Wand et al. 2010 and Marchal et al. 2012). This has been reported as particularly true when dealing with complex interventions which require a close evaluation of, not only individual components, but also their interactions (Pawson and Tilley 1999, Pedersen and Rieper 2008, Byng et al. 2008). Finally, as a consequence of the above, the use of realist evaluation can become costly since researchers will need, not only ample resources to produce useful results for policymakers, but also a high level of expertise and experience in the use of this methodology (Marchal et al. 2010, Salter and Kothari 2014).

2.4.6 Realist evaluation and RCTs

The value of realist evaluation and its potential role in enhancing RCTs, such as the OTCH trial, is the source of an ongoing debate (Blackwood et al. 2010).

Whilst some authors such as Bonell et al. (2012) propose the use of 'realist RCTs' and argue that RCTs can benefit from the insights provided by realist evaluation without sacrificing rigour, others propose that a ´realist` approach should only be used for studies which truly follow a realist philosophy and principles (Marchal et al. 2013).

On one hand Bonell et al. (2012) say that the impact of context can be investigated by carrying out several 'realist trials' across different contextual situations, drawing on not only quantitative but also complementary qualitative data. On the other hand, Marchal et al. (2013) describe realist RCTs of complex interventions as an 'oxymoron'. They explain that realist RCTs for complex interventions pose major challenges for RCT design and they also ignore key assumptions that a realist evaluation should have. What Wolff (2001, p.124) had previously argued is that "*the RCT model is unable to control for the effect of social complexity and the interaction between social complexity and a dynamic system change".* A balanced solution which involves realist evaluation informing the design of 'theory informed RCT' has been proposed by several authors (Blackwood et al. 2010, Marchal et al. 2013). They argue that using realist evaluation to 'theoretically inform` RCTs may provide a pragmatic middle-way, where realist analysis of trial data may identify new insights which can contribute to the explanatory power of the trial (Byng et al. 2008, Randell et al. 2014). Along these lines, Porter and Halloran (2012, p.21) further state that:

> "*The RCT can be used to ascertain whether the particular causal mechanisms embodied in an intervention are efficacious, while realist evaluation can establish what effect the interaction of other mechanisms operating in the open contexts studied has upon the intervention's effectiveness and identify which mechanisms promote and which inhibit that effectiveness".*

The views of the author of this thesis regarding the tension between positivist paradigms informing RCTs and the use of realist evaluation is in line with Marchal et al. (2013). She considers that using realist evaluation to evaluate processes taking place during the conduct of the OTCH RCT trial, which is

highly driven by a positivist paradigm, does not in any way generate conflict. Realist evaluation is therefore viewed by the researcher as a feasible path to 'theoretically' understand the OTCH intervention and identify what mechanisms are taking place and what triggers them.

So far, the contents of this chapter have discussed the ontological and epistemological underpinnings of this study and have presented the researcher's overall flexible stance informed by critical realism. This has then been linked to the justification for the choice of realist evaluation to guide the process evaluation of the OTCH trial presented in Chapters 3 and 4.

2.5 Conclusion

The contents of this chapter have presented the path undertaken to reach the choice of the study's philosophical and methodological underpinnings. Critical realism emerged as being the most suitable paradigm to address this study's aims and objectives. However, the researcher has taken a flexible stance which considers that the lines dividing paradigms are often blurred. The researcher has further provided justification for the choice of using a mixed method data collection approach to address the study's research questions. The justification for the choice of realist evaluation as a methodology that is in line with the researcher's approach has been described. As discussed above, the application of realist evaluation to health research has been growing in importance during the last decade. Although a number of challenges linked to its use have been identified there is a widely accepted respect for this methodology. The researcher trusts its ability to seek the generative mechanisms underpinning the OTCH intervention and identify the role that context plays in firing them. There is a strong need to further develop ways in which the application of realist evaluation to rehabilitation research can become more accessible and less daunting for researchers interested in understanding how complex interventions work. In the following chapter the researcher, through the OTCH case study, provides further knowledge into how this can be achieved via applying realist evaluation principles to carry out a process evaluation.

CHAPTER 3:

Designing the theory driven process evaluation of the OTCH trial

3.1 Introduction

This chapter describes in detail the process evaluation of an RCT looking at Occupational Therapy in Care Homes (OTCH study). It addresses the challenge of investigating fidelity in the implementation of a complex rehabilitation intervention, designed to increase the level of independence in personal ADLs of stroke patients living in UK care homes. This chapter will start by briefly describing the OTCH trial and its results (more details in Chapter 1). It will continue by providing background information on fidelity research and what it means for process evaluations linked to trials investigating complex interventions. The justification for the choice of realist evaluation as a methodological guide for this process evaluation will then be presented. Details will be provided in regards to the methodological steps that were taken following a realist cycle, which led the research from an initial programme theory, to a final refined programme theory, describing how the OTCH intervention worked, for who, and under what circumstances. Both, quantitative and qualitative data collection and data analysis methods used to identify all factors underpinning implementation fidelity of the OTCH intervention will be described.

3.2 Background information

3.2.1 The OTCH trial – brief overview

As already explained in detail in Chapter 1, the OTCH trial is a pragmatic, cluster randomised controlled trial aimed at assessing the impact of a targeted course of occupational therapy on people living in nursing and residential

homes after suffering from a stroke (Sackley et al. 2004). This HTA funded cluster trial compared the level of independence in activities of daily living achieved by stroke patients at control care homes, with the level of independence of patients living at care homes that have had active occupational therapy input. The OTCH trial aimed not only to identify the possible impact that occupational therapy had on promoting independence in activities of daily living, but also on other health aspects such as depression and quality of life. As explained in Chapter 1 the OTCH intervention was a clear example of a complex rehabilitation intervention which needed detailed investigation, in terms of its components and underpinning interactions.

Results of the OTCH trial outcome evaluation showed no significant difference between intervention and control group in the primary and secondary outcome measures. The study therefore provided no evidence, at any observational time points, of the benefits of occupational therapy for all care home residents suffering from stroke related disabilities in terms of level of functional capacity (measured by the Barthel index). The research also found no evidence of any impact of the programme on secondary measures such as mobility, mood or health related quality of life (Sackley et al. 2015). As will be described in detail during this chapter, the process evaluation of the OTCH trial was carried out in order to throw light on the mechanisms and processes (i.e. the intervention theory) that explain the impacts (success and failure) of this complex rehabilitation intervention.

3.2.2 Assessing fidelity within the context of process evaluation

In this study, fidelity is defined as a thread that pulls together implementation processes within a clinical trial, along with the theories embedded in a complex intervention. Simply put, fidelity is a reflection of ‘high quality implementation’. By investigating fidelity, researchers maximise their chances of being able to unpin and understand implementation processes (see Chapter 1 for further information). However, there is a lack of a standard approach to the conceptualisation of fidelity and its assessment (Dusenbury et al. 2003, Holliday et al. 2009, and Hasson et al. 2012). The CFIF (Carroll et al. 2007) presents a synthesis of conceptualizations of fidelity, comprising concepts of

adherence (intervention content, coverage, frequency and duration), and 'moderating factors' which can potentially affect the degree of implementation fidelity (please refer to Chapter 1 for more information). As explained in Chapter 1, the CFIF was subsequently extended to include *context* and *recruitment* as two additional moderating factors (Hasson 2010). These modifications to Carroll's (2007) framework are closely in line with the identified vital need of health care research to understand how complex interventions work (Rogers 2008) and how closely their impacts are affected by their surrounding context (Byng et al. 2008)

As discussed in detail in Chapter 1, understanding implementation theories and their significance is vital for the investigation of fidelity. There are a number of conceptual and theoretical frameworks which have been developed within the implementation literature. These have been synthesised in the CFIR. This framework highlights additional factors relating to the intervention itself, the people involved, and support with implementation which, cumulatively, may explain the success (or not) of implementation (Damschroder et al. 2009). Consequently the CFIR is a tool which has been used in this process evaluation in order to unpin and understand fidelity. The breadth of this framework highlights the challenges that can be associated with bringing a complex intervention into practice with high fidelity within the care home setting. These challenges must be addressed if they are to improve outcomes for care home residents. This framework, which has already been described in detail in Chapter 1, includes 39 constructs grouped into the following five domains: *Intervention characteristics*, *inner context*, *outer context*, *the individuals* involved with implementation (in this case predominantly OTs and care home staff) and the *Implementation Process* itself (for full details see Chapter 1).

As discussed in Chapter 1, process evaluations can be designed to address aspects of fidelity including: recruitment strategies, adherence to the intervention, the quality of delivery, exposure or dosage, and participant responsiveness (Dane and Schneider 1998, Steckler and Linnan 2002, Dusenbury et al. 2003, Carroll et al. 2007, Craig et al. 2008). They can also

help differentiate the ‘active ingredients’ within a multi-component intervention, investigating how these components interact with each other to generate (or constrain) outcomes across different clinical, individual and social domains. Particularly relevant to fidelity, different components may be associated with different implementation challenges.

In recent years there has been a strong increase in published research on theories and frameworks driving and guiding process evaluations for complex interventions (please refer to Chapter 1 for more in depth information). However, process evaluations alongside trials investigating the impacts of rehabilitation occupational therapy and multidisciplinary therapies interventions are still very rare. A number of trials looking at possible impacts of various rehabilitation interventions for patients with neurological conditions have failed to show significant impacts of promising OT (Parker et al. 2001, Logan et al. 2003, Tsang et al. 2009, Guidetti et al. 2010, Mew 2010, Jarvis et al. 2012, Mödden et al. 2012) and physiotherapy interventions (Schachter et al. 2003, Elsworth et al. 2011, McCurry et al. 2011). Furthermore recent reviews have reported that at present there are not an adequate number of high quality trials to be able to make recommendations that support or refute the use of specific rehabilitation interventions to improve functional outcomes for neurological rehabilitation (Grabois 2007, Whyte et al. 2009, and Turoni et al. 2012). A process evaluation alongside these trials and research studies would have potentially identified whether non-significant responses were solely due to the intervention being ineffective or if there were other contextual and peripheral factors limiting the potential success of these interventions.

The MRC (MRC 2001, 2008) has proposed an approach to the evaluation of complex interventions which includes developing theory-based explanations of how interventions work. This guidance highlights that process evaluation can provide insight into why an intervention fails unexpectedly or has unanticipated consequences, or why a successful intervention works and how it can be optimised. It is widely accepted that process evaluations serve a very important role, not only when checking whether the trial intervention was performed as planned (fidelity), but also in providing detailed insight into the

experiences of those exposed to the intervention (Steckler and Linnan 2002, Oakley et al. 2006). More importantly, results from a process evaluation can be used to improve the intervention, either during its application, or afterwards, at an implementation stage (Hulscher et al. 2003). Trials which include a process evaluation will produce higher quality results that can help clarify the potential generalizability and optimisation of the proposed intervention in routine practice (Bonell et al. 2006, Moore et al. 2015).

The process of understanding how neurological rehabilitation interventions, such as the OTCH intervention, work (or fail) presents a number of methodological challenges such as:

- Clarifying the processes through which clinically significant changes are produced by the interventions, and assessed through the measurement of outcomes,
- Identifying the differing personal, organisational and social contexts within which complex interventions are to be embedded, and their influences on intervention delivery and impact, and
- Balancing the need to standardize intervention delivery across different contextual circumstances without sacrificing its integrity (Tones 2000, Hawe et al. 2004b, Shiell et al. 2008, O'Cathain et al. 2013)

3.3 The OTCH process evaluation: aims and objectives

The process evaluation of the OTCH trial was carried out in order to throw light on the mechanisms and processes (i.e. the intervention theory) that explain the impacts of this complex intervention. As part of this, the OTCH process evaluation would clarify how the OTCH interventions were carried out in reality, and what factors shaped this (fidelity). By carrying out a process evaluation it would be possible to identify if observed impacts were solely due to the trial intervention, or if these impacts were a result of a number of external and internal variables that are closely linked to the environment and the context in which the intervention took place (Oakley et al. 2006, Carroll et al. 2007, Grant et al. 2013).

The underpinning methodological framework of this process evaluation adopted a realist perspective. The theories of the OTCH interventions and their implementation could then potentially play a vital role in explaining and identifying important contextual factors that shape the implementation of OT interventions and their impacts.

The overall aim of this process evaluation was to evaluate and understand what worked for whom and how, at the time of the OTCH intervention implementation.

Specific objectives were to:

- Investigate how the OTCH intervention was put into action and which were the barriers and enablers.
- Identify and investigate health professionals' views and perceptions regarding the OTCH intervention.
- Explore health professionals' experience of implementation, identifying the actual practices and interactions that took place within the care home setting.
- Test the applicability and relevance of current frameworks of implementation and fidelity research to inform a process evaluation.
- To contribute to fidelity research by identifying potential improvements/modifications to current published frameworks.
- To assess the usefulness of realist evaluation as a methodology to guide process evaluations of complex rehabilitation interventions

3.4 Methodology and methods

3.4.1 Realist evaluation - justification

The methodological approach for this process evaluation was realist evaluation which addresses the importance of context in shaping the theories of how interventions work (Greenhalgh et al. 2009, Marchal et al. 2012, Rycroft-Malone et al. 2012) (For a review of realist evaluation please refer to

Chapter 2). As explained in detail in Chapter 2 the purpose of realist evaluation is to uncover explanatory, contingent programme theories in the form of context-mechanism-outcome (CMO) configurations. As Pawson and Tilley (1997) explain, mechanisms are the combination of reasoning (e.g. values, beliefs and attitudes) and available resources (e.g. skills, funding, support) that will enable a suite of interventions (i.e. programme) to work. In other words, 'mechanisms' relate to 'how' interventions work. Mechanisms "*describe what is about programmes and interventions that bring about any effects"* (Pawson and Tilley 1999). These underlying causal mechanisms will often not be apparent, they will be hidden and can be described as the building blocks of middle range theories. Realist evaluation understands causality in terms of underlying causal mechanisms generating regularities (Pawson and Tilley 1997). This generative theory of causality assumes that interventions will bring about different outcomes because the responsible mechanisms are not necessarily or equally activated in all contexts. Under a realist evaluation approach, context is pre-existing structures that may or may not activate a mechanism (Pawson and Tilley 1997). Context is embedded and accordingly, mechanisms will operate differently in different contexts (Westhorp et al. 2011). Applying these realist evaluation principles to the OTCH process evaluation was considered appropriate. Furthermore, realist evaluation is open to the use of mixed methods. Its aim is to explain how and where programs generate outcomes and it believes this can be achieved via both, qualitative and quantitative methods. As Westhorp et al. (2011) explain, qualitative methods help unpin and explore developed hypotheses and understand the way mechanisms work. Additionally, qualitative methods can also be used to identify unplanned events or outcomes.

Finally, there is a strong need for further research on the applicability of realist evaluation to fidelity research and what this means to process evaluation (Byng et al. 2005). Thus, this study aims to further contribute to the body of evidence of realist evaluation research.

3.4.2 The OTCH process evaluation – realist cycle

Following realist evaluation principles, the starting point of the OTCH process evaluation realist inquiry was the formulation of an initial programme theory that was then refined across cycles of evaluation (see Figure 3.1). The researcher's starting question was: *How did the OTCH intervention work? For whom? And why?* In line with realist evaluation principles a mixed methods approach was chosen, which consisted of both qualitative and quantitative data collection procedures. It was considered that by collecting both sets of data this study was highly likely to answer the research question.

This realist process evaluation firstly led to the development of a set of tangible assumptions that explained how researchers envisaged the OTCH intervention to reach its expected outcomes (Marchal et al. 2012). This initial programme theory was then used to guide further qualitative and quantitative data analysis and synthesis which finally led to the development of a tested theoretical account (refined programme theory) of the OTCH intervention implementation and its impact on outcomes. Applying realist evaluation principles to this process evaluation guaranteed a thorough identification of CMO configurations which formed patterns, or demi-regularities of what in the OTCH intervention worked, for whom, why and under what circumstances.

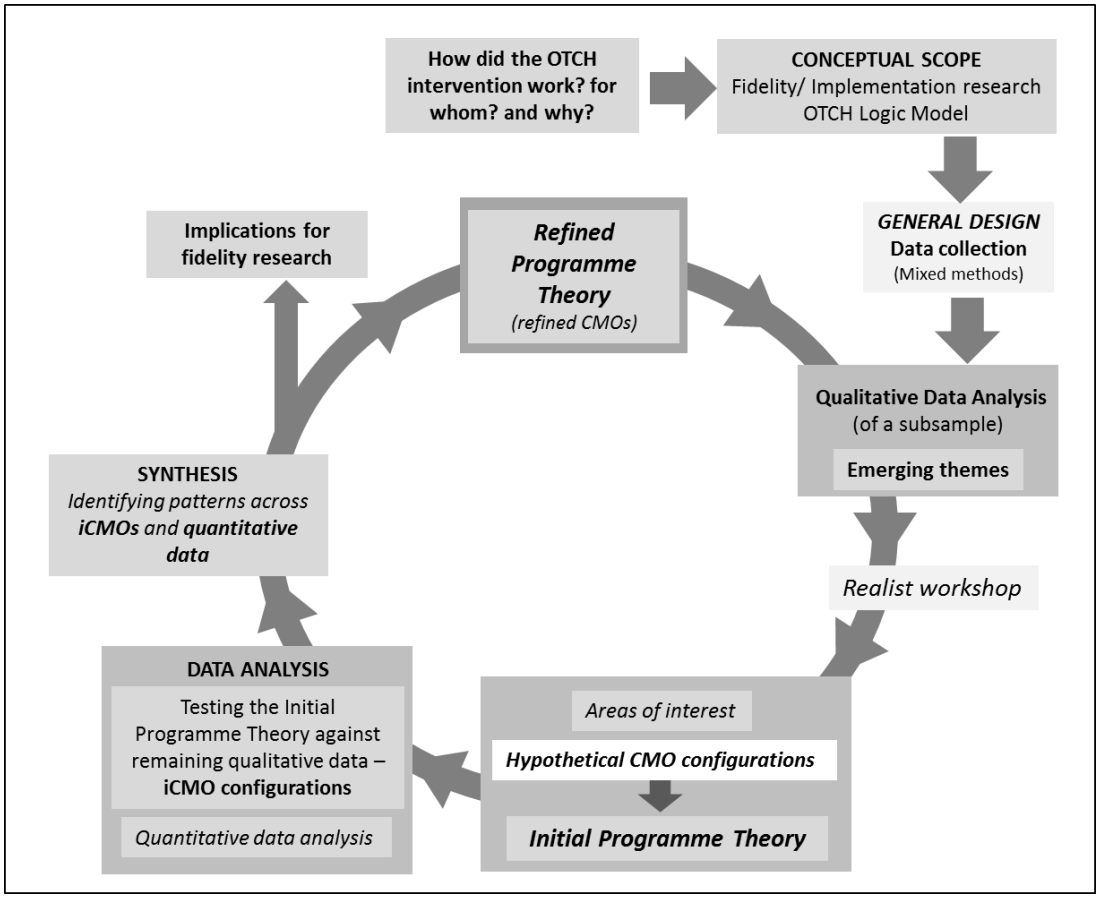

Figure 3.1 The OTCH process evaluation - realist cycle

3.4.2.1 The creation of an initial conceptual scope

Drawing from a number of sources a conceptual scope of the OTCH intervention as a complex intervention was generated. This conceptual scope was generated using the following sources:

A. A **logic model** was created for the OTCH intervention (Figure 3.2) informed by work by McLaughlin and Jordan (1999). As McLaughlin and Jordan (1999, p.65) explain, a logic model is a tool that can be used by program evaluators in order to "*develop and tell the performance story for their programme"*. The logic model describes the logical linkages, inputs, programme resources, outputs (what is done and which customers are reached) and short, medium and long term outcomes. Also, the logic model will require a description of underlying assumptions underpinning the proposed intervention and the external factors that might influence its impact.

According to Chen (1990) the logic model is closely related to programme theory which should be both prescriptive and descriptive. In other words, it should explain the elements of the programme but also describe the logic of how the program works. The researcher followed four steps in order to generate the logic model (McLaughlin and Jordan 1999):

- Collecting relevant information: the researcher collected information relevant to the OTCH intervention from multiple sources such as trial documentation (e.g. protocol, published articles) and discussions with principal investigators and project staff.
- Defining the problem and underlying assumptions: the researcher worked at understanding the problem in which the OTCH trial was grounded. This included understanding the problems and current state of therapy services for residents in UK care homes and the underlying assumptions underpinning the OTCH intervention.
- Drawing the Logic Model: the researcher used a diagram with columns and rows connected with one-way arrows (Figure 3.2). Then she listed the elements of each of the logic model components (inputs, outputs and outcomes) within their respective column. External factors and underlying assumptions were entered at the bottom of the model.
- Verifying the Logic Model with the research team members: the researcher met with the members of the research team in order to discuss the contents, clarity and relevance of the Logic Model. The team evaluated the Logic Model and discussed its level of detail and its contents (is it complete? are all key elements accounted for? do the elements fit together logically?).

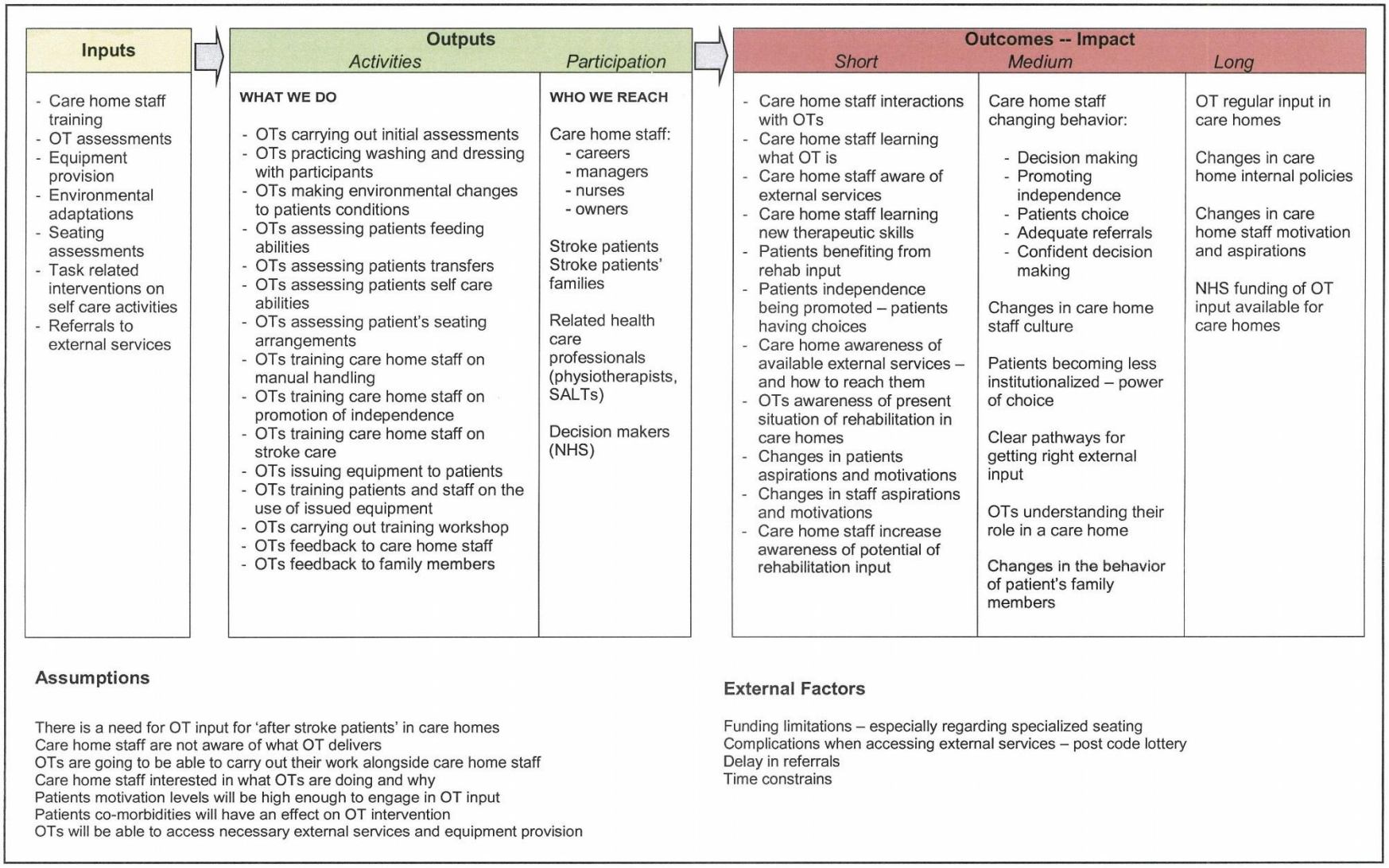

Figure 3.2 OTCH Logic Model

B. The **CFIR framework** was used to guide an in depth evaluation of the OTCH intervention in order to unpin all aspects of its implementation. As previously mentioned, the CFIR is a 'meta-theoretical' framework that is informed by a range of dissemination theories such as implementation, knowledge translation, innovation, organizational change, dissemination and research uptake. This framework has been used to investigate the implementation of well-defined interventions, although it can be of use and successfully applied to build a broader knowledge base in a range of situations and contexts (Fredriksson et al. 2014).

Informed by the CFIR domains and sub-domains, the OTCH intervention was analysed in detail and both aspects of the intervention and its implementation were identified. As a result, a detailed picture of the OTCH intervention and its components was generated. Results from this process are now presented and each CFIR domain (and sub-domains) is discussed in detail:

CFIR Domain 1: Intervention Characteristics (Table 3.1):

Implementing the OTCH intervention is likely to be highly complex since it is targeting a large number of organizations and it is offered multiple times to multiple groups (e.g. patients, care home managers, etc.). The OTCH intervention will be brought into the care homes through external OT input. Prior to the start of the trial, researchers would have possibly identified this intervention as having the potential to fill a gap in nursing home patients' care. There could, therefore, be an innovative component linked to the OTCH intervention and this can have a direct impact on its implementation. It is likely that the OTCH intervention will have to be adapted to fit into the care home setting and to fit the needs of this particular group of patients. This is likely to be challenging for those OTs in charge of delivering the OTCH intervention. The OTCH intervention protocol will potentially impact on the degree of tailoring which OTs choose to apply. The clarity and relevance of the information contained in the protocol will potentially have a strong influence at the time of implementation.

Table 3.1 Detailed deconstruction of the CFIR Domain 1 linked to the OTCH intervention

CFIR Domain 1: INTERVENTION CHARACTERISTICS		OTCH TRIAL INTERVENTION
a. Intervention Source	This intervention has been externally developed - OT input will be brought into care homes through an external source. If the OT intervention is effectively tailored to the care homes there can be a positive implementation outcome.	The intervention has been developed by researchers who identified a gap in patient care (Sackley and Dewey 2001). OTs through their intervention will have an impact on managers and staff in care homes – if this impact is positive then there will be a higher probability of a successful implementation. The perception of the OTCH intervention as greatly innovative can have direct (positive and negative) impacts on implementation. OTs carrying out the trial intervention are likely to have to work towards tailoring the intervention to best meet the needs of their patients; The OTCH intervention has a 'soft periphery' that is made up of elements and structures that are likely to require tailoring and remain flexible in order to be introduced to the care home where it is being implemented (Sackley et al. 2012). OTs are likely to have to: • Carry out their work around staff shifts in order to minimize disruption to the running of the care home. • Produce client centred treatment plans that can be carried out in patients' rooms and available resources at the care home without causing major disruption. • Adapt to patients schedules and liaise with them and their relatives in order to decide best time for therapy. A small number of OTs working in the OTCH trial had the possibility to 'practice' the intervention and familiarize themselves with the care home environment during the pilot study (Sackley et al. 2006). However for the majority of OTs this won't be the case.
b. Evidence Strength & Quality	There is scarce evidence-based research looking at the benefits of OT for after stroke care. Small trials have shown positive outcomes regarding activities of daily living and mobility which could play a role at reducing the risk of poor outcomes after stroke (Legg et al. 2007). The number of care home residents with a stroke is unknown (Rudd et al 1999). According to Sackley and Dewey (2001) few care home stroke patients have any access to rehabilitation (Sackley and Dewey 2001). Care homes in the UK rarely offer OT to residents (Fletcher-Smith et al. 2013).	
c. Relative Advantage	The OTCH trial aims to provide evidence that will clarify and explain the advantages and positive changes to patient's functional abilities that the implementation of the OT intervention can bring to care home residents across the UK. If care home owners, managers and staff perceive a clear, unambiguous advantage then the implementation will be successful.	
d. Adaptability	The OTCH intervention implementation might have to be adapted in order to meet specific needs for patients and staff in each care home. The degree of flexibility of the trialled intervention can be associated with positive implementation.	

CFIR Domain 1: INTERVENTION CHARACTERISTICS		OTCH TRIAL INTERVENTION
e. Trialability	The OTCH intervention was piloted in a residential home and the results showed that it was appropriate to the setting and the needs of the residents (Sackley et al. 2006). The piloting allowed individuals involved in the study to build experience and expertise. Being able to pilot the intervention will increase the possibilities of effective implementation (MRC 2001, 2008).	The OTCH intervention is complex; it targets different groups of patients in different types of settings (care homes) as identified in the study protocol (Sackley et al. 2006). Furthermore the intervention comprises a number of components (e.g. assessments, hands on therapy, referrals etc.) which will manifest themselves in different ways and situations. The OTCH trial protocol provides a simple and clear outline of the trialled intervention (Sackley et al. 2006). OTs carrying out the intervention will have access to this protocol. Additionally, OTs involved in the trial will attend training sessions where further guidance will be provided. However, these guidance will potentially have a small impact on the degree of tailoring which OTs choose to apply. The OTCH intervention is aimed at promoting patient's independence in functional activities. Accordingly, OTs will potentially work hard trying to minimize the need for equipment or assistance and will focus in the 'do it yourself' principle. This could potentially lead to a reduction in the time that carers need to spend with a particular patient and therefore a decrease in staffing costs.
f. Complexity	The process of implementation for this intervention is considered to be complex due to the scope and magnitude of it. The implementation is targeting a high number of potential organizations and the intervention is offered multiple times to multiple participants that will belong to a number of different groups (patients, providers, care home owners, managers). This heterogeneity is what defines complex interventions (Horner et al. 2006). This implementation regardless of its complexity will require simple, clear and detailed implementation plans in order to be successful.	
g. Design Quality and Packaging	The potential positive implementation of new procedures and approaches regarding patient care in residential homes will be directly linked to the intervention being delivered in a simple and accessible form. A clear intervention protocol including guidelines can positively influence implementation. These will require to be clear, accurate and reliable.	
h. Cost	The OTCH intervention implementation can be considered costly but once implemented daily cost is expected to remain manageable. However, due to the intervention complexity, the cost of implementation will be highly dependent on what the therapy plan entitles.	

CFIR Domain 2: Outer setting (Table 3.2):

The OTCH intervention will be delivered in care homes which will have different degrees of cosmopolitanism. In other words, care homes will network with outside organizations at different levels. Furthermore, implementation of the OTCH intervention could potentially be influenced by the reasons behind the care home's decision to join the research trial. The OTCH intervention is likely to have a stronger impact in those care homes who believe joining the trial could benefit their patients. The OTCH intervention can therefore be described as having a 'peer pressure' component that can potentially impact on outcomes. Furthermore it is interesting to investigate how possible incentives to implementing the OTCH intervention can impact on outcomes. The OTCH intervention will provide free OT service to care home patients and free training to care home staff. This component of the intervention can possibly, impact on the success (or failure) at the time of implementation.

Table 3.2 Detailed deconstruction of the CFIR Domain 2 linked to the OTCH intervention

CFIR Domain 2: OUTER SETTING		OTCH TRIAL INTERVENTION
a. Patient Needs & Resources	There is a need for research into the OT needs of stroke patients in care homes. At present few care home stroke patients have any access to rehabilitation, especially OT (Sackley and Dewey 2001). OT has a role in reducing the risk of poor outcomes after stroke (Legg et al. 2007). It is essential for the success of future implementation that the trialled intervention achieves strong 'patient-centeredness'.	Due to the nature of OT interventions which are strongly influenced by 'do it yourself' principle patient engagement in the process will potentially influence outcomes. Participants' characteristics in the OTCH trial are likely to be heterogeneous. OTs will need to address patients' needs and therefore tailor their intervention not only to these but also to the available resources. Each care home will be likely to welcome external services differently and OTs will need to assess this in order to learn how to best implement their intervention plans. It will be more challenging for OTs to suggest innovations in a care home that does not promote external linkages with outside organizations and services. Care homes do not usually need to 'fight for patients' and are normally in a position of being able to accept or reject patients as it suits the organization best. It is likely that care homes did not agree to be part of the trial in order to become more competitive but because they believed the trialled intervention could benefit their residents. Care homes are not receiving any incentives to join the trial. However, they will benefit from external support (the OTs) at no extra charge. Furthermore their staff will received training in regards to stroke rehabilitation also free of charge.
b. Cosmopolitanism	The degree to which care homes network with outside organizations will determine their cosmopolitanism. In this trial cosmopolitanism will be care home dependent and will have an impact on the assimilation of proposed innovations.	
c. Peer Pressure	Do care homes feel pressured to welcome research initiatives as part of the service they provide to patients? If care homes were part of a highly competitive market this would make them more likely to implement new interventions such as OTCH, driven by the 'need for customers' and the pressure to 'stand out' from the crowd. Furthermore 'mimetic pressure' can have some form of influence in the success of the OT intervention implementation – if a number of care homes decide to adopt this intervention others might feel compelled to do so as well.	

CFIR Domain 2: OUTER SETTING		OTCH TRIAL INTERVENTION
d. External Policy & Incentives	A 'policy push' can increase motivation of care homes to implement the OTCH intervention. At present there is not robust evidence showing that documents such as for example NICE guidelines will influence implementation. However, it is possible that 'public reporting' (as explained by Greenhalgh, 2004) will motivate care homes to adapt OT intervention in an effort 'not to look bad' compared to others.	It will be a challenge to investigate care homes motivations for joining the trial which could be simply linked to 'box-checking' or to truly commit to its implementation for the benefit of their residents. If the OTCH intervention was found to bring positive outcomes in stroke patient's recovery then incentive measures could be carried out (e.g. NHS rewarding and supporting care homes that decide to include OT as part of their services).

CFIR Domain 3: Inner setting (Table 3.3):

A number of vital elements were identified when describing the inner setting of the OTCH intervention and its potential impact on implementation.

The quality of communication systems that are part of the care home routine (e.g. team meetings, handover procedures, feedback opportunities) could potentially impact on implementation success. The OTCH intervention will have a communication component which will need to be addressed and put into action effectively in order to increase the chances of positive impacts on outcomes. Mapping the culture of OTCH care homes can provide OTs with important insight regarding how to work towards increasing chances of implementation success. If OTs identify that a care home is driven by principles and values based on promotion of independence and self-esteem, they will be likely to expect staff at that care home to be more prone to embrace OT interventions. In the same way a care home with a culture that promotes innovation as a way to offer 'best possible care' will be likely to work in tune with OT principles and proposed intervention plans.

Leadership engagement will play a vital role in the success (or failure) of the OTCH intervention and its implementation. If middle managers feel they are part of the process and are asked to be engaged, it is more likely that they will embrace the trial and its aims. Thus, a major component of the OTCH intervention will be 'networking' and promoting managerial involvement. In line with this if OTs propose interventions which interfere with the existing workflow and organizational systems in place, they are likely to be rejected (e.g. an ADL intervention aimed at promoting independence might be perceived as a threat to carers since they might think their job is at risk). The OTCH intervention will therefore have a 'compatibility' component which can potentially play a major role in determining possible impacts.

Table 3.3 Detailed deconstruction of the CFIR Domain 3 linked to the OTCH intervention

CFIR Domain 3: INNER SETTING		OTCH TRIAL INTERVENTION
a. Structural Characteristics	Overall it appears that care homes have a simple structure. Decision making is largely down to the care home manager and this could potentially lead to ineffective implementation. The knowledge base is scarce and the degree of specialization very low.	Care homes in the OTCH study are different sizes and have different sources of funding (e.g. NHS, private). Some care homes are residential others provide nursing care. OTs in the trial are likely to have to spent time assessing and understanding how care homes are run. The ways in which communication (e.g. interchange and passing on of information) happens between members of the care home staff team will need to be described and its efficiency assessed. OTs success in understanding care home communication paths is likely to have a significant impact on how well the OTCH intervention is assimilated by the care home. The OTCH trial care homes' culture including assumptions and principles should be measured and identified during the running of the trial. The OTCH trial presents an intervention that has been developed externally as a result of identifying the need for change. If stakeholders (e.g. care home managers and staff, patients) had identified this need for change prior to the OTCH trial it is likely that the OTCH intervention will be highly welcomed and embraced. The proposed intervention plans that OTCH OTs propose will have more chance of being successfully implemented if they are compatible with the 'climate' at the care home. It is vital to understand the relative priority that OTs involved in the OTCH trial and also care home staff give to the OTCH intervention. The training that OTs receive prior to starting to work on the trial could influence the relative priority they assign to the OTCH intervention. During this training OTs were potentially able to identify aspects of the intervention such as innovation or need for it. In the same way the relative priority that staff assign to the intervention can
b. Networks & Communications	Greenhalgh (2004) explains that organizations can be networked formally or informally but that regardless of this, communication across the organization is vital. Communication systems (assessment records, interdisciplinary team meetings, case notes, handovers etc.) should be mapped for each of the OTCH care homes in order to get a 'real picture' and predict the future success or failure of implementation.	
c. Culture	Each of the care homes in the OTCH trial will have a series of norms, values and basic assumptions that 'belong to that care home'. The culture of an organization affects all social groups that form part of it. Employees will impart this culture to new staff; furthermore, this culture will cascade down and will have an impact on the patient. Culture will affect all social relations amongst groups at the care home (Damschroder et al. 2009).	

CFIR Domain 3: INNER SETTING		OTCH TRIAL INTERVENTION
d. Implementation Climate d.1. Tension for change d.2. Compatibility d.3. Relative priority d.4. Organizational incentives & rewards d.5. Goals and feedback d.6. Learning climate	Will care homes support the OTCH trial? If yes, to what extent? The OTCH trial is justified by evidence showing the lack of provision of OT and rehabilitation therapy as part of standard care (Fletcher-Smith et al. 2013). The current situation can therefore be perceived as intolerable and this can strongly influence success of intervention implementation. If the proposed OTCH intervention is in alignment with patient's and staff's own norms and values the chances of implementation success will increase. If employees or staff involved in the implementation of an innovative intervention regard it as a distraction from their 'real work' this could negatively influence the chances of successful implementation. In this case staff perceive the intervention as having low relative priority. Care homes in the OTCH trial have accepted to be involved in it regardless of incentives or rewards. This can be interpreted as showing that care homes are interested in providing the best possible care to their residents are therefore are open to innovations proposing to better it.	potentially be affected by how OTs communicate with them and train them on OT principles. Care homes involved in the trial do not receive any monetary compensation. However they do benefit from OT input free of charge which could, on its own be a major reward for joining the trial. Also, OTs carrying out the intervention have put in place a training package that will issue certificates of attendance which can be seen as a reward since it will contribute to staff's professional development portfolio. Also they can act as an incentive to attend the training. The OTCH intervention plans will be goal orientated, therefore it is vital that OTs get the chance to have frequent discussions with staff in order to go through the reasoning behind the choice of goals and how to best work to achieve them. Feedback on progress on OTCH interventions will need to be frequent and in the form of for example discussions, report and note writing. Variability of methods will increase the chance of efficient communication in this setting where staff turnover is very high. OTs working on the OTCH trial will need to work hard at creating learning opportunities for care home staff during the time treating OTCH patients. The OTCH intervention will involve a series of components and the success of implementing these will be strongly affected by how staff are made to be feel included and valued. A learning climate will enhance staff's confidence at the time of embracing the OTCH intervention. For OTs to be able to implement the OTCH intervention they will need to feel like they have the support from the managerial team which is in charge of decision making. If agreement to take place in the study was signed by high level managers and middle level managers haven't been informed this could work negatively impact in the ability of OTs to do their work.

CFIR Domain 3: INNER SETTING		OTCH TRIAL INTERVENTION
	For successful implementation to take place it is vital for the care homes to have efficient feedback and communication systems in place. Only if goals are clearly explained and recorded they will have a chance to be achieved. If care homes spend time and resources in providing learning opportunities for staff it is likely that staff will have higher confidence levels and they will feel as they have a valuable role to play. The implementation of a complex intervention such as OTCH will be directly impacted by the degree in which care homes make their staff feel valued.	The OTCH intervention will often involve the issuing equipment. Although funding for small pieces of equipment is available bigger and more sophisticated equipment will need to be funded by alternative sources. This can prove challenging for OTs who will need to work with the care home staff to identify these sources. Care homes in OTCH are heterogeneous in terms of who funds them and this can become an added difficulty. The OTCH intervention provides education and training resources not only to OTs carrying out the intervention but also to care home staff. This education will not only be available as formal training but also present in everyday conversations and daily sessions with care home residents.
e. Readiness for Implementation e.1. Leadership engagement e.2. Available resources and access to knowledge and information	It is of vital importance for the success of the OTCH intervention to have a clear understanding of how committed and accountable for the success of its implementation stakeholders and care home managers are. Implementation of the OTCH intervention will require funding and training to be widely available to all OTCH care homes. A lack of funding or a complex system in place in order to access it can negatively impact the trial outcomes.	

CFIR Domain 4: Characteristics of individuals (Table 3.4):

The OTCH intervention will be delivered by a number of OTs with different backgrounds, levels of experience and values. This 'variable' component will potentially play a major role in shaping impacts on outcomes. It is therefore important to gather information which will provide an overall understanding of the trial's OT force. Furthermore, OTs will perceive their role in the trial differently and they will have preconceptions regarding the 'need for change' in the way patient care is managed. This is likely to further impact on the implementation of the intervention.

Intervention OTs' self-efficacy levels will require close attention in order to predict how efficiently they will be able to manage the challenges and obstacles they will be likely to encounter. In the same way it will be important to identify the variety of tools and resources that OTs will potentially use in order to 'tackle' the challenges.

CFIR Domain 5: Process (Table 3.5):

An OTCH trial protocol has been published (Sackley et al. 2012). This protocol described in detail the aims and objectives of the OTCH intervention as well as its content. OTs will execute the OTCH intervention making use of different tools and resources to hand (e.g. peer help, published evidence, etc.). However, it is expected that each OT will further apply an individual approach to practice and this 'individual practice' component of the intervention can potentially impact on outcomes. Furthermore, implementation success (or failure) will be linked to the ability of OTs and staff involved in the trial to evaluate progress and act accordingly.

Table 3.4 Detailed deconstruction of the CFIR Domain 4 linked to the OTCH intervention

CFIR Domain 4: CHARACTERISTICS OF INDIVIDUALS		OTCH TRIAL INTERVENTION
a. Knowledge & Beliefs about the intervention	A strong motivation and a belief in the benefits of the intervention will positively affect implementation. Both, OTs and care home staff's believes will play a role in shaping future implementation.	The OTCH intervention will be delivered by a number of OTs. Each OT will be strongly influenced by her/his culture, norms, values and interests at the time of implementing the OTCH intervention. OTs in the trial will perceive care homes in a different manner and in the same way care home staff will have preconceptions regarding the uses and purpose of OT. The degree of commitment that different OTs and care home staff have to improve patient care will strongly impact on the success of OT intervention. OTs working in the trial have different expertise not only working in care homes but also treating the elderly and stroke rehabilitation. OTs are at different stages in their careers and will have different levels of enthusiasm when it comes to their professional role. OTs working in the OTCH trial will face the challenge of 'gaining a place' in the care homes where they are delivering the intervention. OTs will use their skills and tools at hand to achieve this. OTs personal attributes such as tolerance of ambiguity, flexibility in thinking, competence, learning and teaching style, intellectual ability etc. will impact on the intervention and implementation success
b. Self-efficacy	The success of professionals at the time of implementing the OTCH intervention will be affected by their level of confidence and self-efficacy.	
c. Individual Stage of Change	The level of expertise of those involved in delivering and implementing the trial intervention will play a role in its success at impacting patients' level of independence and functional activity.	
d. Individual Identification with Organization	The implementation of the OTCH intervention takes place in care homes, if OTs in charge of delivering it feel they are part of the care home team and have a place in it then success of implementation will be enhanced. Implementation will also benefit from staff at the care home feeling confident and being able to identify what is their role in regards to patient care.	
e. Other Personal Attributes	The set of skills and personal attributes that professionals delivering the OTCH intervention have will strongly impact on their ability to overcome challenges and therefore successfully implement the intervention in different care homes. Care home staff personal attributes will further contribute to this success (or failure).	

Table 3.5 Detailed deconstruction of the CFIR Domain 5 linked to the OTCH intervention

CFIR Domain 5: PROCESS		OTCH TRIAL INTERVENTION
a. Planning	The OTCH trial intervention was planned prior to the start of the trial and a protocol was published (Sackley et al. 2012). Guidelines for OTs in the trial were created in order to establish priorities and goals of those interventions. This could potentially influence the degree of success at the time of implementation.	OTs in the trial are expected to follow the OTCH study protocol. It is expected that each OT will apply an individual approach to practice and therefore will follow the protocol to a different degree. The Barthel Index and Rivermead mobility score was chosen as the outcome measure helping inform the assessment and future treatment plan. OTs working in the OTCH trial are expected to offer OT treatment and propose treatment plans that are in line with the aims of the trial (described in the study protocol). As a results of pre-trial training and guideline provision OTs would be aware of what treatments they would be expected to offer. Assessing how the OTCH intervention will be carried out not only across sites but also at care home and patient level. This will be extremely important in order to identify how this complex intervention is working as a 'whole' but also at each component level. The pilot study (Sackley et al. 2006) has provided a solid base to do so since it allowed the testing of procedures.
c. Executing	The quality of execution will be influenced by a number of factors (all discussed above). The degree in which the protocol was followed will be assessed via the data contained in the intervention logs and OTs notes. A good in depth understanding regarding how the intervention is executed by the trial OTs (and joint working with care home staff) will strongly impact in the research team's ability to explain the success (or failure) of implementation.	
d. Reflecting & Evaluating	Reflection and evaluation can help OTs involved in the OTCH trial identify their own progress and their weaknesses when dealing with all aspects of their role in the trial (interventions, communicating with staff, success of treatment plans, training session, etc.). Implementation success (or failure) will be linked to the ability of OTs and staff involved in the trial to evaluate progress and act accordingly.	

As a result of the work described above (Table 3.1-3.5), the researcher was able to conceptualize the OTCH intervention and generate its 'conceptual scope'. This would be the knowledge base leading to the application of realist evaluation principles, as explained in Figure 3.1. This conceptual scope was also vital in order for the researcher to make decisions in regards to the best possible data collection methods. These are described in the following section.

3.4.3 Data collection - mixed methods

A mixed method approach was chosen in order to collect data for the realist OTCH trial process evaluation. As previously explained, realist evaluation has no preference for qualitative or quantitative methods. It is methodologically neutral and does not reject any experimental methods (Marchal et al. 2012, Salter and Kothari 2014). Realist evaluation acknowledges the richness in mixed methods, as long as the balance of chosen methods is in line with the realist hypothesis, the research question and the possibilities of data collection. The researcher, in line with authors such as Steckler and Linnan (2002) and Grant et al. (2013) considered that the use of mixed methods could add complementary insights. A mixed methods approach involves collecting both, quantitative and qualitative data as part of the same study. This data is then integrated as part of the research process (Denzin 1970, Steckler et al. 1992, Creswell et al. 2003, Johnson and Onwuegbuzie 2004). Mixed method research is currently gathering momentum and growing in social sciences research (Creswell 2003, Tashakkori and Teddlie 2003) (please refer to Chapter 2 for further information).

The researcher, in agreement with what has been suggested in the literature by several authors, believes that by using simultaneously qualitative and quantitative methods, rehabilitation researchers are able to address all aspects and concerns of current practice and its inherent complexity (Rauscher and Greenfield 2009, Shaw et al. 2010). Mixed methods research is well suited for rehabilitation research as it broadens the scope of enquiry in order to better understand patients' illness and rehabilitation process.

3.4.4 Qualitative data collection methods

3.4.4.1 In depth semi-structured interviews

The use of qualitative in depth interviews, or 'purposeful conversations' (as Rubin and Rubin (2005) refer to them) is supported by the interpretivist paradigm, since it believes that it is the meaning behind personal experiences and situations that is important and this should be the aim of in depth interviews. In depth interviews are a data collection method that is not linked just to one methodology but it can be used across many of them (Carpenter and Suto 2008). Carrying out interviews is a widely accepted strategy for data collection since it has the potential to generate rich and in depth data. It is also probably the most commonly used data collection method in qualitative research (Fontana and Frey 2000) and is frequently used in rehabilitation research (Scheer et al. 2003, Lund and Nygaard 2004).

<u>The interview process</u>

As Carpenter says regarding the interviewing process "*it is not a process that can be hurried"* (Carpenter and Suto 2008, p.85). The term semi-structured interview refers to an interview that is not completely unstructured. However, authors such as Mason (2002) explain that all interviews, in order to achieve their purpose will need some form of structure, they cannot be completely lacking one. Additionally, interviews, do not always need to be 'face to face' (although most of them are), they can also be online or by the phone. They can be short or they can be a lengthy process that includes a series of interviews. As Carpenter and Suto (2008, p.83) say most studies in "*health care seem to consist of single interviews of approximately 90 minutes"*. Regardless of the length and structure of the interview, researchers must have attention to detail and be rigorous when planning its content and delivery (Mason 2002). Additionally researchers will need to work on developing the right set of skills required to carry out a successful interview (Denzin and Lincoln 1998). Carrying out a qualitative interview is a complex, difficult task that requires experience (Lincoln and Guba 1985). Ultimately each researcher will need to develop and reflect on their own interviewing style. Firstly, in order

to be successful the researcher will be responsible for the important task of pacing the interview (Lincoln and Guba 1985) and will need to be creative and able to make decisions on the spot as the interview progresses. In this way, the researcher can guarantee that the interview is producing data consistent with the research purpose/question (Carpenter and Suto 2008). Secondly, the researcher must use probes and prompts to ensure the 'richness of data' and in depth content in the response (Patton 2002). As Mason (2002, p.67) argue: "*they need to ensure that the interview interaction actually does generate relevant data, which means simultaneously orchestrating the intellectual and social dynamics of the situation*".

Additionally as Patton (1990, p.327) says "*effective interviews should cause both the interviewer and the interviewee to feel that a two way flow of communication is going on"*. A constructivist interview should advocate an equal balance of powers and hideaway from traditional approaches which presented the interviewee as a subordinate of the researcher (Fontana and Frey 2000). Narratives generated in the interviews should be constructed by the person being interviewed, based on their own experiences, what they chose to disclose and what they know about the issue (Nunkoosing 2005).

The researcher will need to pay attention to work on 'building rapport', by both engaging with the interviewee and communicating empathy and understanding, whilst avoiding judgemental comments (Patton 1990). Also, by making sure they achieve a balance between talking, listening and being responsive to participants' reactions (Mason 2002).

A number of useful techniques aimed at improving the quality of data gathered from in depth interviews have been reported, such as asking open-ended questions and avoiding the use of multiple questions, technical terms or questions that sound like the interviewee's knowledge is being tested. Patton (2002) explains that interviews should include different types of questions exploring a number of issues such as the interviewee's background, experiences, behaviours, opinions, values, feelings and emotions. However, ultimately all questions must have a purpose and remain relevant to the research question.

Collection of interview data

It is widely accepted that the recording and transcribing of interviews is the best way to make full use of the data gathering process. Recording the interview means that the researcher does not run the risk of missing out on what a participant says whilst trying to manually record the answers (Patton 2002). Additionally, by recording the interview the researcher will be able to focus on making field notes 'in situ' which can be of good use and contribute to the data analysis process (Patton 1990). A general limitation of recording all data is the need to then transcribe it. Transcriptions are often time consuming and expensive if someone is hired to do them (Carpenter and Suto 2008). In answer to this Patton (2002) suggests that in order to minimize costs the researcher could listen to the recordings, determine which are the most valuable sections and transcribe these.

3.4.4.2 In depth semi-structured interviews in the OTCH process evaluation

Creating the OTCH interview schedule

The OTCH interview schedule targeted all potential areas of the OTCH intervention and its implementation which were described in detail in the OTCH process evaluation initial conceptual scope. Drawing from the conceptual scope, questions were generated to address all identified intervention components and implementation factors. Since the aim was to carry out semi-structured interviews, all potential issues were grouped accordingly to produce the final OTCH interview schedule, which consisted of nine broad questions and related probes and prompts (Appendix 3.1). With the help of prompts and probes these nine questions guaranteed the collection of in depth data targeting all issues relating to the intervention and its implementation identified in the conceptual scope phase.

As a quality assurance measure the OTCH interview schedule was piloted with two of the OTs involved in the trial. Doing so was an opportunity to gain experience and get feedback regarding interview skills. It also provided an opportunity to refine prompts or particular aspects of the interview schedule content. No changes to the interview questions were required.

Carrying out the OTCH interviews

In depth semi-structured interviews (n=17) were carried out with all OTs delivering interventions within the OTCH trial. The characteristics of the OTs are described in Table 3.6. Prior to the interview, written information (via email) was sent to all OTs explaining the aims of the process evaluation and the reasons underlying the importance of collecting data via individual interviews. Interviews were carried out by the PhD student (PM) who, as a qualified OT, brought an awareness of the study practice and setting contexts. In order to assure quality and objectivity of the interview data PM was not known to the OTs prior to the interviews. OTCH was a UK wide study, and so in order to save time and resources, interviews were conducted over the telephone. These interviews have been reported to lead to high quality data since they allow respondents to feel more relaxed and able to disclose sensitive information (Novick 2008). Interviews were digitally recorded and fully transcribed and then checked by the interviewer, keeping all names of participants anonymous.

Table 3.6 OTCH occupational therapists characteristics

OCCUPATIONAL THERAPISTS	**n = 17**
Years since qualifying Mean number of years (± SD)	9.5 (±6.5)
First job since qualifying? Yes (%) No (%)	2 (12) 15 (88)
Previous experience in stroke care? Yes (%) No (%)	15 (88) 2 (12)
Previous experience in care homes? Yes (%) No (%)	7 (41) 10 (59)
Previous experience in elderly care? Yes (%) No (%)	16 (94) 1 (6)
Previous research experience? Yes (%) No (%)	8 (47) 11 (53)

OTs were asked to give consent to the recording prior to the start of the interview and were invited to take part in the interviews at a time and date that

suited them. Interviews with OTs lasted on average 51 ± 17.93 minutes (Range: 11-98min). In order to collect in depth information, interviews were conducted when OTs had been actively involved in the OTCH trial for a minimum of 10 weeks.

Each interview started with an 'ice breaker' question: "*Tell me about your role within the OTCH trial. Have you enjoyed it?"* This allowed the OTs to talk freely and in general terms about their experience working in the project. It also allowed the interviewer to familiarize herself with the OT. Whilst allowing OTs to express themselves the interviewer then continued collating in depth data regarding three areas: OTs previous experience and opinions regarding care homes and rehabilitation provision, the OTCH intervention and finally OT/care home staff dynamics. Interviews remained semi-structured throughout. Interviewees were encouraged to talk openly and discuss failures and problems as well as successes. In some cases, participants were allowed to talk more abstractly about what might have occurred had things been different.

As a recommended quality assurance measure, transcriptions were made available to the OTs (member checking) as a way to ensure the validity and accuracy of findings (Cohen and Crabtree 2008). OTs were also given the opportunity to provide subsequent reflections if they considered necessary. However, no OTs did.

<u>Post interview reflections/self-evaluation</u>

Qualitative research and qualitative researchers recognize that the nature of reality is socially constructed, relative and multiple (Denzin and Lincoln 2005). In other words, the researcher is considered an integral part of the process that shapes the collection and interpretation of data. As Carpenter and Suto (2008, p.125) discuss:

> "*The central role (of the researcher) makes it impossible for the qualitative researcher to present an objective, dispassionate, distanced, non-contested account of other individuals' experiences".*

They further define reflexivity as:

> "*an essential strategy that enhances the quality of research by making explicit the deep-seated views and judgements that affect the research topic, including full assessment of the influence of the researcher's background, perceptions and interests on the research process"* (p. 125).

Self-evaluations can help construct the reflexive account of the interview process. Through self-evaluations researchers can interrogate their own beliefs and feelings and see how these might have impacted on the collected data (Carpenter and Suto 2008). Furthermore, through the self-evaluation process, the researcher can explore thoughts and feelings about the research process.

The PhD student completed a post-interview reflection/self-evaluation after each interview which identified any issues regarding delivery or content of the interview (see Appendix 3.2). These were addressed through discussion with the research/supervision team prior to carrying out another interview.

3.4.4.3 Critical incident reports

As an additional data collection method a critical incident technique was used. The aim of it was to further investigate the sense that OTs made of particularly challenging or memorable situations that took place during their involvement in the OTCH trial. Data was collected in the form of critical incident reports (n=20) (see Appendix 3.3). Critical incident reports followed a reflective cycle (Gibbs 1988) prompting therapists to analyse their practice throughout the trial (Schluter et al. 2007). Guiding questions were designed to bring to the surface, deeper, double-loop reflections, examining the reasoning and values underpinning practice (Argyris and Schon 1974). In this way, it was hoped that the data would reveal therapists' 'theories in use' rather than any espoused practice to conform to researchers' expectations of their work within the trial.

OTs receive substantial information on reflective techniques during their professional training and reflection is a normal activity in everyday OT practice. The researcher thus considered this data collection method would be well received. Additionally, in order to assure quality data, OTs were briefed

regarding the purpose and content of critical incident report forms. They were asked to submit their completed forms by post or by email. Throughout the duration of the trial and process evaluation, reminder emails were sent by the PhD student in order to enhance data collection. By the end of the trial a total of 20 reports had been collated from seven of the OTs involved in the OTCH trial.

3.4.5 Quantitative data collection: OT Intervention Logs

In accordance with the mixed methods approach chosen to carry out the realist OTCH trial process evaluation, the researcher carried out the collection of quantitative data alongside qualitative approaches previously described. OTs involved in the OTCH trial were asked to complete an 'Occupational Therapy Intervention Log' (see Appendix 3.4). This log represented a data source from the main trial which was further used for the purpose of the process evaluation. In this intervention log, OTs working in each of the study sites (Table 3.7) had to record the number of minutes they had dedicated to various aspects of the OTCH intervention at each visit during each wave. The intervention log included the following categories of the OTCH intervention:

- Assessment and goal setting.
- Communication: including listening to residents' concerns or life story, information giving (to residents, staff or relatives), referrals to other agencies and ordering equipment.
- ADL training.
- Transfers and mobility: including aspects of wheelchair provision if directly concerned with mobility rather than seating.
- Adaptive equipment, seating, postural management and environmental adaptations: including preventative interventions, such as wheelchair cushions and palm protectors.
- Other: including treating impairments directly and the use of leisure activities.

Table 3.7 OTCH trial study sites and waves - number of OTs working on each site

Site	Number of waves	Number of OTs
Site 1	3	2
Site 2	4	1
Site 3	3	1
Site 4	3	2
Site 5	3	1
Site 6	1	1
Site 7	1	2
Site 8	1	1
Site 9	2	1
Site 10	1	1
Site 11	1	3

3.4.6 Data analysis methods

3.4.6.1 Quantitative data – statistical analysis

Descriptive statistics were carried out on the Intervention Log data in order to identify the distribution of OT 'minute usage' across waves and between sites. Data for each of the variables (Table 3.8) at each site and wave was analysed and mean, standard deviation and standard errors calculated. All data analysis was carried out using IBM SPSS statistics 20 and Excel.

Table 3.8 Statistical variables used in data analysis

Fixed factors	Dependent variables
• Site • Wave	• Proportion of minutes dedicated to: ▪ Assessing ▪ Communicating ▪ Carrying out ADL interventions ▪ In 'transfers and mobility' ▪ Equipment provision ▪ Other activities • Number of OT visits per patient • Total number of OT minutes per patient

In order to investigate the possible changes in the way OTs chose to use their time with patients throughout their involvement in the trial, analysis of variance (ANOVA) was carried out on the data for each site. A complete list of investigated variables is provided in Table 3.8. ANOVA was used to determine if the difference in 'minute usage' between waves was significant. As shown in Table 3.7 only five sites completed three waves. Therefore in order to carry out this analysis only data for these sites was considered. Prior to ANOVA 'homogeneity of variances' was investigated using Levene's test. This test is designed to test the null hypothesis that the variances of the groups (waves) are the same. When Levene's tests for the data was significant (i.e. the value of p is less than 0.05) then it was concluded that variances were significantly different and this meant that the data was contradicting the principle assumption of ANOVA. In this case data transformation took place (square root and logarithmic) and Levene's tests were ran again. In the cases when even after transformation the data did not pass the Levene's test, data were analysed using the non-parametric test Kruskal Wallis.

The Tukey post hoc test was ran on those variables that showed a significant difference between waves. The aim of this test was to provide information on which waves were significantly different from each other. The Tukey test compared:

- Wave 1 and Wave 2
- Wave 1 and Wave 3
- Wave 2 and Wave 3

Limitations of the quantitative data

For the purpose of this study the researcher had access to the Interview Log data. Throughout the process, the researcher was aware that these data presented some limitations. The OTCH intervention was complex, and hence a number of factors could potentially impact on the quality and reliability of available data. Firstly, a high proportion of patients recruited for the OTCH trial had some form of co-morbidity and different degrees of cognitive impairment. Secondly, the Intervention Log recording sheet could have led to different OTs

interpreting the meaning of the different categories in a slightly different way. This could have been accentuated by the fact that, as shown in Tables 3.6 and 3.7, OTs that delivered the OTCH intervention had different levels of research and professional experience. Also, whilst some sites only recruited one OT to implement the intervention, in other sites two or even three OTs were recruited. The researcher was aware that available quantitative data would not be able to identify the impacts that these factors might have had on the results.

3.4.6.2 Qualitative data - initial coding

Generating a coding framework

Prior to coding the transcribed interviews and critical incident reports, an initial coding framework, including components of both the intervention and its implementation, was generated (see Appendix 3.5). The coding framework was guided by information gathered in the initial 'conceptual scope' (Table 3.1 to 3.5 for details). Individual codes were created for:

- Each of the components of the OTCH intervention that had been previously identified as activities that OTs were likely to carry out with care home residents.

- All aspects of the implementation of the OTCH intervention which had been identified belonging to each of the constructs of the CFIR.

Initial data analysis of interview and critical incident report data – initial emerging themes

As Rubin and Rubin (2005, p.201) say when talking about qualitative data analysis:

> "*Analysis entails classifying, comparing, weighting and combining material to extract the meaning and implications, to reveal patterns, or to stitch together descriptions of events into a coherent narrative".*

A subsample of the interviews (seven) was analysed following a thematic interpretive approach (Miles and Hubermann 1994). This process relied on an

inductive reasoning process which aimed at interpreting and finding a structure to the meanings derived from the data (Thorne 2000). This process consisted in an initial data reduction/display phase followed by a conclusion drawing phase. The data reduction phase started with reading and re-reading the data. As Mason (2002, p.149) explains, this phase involves "*reading through and beyond the data"*. During the first part of the process the researcher collated all qualitative data, transformed it and organized it in the most suitable way for the coding process to start. The next step involved the coding of the qualitative data which aimed at organizing all data related to specific codes in the same place. As Miles and Hubermann (1994) explain, through coding the researcher can find the links between the data and his/her interpretive decisions (in this case via generation of a coding framework that is linked to in depth understanding of the OTCH intervention).

The PhD student carried out the coding of all data using Atlas.ti software. Units of meaning (quotes in the case of the interview data) within the text were allocated to each code (Rubin and Rubin 2012). Codes were not '*carved in stone'* (Carpenter and Suto 2008, p.117) and the researcher, in order to interrogate the data to its full potential, grouped or renamed codes as appropriate. A new code was created if the researcher identified information in the interview data which did not correspond to any of the codes in the coding framework. Crosschecking by a different member of the research team was carried out with 10% of transcripts, to identify codes where there was lack of clarity.

Once the coding was completed and throughout this first phase of the research process, the researcher had already gained an in depth understanding of the topics of interest and relationships between data. The researcher continued the analysis by reading and re-reading all quotes and units of meaning that had been assigned to each code and generated charts (using Atlas.ti) which displayed this information. This process led to the researcher identifying emerging categories which were put together in different overarching initial themes in order to reach the next higher level of abstraction. Following the recommendations of Miles and Hubermann (1994)

as to how to find and generate themes, the researcher compared the data, for example counting how many OTs had given similar answers, or looking for cause-effect examples amongst the data, etc. Throughout the different phases of the data analysis the researcher understood that although this was an interpretive exercise it was of vital importance to remain consistent in the way she engaged in the process.

A realist workshop – identifying 'areas of interest' to generate an initial programme theory

Following the realist evaluation cycle described in Figure 3.1, an interim analysis was carried out after analysis of data from a subsample of seven interviews and all critical incident reports was completed. A workshop including all members of the research team and an OT who had recently completed work in the trial was organized. This workshop followed a realist evaluation approach and aimed at identifying a number of 'areas of interest' and hypothetical CMOs which would direct the remaining data analysis (Figure 3.1).

During the discussion the team generated ideas about which contextual factors were likely to be most important and which potential mechanisms would potentially be responsible for triggering intervention impacts and outcomes. Team members discussed potential relationships between codes and initial emerging themes, potential contextual factors embedded in the OTCH intervention, potential barriers/limitations to implementation and finally OTs role in implementing it. The PhD student identified substantial coded 'quotes' that led to open discussion amongst members. Discussions were recorded in the form of flipchart diagrams and notes. According to realist evaluation this open discussion was useful in that it generated an understanding of what was happening, who was it happening to and how.

Following the results from the workshop in which a number of '**areas of interest'** were identified, data were revisited and coding of all remaining interview and critical incident report data was completed. Remaining data was analysed and tested against the identified 'areas of interest' and their

hypothetical CMOs. As illustrated in Figure 3.1, this analytical task resulted in detailed (narrative) *initial CMO configurations* (iCMOs) for each of the identified 'areas of interest'. The researchers' choice to present identified CMO configurations in the form of contingent narratives was justified by a belief that in order to unpick how the OTCH intervention worked, for who and under what circumstances, these narratives provided *"the most effective way to tell the story, to convince the audience"* (Denzin and Lincoln 1998, p.47). These contingent narratives can be a very powerful means of telling a story, as long as they remain close to the data. In other words, they are plausible explanations of observed outcomes that are based on evidence (Greenhalgh et al. 2011). As in the work carried out by Rycroft-Malone et al. (2014), the contingent narratives reported in this thesis were developed by synthesizing and summarizing the characteristics of the evidence that was underpinning the OTCH intervention.

Generating a refined programme theory – patterns across iCMOs and synthesis of quantitative data

The next step aimed at looking for patterns (demi-regularities) across all identified iCMOs for each 'area of interest' and synthesizing this data with quantitative findings in order to generate explanations about what worked, for whom, how and in what circumstances. This generated a set of higher level *refined CMO configurations* (Figure 3.3). The transition from 'area of interest' specific iCMOs to cross-areas refined CMOs and a refined programme theory represents the shift to more generalizable theory and corresponds to the 'cumulation of knowledge' discussed by Pawson and Tilley (1997).

The researcher considered all quantitative findings and read and re-read all identified iCMOs in the search for patterns and their underpinning mechanisms (Figure 3.3). The researcher then focussed on 'unpicking' all aspects of each of these identified mechanisms. These led to the development of refined CMO configurations in the form of contingent narratives describing how identified mechanisms were 'triggered', under what circumstances and what were the impacts. Throughout the described process the team regularly

met to crosscheck results in order to ensure integrity of interpretations and synthesis of data sources.

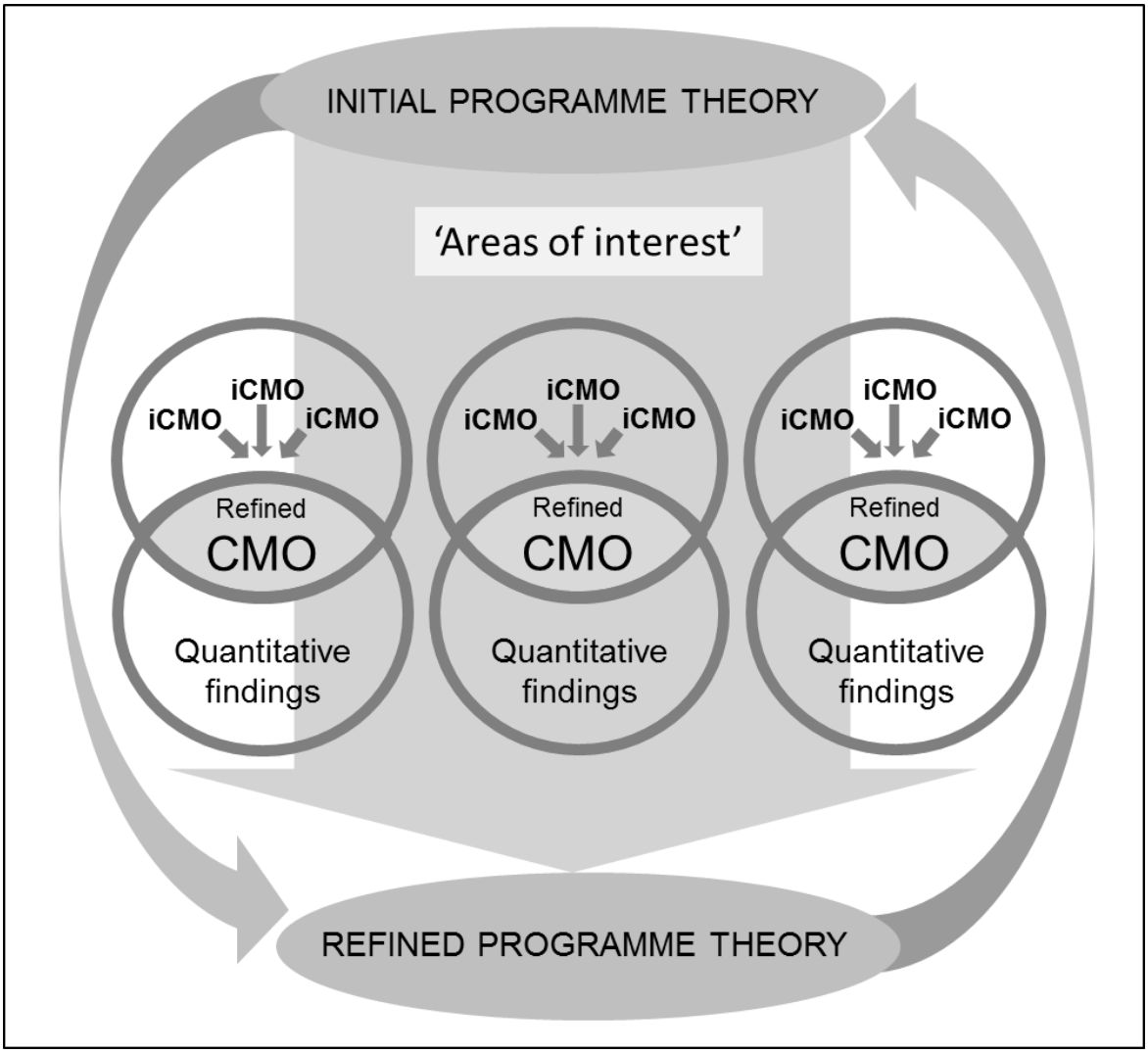

Figure 3.3 Thinking process guiding the generation of a refined programme theory

The research presented in this chapter is in line with the philosophical and methodological underpinnings of this thesis which supports a pragmatic approach to data collection and data analysis methods. In this process evaluation research, qualitative and quantitative data work in unison in order to answer the research question.

It was not expected that the end result of a realist evaluation would explain all possible patterns (demi-regularities) of outcomes associated with the intervention. It was not even expected that the refined programme theory

would provide generalizable configurations of what worked in the OTCH trial, for whom and in what circumstances (Pawson and Tilley 1997). The results from this realist evaluation were expected to become part of an ongoing cycle where theories are constantly being refined to produce further cycles of inquiry, so the process of theoretical development is ongoing.

3.5 Conclusion

This chapter has provided a detail description of how the theory driven process evaluation of the OTCH trial was carried out. The methodological and research design choices that the researcher made in order to complete this process evaluation are closely in line with the philosophical underpinnings of this thesis. The researcher has applied a flexible lens to the choice of data collection methods and data analysis which was underpinned by a realist evaluation methodology. Thus, the researcher considers the design of this process evaluation, which this chapter reports on, to be innovative and to further contribute to the development of fidelity research of complex rehabilitation interventions. This design was tested on the OTCH trial and the results from its application are presented in the following chapter.

CHAPTER 4:

Findings from process evaluation of the OTCH trial

4.1 Introduction

This chapter presents the findings of the theory driven process evaluation alongside the OTCH trial. In line with realist evaluation principles results from each stage of the realist cycle (Figure 3.1) are discussed. Data analysis results from both quantitative and qualitative sources are reported and discussed in detail. A newly developed refined programme theory drawing on principles of realist evaluation and informed by implementation and intervention fidelity frameworks is described. The programme theory incorporates four potential mechanisms through which fidelity within the trial can be investigated. These four programme theory areas are (1) the balancing of research and professional requirements that therapists performed in a number of areas whilst delivering the study interventions; (2) the OTs rapport building with care home staff; (3) the work focussed on re-engineering the personal environments of care home patients, and (4) the learning about the intervention within the context of the trial and its impacts over time.

The findings presented in this chapter characterise the real-world nature of fidelity within intervention research, and specifically the negotiated nature of implementation within clinical settings, including individual patients' needs. This research adds to the evidence base because current frameworks for fidelity neglect the importance of learning over time of individuals and across the timespan of a trial.

4.2 Results from quantitative data analysis

4.2.1 Descriptive statistics

As described in Chapter 3, the OTCH trial involved 11 sites throughout England and Wales (Table 3.7). Out of those 11 sites, only 5 of them completed 3 waves, including Site 2 where four were completed (Figure 4.1). The rest completed only one. Overall the results from descriptive analyses show how there was great variability between sites and waves regarding a wide range of variables. All results from descriptive statistics including number of patients, means and standard deviation for each of the considered variables at each site and wave are available in Appendix 4.1. Table 4.1 presents a brief summary.

Table 4.1 Summary of descriptive statistics for all sites across all waves (A: assessment, C: communication, ADL: activities of daily living, T: transfers, E: equipment provision, O: other activities)

			Mean value (across waves)		% of time OTs spent delivering the different components of the OTCH intervention (mean value across all waves)					
Site	**Waves**	**Total number of patients**	**OT visits per patient**	**OT min per patient**	**A**	**C**	**ADL**	**T**	**E**	**O**
1	3	169	5	189	20	65	5	5	4	1
2	4	35	6	243	31	23	16	11	14	6
3	3	17	3	77	18	28	7	27	4	16
4	3	51	6	135	48	37	4	3	7	1
5	3	22	6	242	34	41	4	10	4	8
6	1	24	3	296	47	23	5	7	10	7
7	1	30	8	358	23	59	1	5	6	6
8	1	40	5	172	41	44	1	3	4	6
9	2	61	5	208	34	49	1	3	8	4
10	1	29	3	103	57	37	2	2	1	2
11	1	10	10	661	21	61	4	5	1	8

In terms of the number of patients who received the OTCH intervention in each of the sites, and during each wave, our results show great variability (Figure 4.1). Site 1 recruited the most patients, a total of 169 between the three waves. Site 11 had only 10 participants which were all part of wave one.

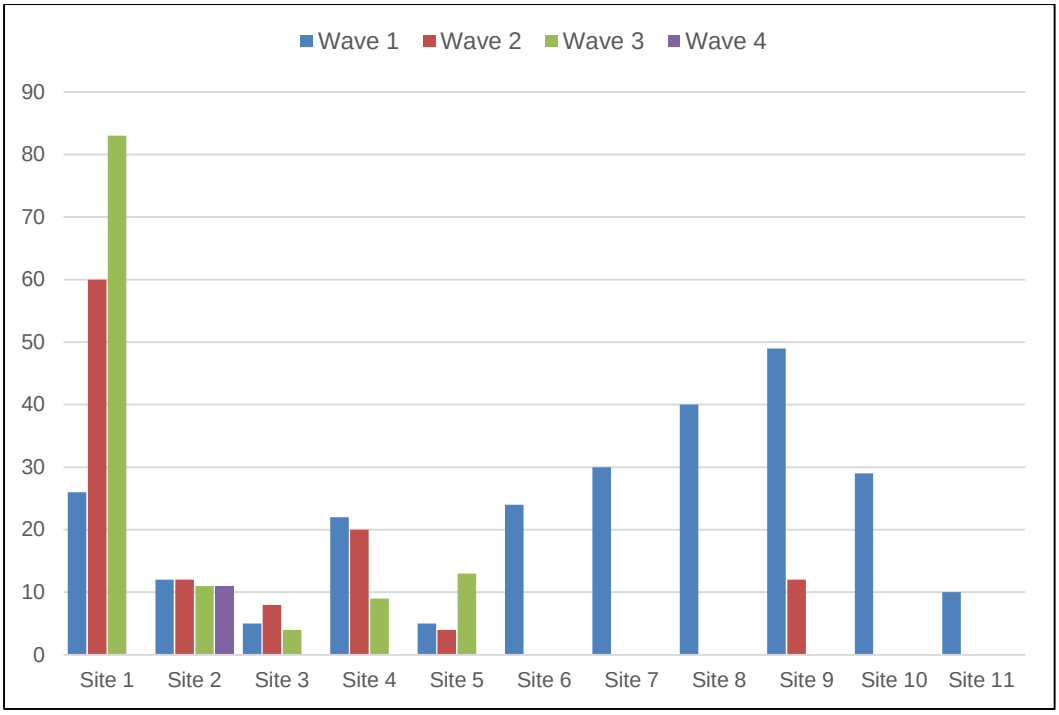

Figure 4.1 Total number of patients per site and in each wave

In some sites results show strong variability in the number of patients across waves (Table 4.1). An example is Site 1 where OTs treated 26 patients during wave 1 and 60 and 83 in waves 2 and 3 respectively. However, other sites such as Site 2 recruited a consistent number of patients across waves (11 and 12 patients in each of the four waves). In terms of the number of OT visits during the duration of the OTCH trial, overall, each patient in Site 11 received the highest number of OT visits (9.6 ± 1.5 SE) whilst each patient in Site 3 received the least (3.06 ± 0.4 SE).

Results show great variability in the way OTs decided to make use of their time with patients (Table 4.1). These differences occurred both between sites and waves involved in the OTCH trial (Figure 4.2). Figure 4.2 shows how OTs in the OTCH trial spent most of their time assessing patients and communicating with them, their relatives and care home staff. In sites such as Site 1, Site 7 and Site 11 OTs spent 63%, 59% and 61% of their time communicating with patients respectively.

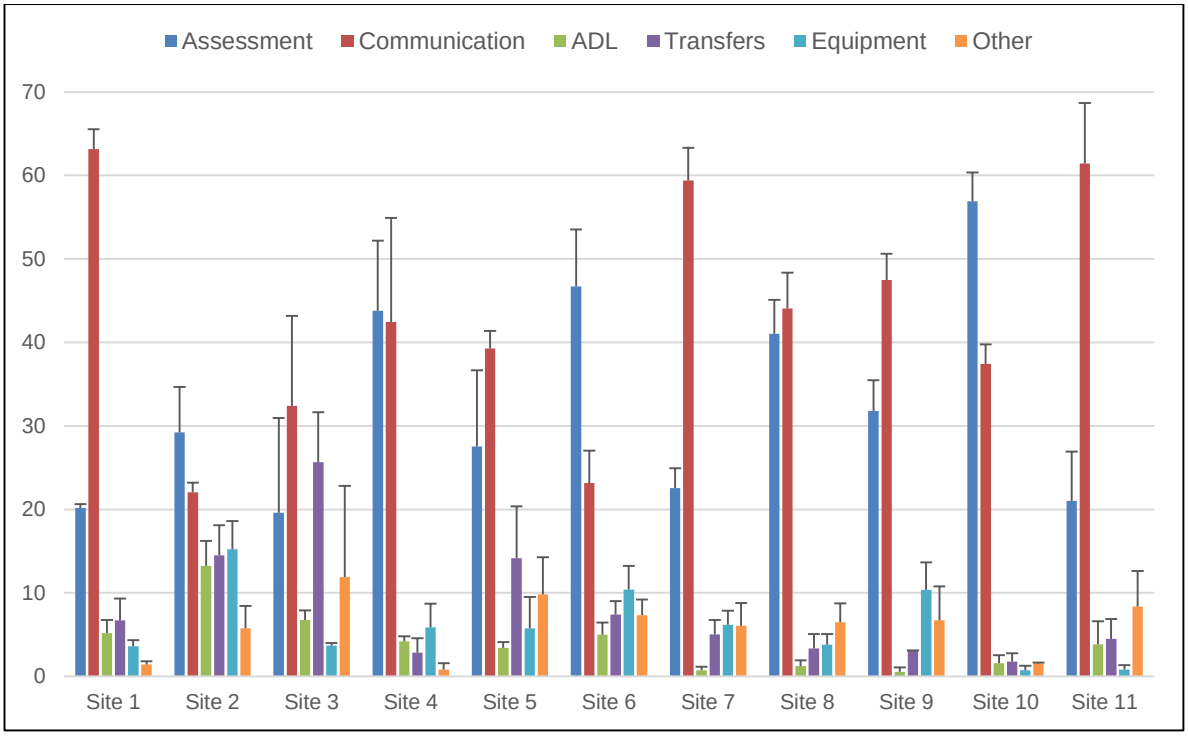

Figure 4.2 Mean values of OT minute usage (± SE) at each site across all waves

OTs in the majority of sites chose to spend most of their time 'assessing' and 'communicating' with patients and spent a relatively small percentage of their time carrying out other components of the OTCH intervention. In Site 4 for example, OTs spent 47.6% (± 3.1 SE) and 36.9% (± 2.9 SE) of their time assessing and communicating with patients and the remaining 15% of their time involved in other components of the OTCH intervention. On the other hand, OTs in sites such as Site 2, Site 3 and Site 5 showed a more equally distributed use of their time across all possible components of the OTCH intervention (Figure 4.2).

Site 2 OTs were the ones, across all sites, who chose to spend the most time in equipment provision related interventions (13.6% ± 2.7 SE) whilst OTs working in Site 10 spent the least of time implementing this type of intervention (0.74% ± 0.5 SE).

4.2.2 Differences between waves – changes over time

The amount of time OTs chose to dedicate to each of the OTCH intervention components changed over time (Figure 4.3). Although, as already mentioned,

most of OTs in the five sites which completed three waves (Site 1, Site 2, Site 3, Site 4 and Site 5) spent the majority of their time assessing and communicating with patients, there were also clear changes with time (between waves). As it is clear from Figure 4.3, throughout the trial, OTs' choices in regards to how to use their time with patients did not remain consistent.

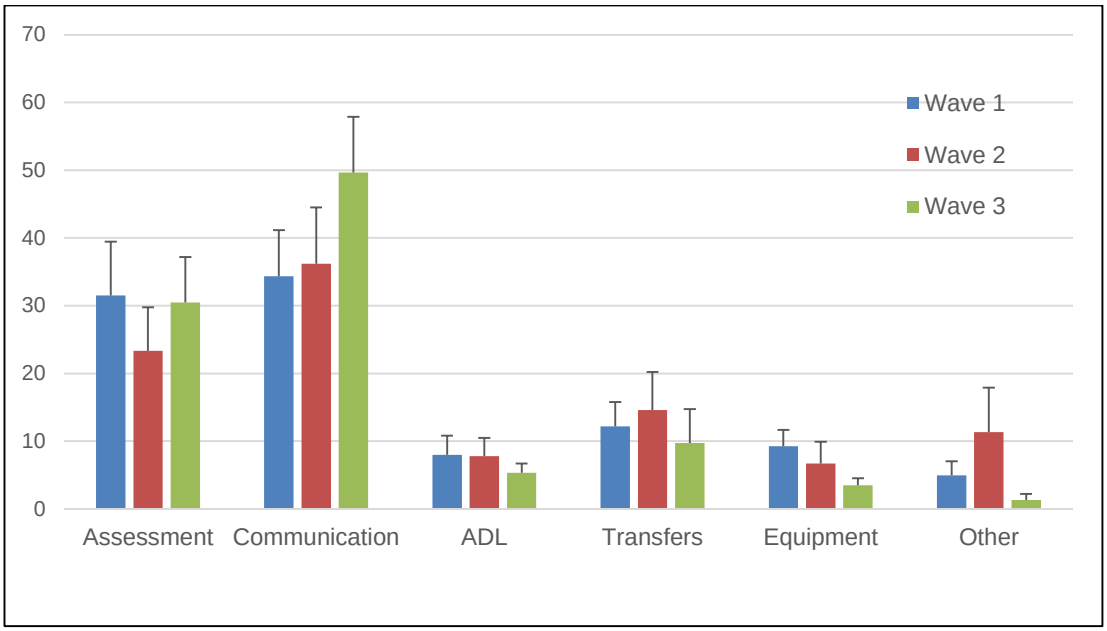

Figure 4.3 Percentage of time (± SE) OTs spent in each of the components of the OTCH intervention across all sites (those who completed 3 waves) at each wave

As described in Chapter 3 ANOVA tests were carried out on those sites which completed three waves. Although four waves took place in Site 2 only data from the first three waves was considered for the data analyses in order to achieve a 'balanced data set'.

Results from the 'homogeneity of variances' test (Levene's test) for each site are available in Appendix 4.2. Data for a number of variables that did not pass Levene's test were transformed; overall logarithmic transformations were more successful than square root transformations. Those variables for which Levene's test was non-significant ($p > .05$) were subject to ANOVA.

ANOVA was carried out on all variables which passed the Levene's test. All results from ANOVA are presented in Appendix 4.3. These results showed

that at each site a number of variables were significantly different between waves.

For those variables that were significantly different across waves, a Tukey post hoc test was carried out in order to compare waves and see which ones were significantly different from each other. Appendix 4.4 provides all results from Tukey tests.

Differences between waves in those dependent variables that did not pass the Levene's test were analysed using the Kruskal Wallis non parametric test. Results are shown in Appendix 4.5. For the variables that showed a significant result in this test ($p < .05$) pairwise comparisons were carried out in order to identify where the difference was present. A detailed description of the variance of each of the investigated variables follows.

4.2.2.1 Total number of OT visits per patient

The results showed a significant difference between the total number of visits that OTs carried out in Site 2 ($F(2, 32) = 3.63$, $p = .038$), Site 3 ($F(2, 14) = 7.41$, $p = .006$) and in Site 4 ($F(2, 48) = 5.96$, $p = .005$) in waves 1, 2 and 3 (Figure 4.4). In Site 2 Tukey test's results (Appendix 4.4) showed that the number of OT visits per patient in wave 1 (8.17 ± 3.07 SD) was significantly different than in wave 2 (5.33 ± 2.14 SD). In Site 3 significant differences were present between number of OT visits per patient that took place in wave 1 (1.40 ± 0.89 SD) and wave 2 (3.63 ± 1.4 SD) and between wave 1 and wave 3 (4 ± 2.3 SD). Finally OTs in Site 4 carried out a significantly different number of visits per patient during wave 1 (5.91 ± 2.15 SD) and wave 3 (3.78 ± 1.48 SD) and during wave 2 (6.55 ± 2.03 SD) and wave 3.

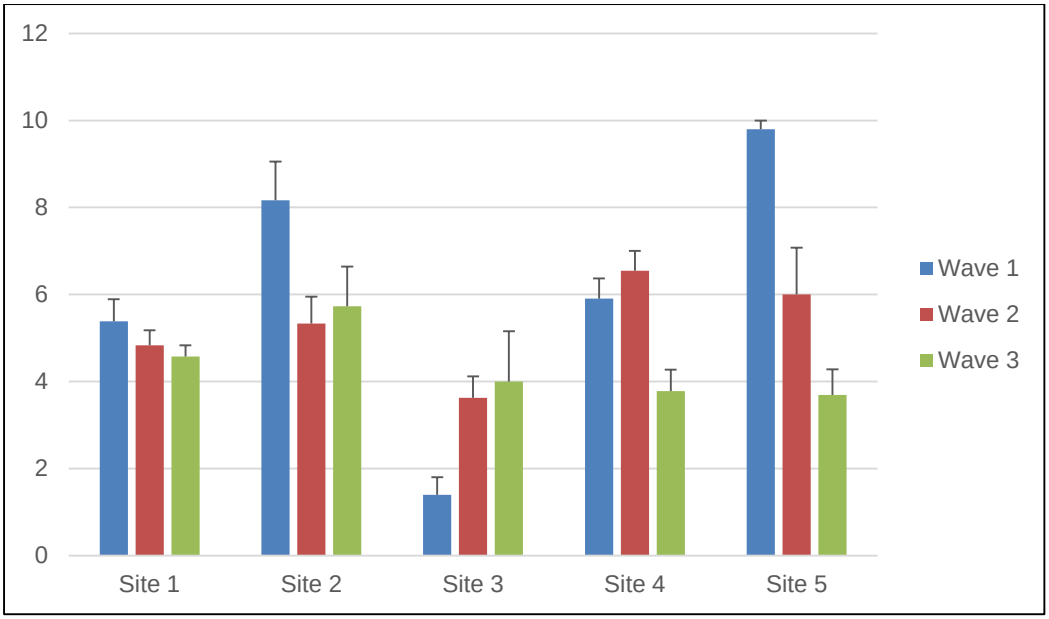

Figure 4.4 Change in the total number of OT visits per patient across OTCH trial waves (± SE)

4.2.2.2 Total number of minutes that OTs spent with each patient

The total number of minutes that OTs spent on average with each patient showed a significant difference between waves in four of the sites: Site 1 (non-parametric test p = .005), Site 2 (F(2, 32) = 8.57, p = .001), Site 4 (F(2, 48) = 4.13, p = .022) and Site 5 (F(2, 19)= 8.39, p = .002) (Figure 4.5). Tukey test and Kruskal Wallis test (in the case of Site 1) showed that this significant differences were present between two of the waves in Site 1, Site 4 and Site 5. In the case of Site 1 it was wave 3 (148.8 ± 100.44 SD) and wave 2 (249.7 ± 217.63 SD) that were significantly different. In Site 4 this was the case between wave 2 (150.25 ± 57.89 SD) and wave 3 (88.33 ± 55.79 SD) and in Site 5 between wave 1 (390 ± 120.05 SD) and wave 3 (168.08 ± 98.09 SD). In Site 2 results showed that there were significant differences between wave 1 (405.42 ± 225.29 SD) and wave 2 (157.9 ± 69.06 SD) and wave 1 and wave 3 (159.5 ± 94.61 SD).

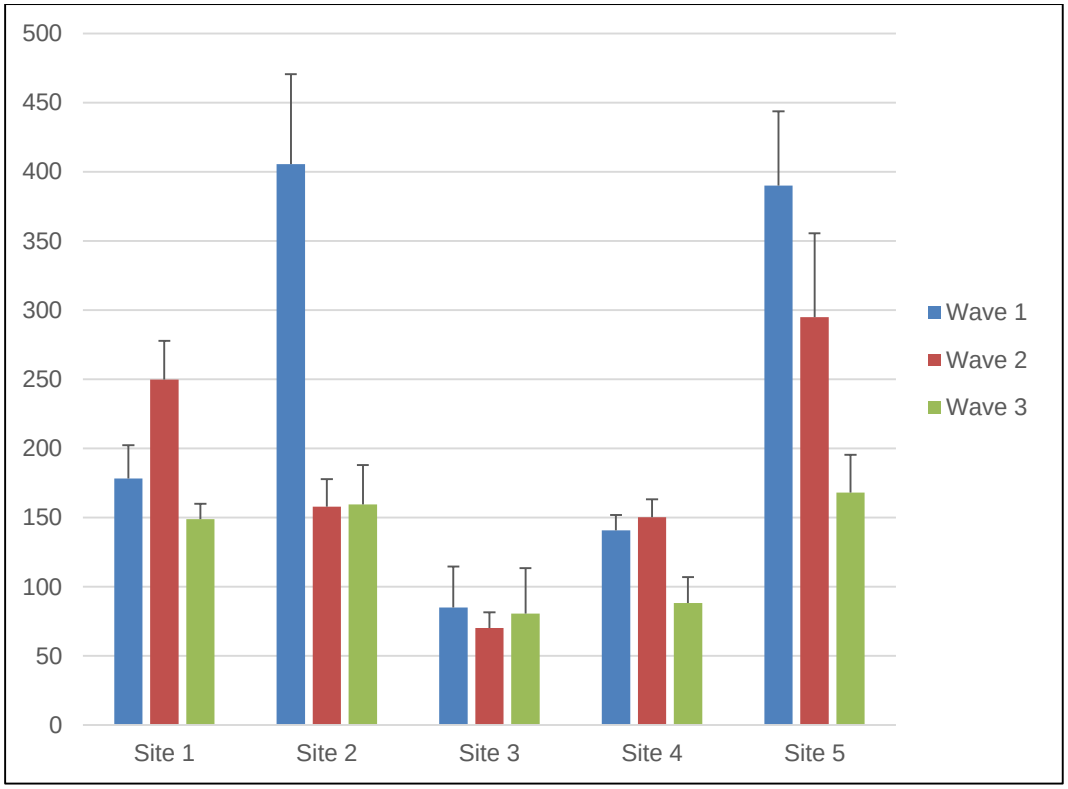

Figure 4.5 Total number of minutes that OTs in the OTCH trial spent with each patient at each site during each wave (± SE)

4.2.2.3 Time OTs spent 'assessing patients and setting goals'

In two sites, Site 3 ($F(2, 14) = 8.66$, $p = .004$) and Site 4 ($F(2, 48) = 6.85$, $p = .002$) ANOVA showed that the proportion of time that OTs spent assessing patients and goal setting showed a significant difference between waves (Figure 4.6). In the case of Site 3 this difference was significant between wave 1 (42% ± 27.06 SD) and wave 2 (5.1% ± 6.03 SD) and wave 1 and wave 3 (11.65% ± 10.5 SD). In Site 4 the differences in the time OTs spent in this component of the OTCH intervention were significant between wave 1 (57.7% ± 21.96 SD) and wave 3 (28.6% ± 17.36 SD).

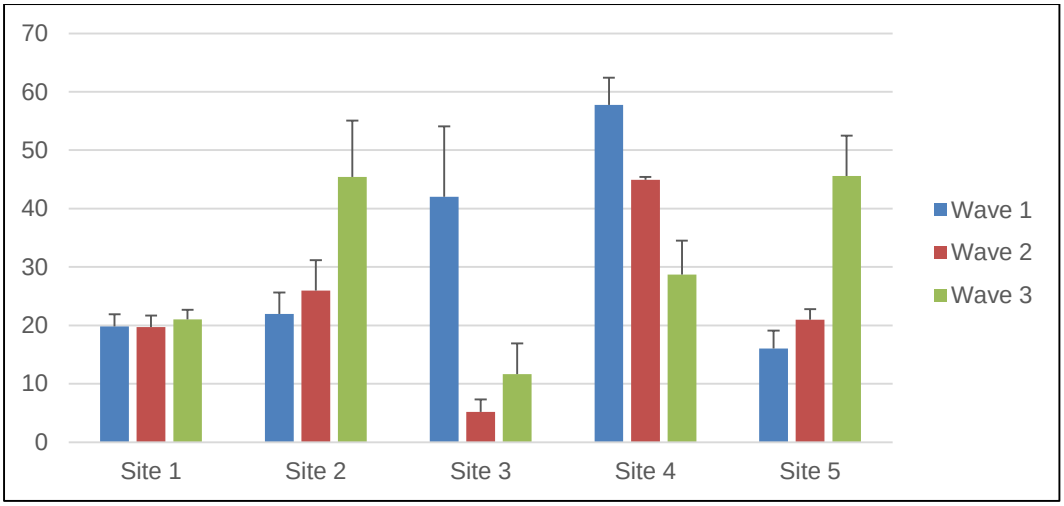

Figure 4.6 Percentage of time that OTs spent 'assessing and goal setting' at each site during each wave (± SE)

4.2.2.4 Time OTs spent 'communicating'

Results from ANOVA show that the proportion of time OT chose to spend communicating with patients, relatives or care home staff during their involvement in the OTCH trial remained consistent throughout (Figure 4.7). Results show that only OTs in Site 4 spent a significantly different proportion of their time communicating with patients, relatives and care home staff between waves ($F(2, 48) = 4.41$, $p = .017$). The difference was significant between wave 1 (20.8% ± 8.82 SD) and wave 3 (64% ± 21.73 SD). ANOVA results from Site 3 show a nearly significant result ($F(2, 14) = 3.61$, $p = .054$).

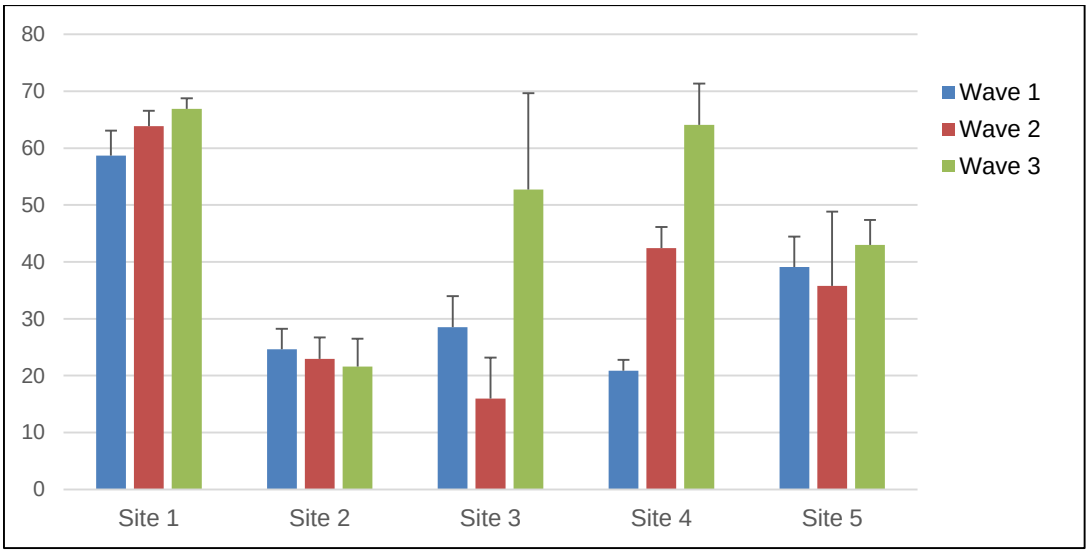

Figure 4.7 Percentage of time that OTs spent communicating with patients, relatives or care home staff at each site during each wave (± SE)

4.2.2.5 Time OTs spent carrying out ADL related interventions

Throughout the OTCH trial, OTs remained consistent in regards to the percentage of their time that they chose to spend carrying out ADL related interventions with patients (Figure 4.8). ANOVA found no significant differences with time across waves. Kruskal Wallis non-parametric tests (Appendix 4.5) showed a significant difference in this variable in Site 1 ($p = .001$). Pairwise comparison tests showed that this difference was significant between wave 2 (7.7% ± 10.6 SD) and wave 3 (2.2% ± 5.5 SD).

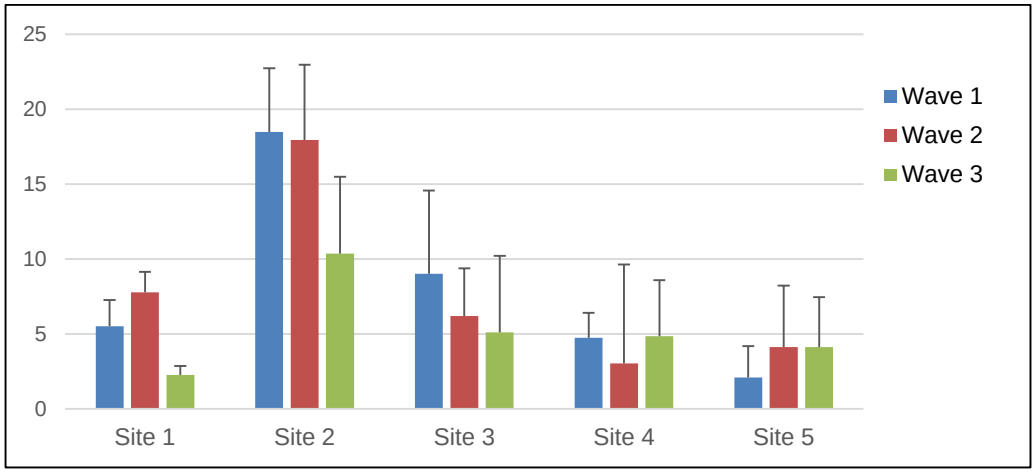

Figure 4.8 Percentage of time that OTs spent carrying out ADL related interventions at each site during each wave (± SE)

4.2.2.6 Time OTs spent in 'transfers and mobility' related interventions

Three sites showed a significant change between waves in the percentage of their time OTs spent carrying out 'transfers and mobility' related interventions (Figure 4.9). These sites were Site 1 (non-parametric test $p = .016$), Site 4 (non-parametric test $p = .011$), and Site 5 ($F(2, 19) = 8.89$, $p = .002$). Pairwise comparison tests showed that in the case of Site 1 these differences were significant between wave 1 (11.8% ± 22.2 SD) and wave 3 (3.2% ± 8.2 SD). In the case of Site 4 this was true for wave 2 (5.8% ± 6.8 SD) and wave 3 where OTs did not spend any time carrying out transfers and mobility related interventions. Tukey tests showed that in Site 5 both, wave 1 (23.9% ± 18.3 SD) and wave 3 (2.5% ± 5 SD) and wave 2 (15.9% ± 10.6 SD) and wave 3 data were significantly different (Appendix 4.4).

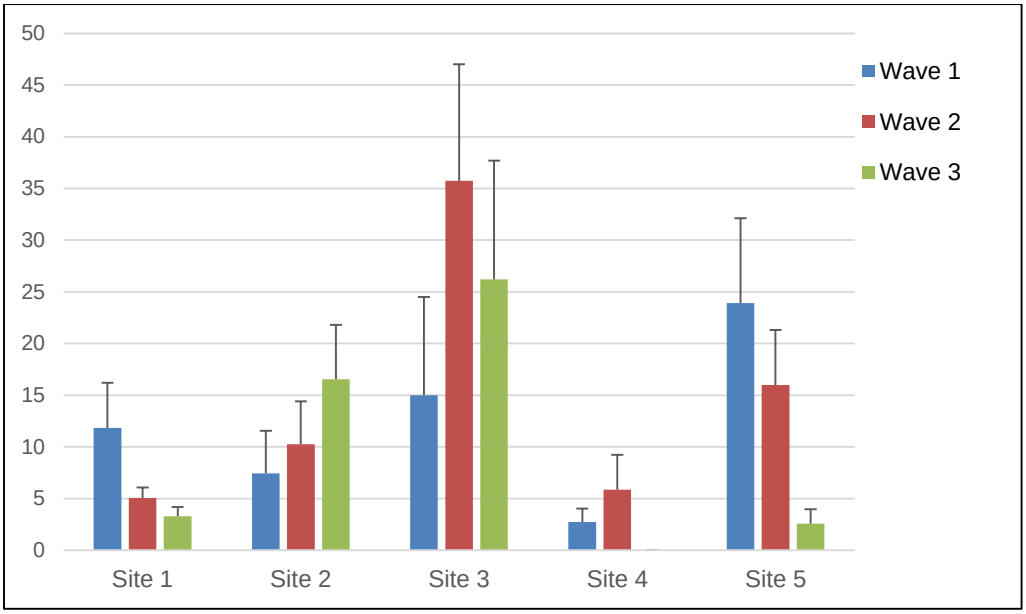

Figure 4.9 Percentage of time that OTs spent carrying out transfers and mobility related interventions at each site during each wave (± SE)

4.2.2.7 Time OTs spent in 'equipment' related interventions

In two sites, Site 5 (non-parametric test p = .003) and Site 4 ($F(2, 48) = 4.84$, p = .012), the percentage of time that OTs chose to spend carrying out interventions which involved equipment provision and environmental adaptations showed a significant difference between waves (Figure 4.10). In both of these sites the time spent in this sort of intervention decreased with time. In Site 5 the significant difference was between wave 1 (12.8% ± 10.9 SD) and wave 3 where OTs did not spend any time in equipment related interventions (Pairwise comparison test, Appendix 4.5). In Site 4, Tukey test revealed that OTs had chosen to spent a significantly different percentage of their time implementing this component of the OTCH intervention in wave 1 (11.5% ± 12.5 SD) and wave 2 (3.7% ± 7.1 SD) and in wave 1 and wave 3 (2.3% ± 5.3 SD). As can be seen in Figure 4.10, Site 2 data followed a similar pattern to that of Site 5 and Site 4; however, no significant differences were found.

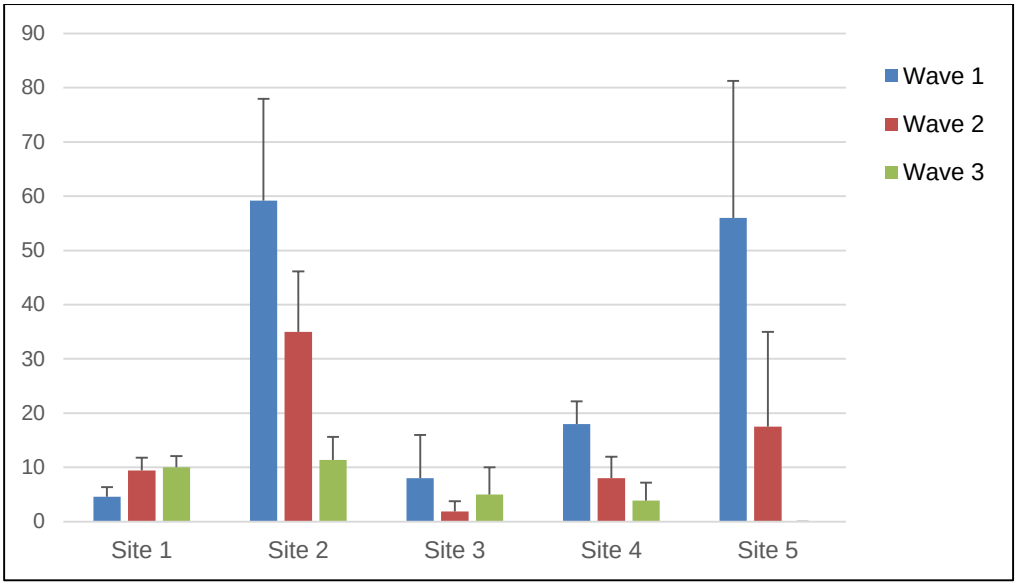

Figure 4.10 Percentage of time that OTs spent carrying out interventions which involved equipment provision and environmental adaptations at each site during each wave (± SE)

4.2.2.8 Time OTs spent in 'other activities'

As it is shown in Figure 4.11 overall OTs spent a small percentage of their time carrying out 'other activities'. The percentage of the time that OTs chose to spend carrying out other activities such as those involving the use of leisure activities showed great variation between waves and sites (Figure 4.11). However, this difference was only significant in two sites: Site 2 (non-parametric test $p = .01$) and Site 3 ($F(2, 14) = 5.31$, $p = .019$). In Site 3 post hoc test showed that a significant difference was present between both, wave 1 (1.5% ± 3.3 SD) and wave 2 (33.8% ± 35.8 SD) and wave 2 and wave 3 (0.35% ± 0.7 SD). In the case of Site 2 wave 1 (12.7% ± 13.7 SD) data was significantly different from wave 3 (0.15% ± 0.48 SD).

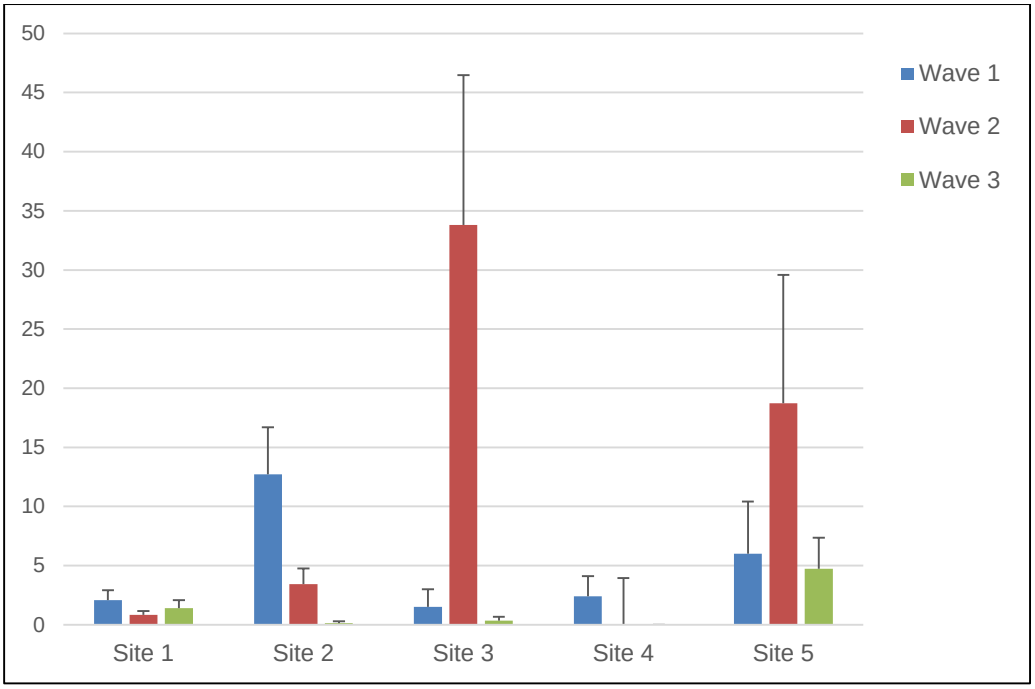

Figure 4.11 Percentage of time OTs spent carrying out 'other activities' such as leisure activities related interventions at each site during each wave (± SE)

Although only five sites out of the eleven completed three waves the data analysis of intervention log data was able to clearly show that the way in which OTs choose to spend their time with patients did not remain consistent throughout the running of the trial. A total of three sites showed a significant difference between the total numbers of visits that OTs carried out in waves 1, 2 and 3. Similarly in four of the sites the total number of minutes that OTs spent with each patient was significantly different between waves. To the contrary, overall, the time OTs spent 'communicating' with patients and carrying out ADL related interventions remained consistent between waves.

4.3 Results from qualitative data

4.3.1 Critical incident reports

A total of 20 critical incident reports were completed by seven of the OTs involved in the OTCH trial. The number of reports that OTs filled was very variable. Whilst one of the OTs completed a total of 10 reports, the remaining OTs completed an average of 2. Ten OTs did not complete any reports

regardless of the researcher's efforts to encourage them to do so via regular email reminders.

16 out of the 20 reports described challenging and difficult situations faced by OTs working in the care homes. Only 4 referred to positive outcomes of a particular OT intervention. Two of the reports described two examples where a straightforward and direct OT intervention had an instant positive impact on a patient's level of independence and quality of life.

In 12 of the reports, OTs described difficult situations all directly related to a number of different organizational characteristics of care homes. Funding limitations were an important factor in all of these 12 incident reports. In OTs words "*the care home is a business and wants to make money, not lose money"* (CIR 10). Four of these reported OTs frustration with care home managers in regards to their engagement in the work that OTs were doing at the care home. OTs described having to confront managers in order to fight for the best possible care for their patients. An OT (CIR 16), after proposing her intervention plan described how a care home manager "*stated the plan was not justifiable giving staffing implications and her own views of the priorities for this participant*". The OT continued to describe how her feelings were of "*shock and disbelief, partly at the tone of voice of the care home manager, very confrontational".* The OT concluded that this incident "*has affected my practice in this home with all residents"*.

Eight of the critical incident reports described OTs negative opinion and frustration in terms of quality of patient care at the care homes. These reports described a lack of knowledge and engagement of care home staff in terms of promotion of independence and awareness of available external services (e.g. referral procedures). As an OT (CIR 9) expressed when referring to carers not trying hard enough to solve straightforward problems: "*I can't understand why the carers don't always try harder to solve such problems. Surely it just takes a little common sense…"* Two of these reports describe instances where OTs found themselves having to voice their concerns to staff which led to a challenging and unwelcoming work environment. As an OT expressed *"there had been a slight power struggle between myself and the carer"* (CIR 11).

OTs incident reports (5) described instances where OTs decided to carry out OT interventions that could be considered to be out of the scope of the trial. OTs explained that improving patients' quality of life was behind this decision. In CIR 9 the OTs explained the following: "*these interventions may not be measured by the Barthel Index but we know they have improved the lives of the OTCH participants".*

In 2 of the incident reports OTs described how they had to deal with patients with complex health needs. OTs described how they had faced the challenges and what sources of support they made use of in order to propose appropriate intervention plans. As examples of challenging situations, one OT described the patient's lack of motivation and engagement as the reason to end OT input. In another report (CIR 19) the OT reflected that:

> "*With better local knowledge (regarding funding sources and available services) I may have had more success in accessing services and following up with more therapy"*.

Overall the data collected in these 20 critical incident reports provides an in depth insight into how OTs dealt with difficult situations and how these may have impacted on their ability to carry out their role delivering the OTCH intervention in the trial care homes.

4.3.2 Results from initial coding of qualitative data

All 17 OTs involved in implementing the OTCH intervention were interviewed. OTs were happy to discuss the work they had carried out during their involvement in the project. Overall they were interested in expressing their opinions regarding a number of issues such as the level of rehabilitation being offered in care homes or the difficulties they faced when first arriving at the care homes.

A total of nine themes (Table 4.2) emerged from the initial thematic analysis of the data from a subsample of 7 in depth interviews with OTs in charge of delivering the OTCH intervention and 17 critical incident reports.

Table 4.2 Emerging themes from initial thematic analysis of qualitative data

Emerging Themes
• The 'culture' of care homes • Patient allocation to the OTCH study • 'Small interventions' versus 'costly interventions' • Challenges in OT/care home staff joint working • Impact of the characteristics of the care home • Impact of care home's postcode • Challenges of being both, an OT and a researcher • The challenges of following the trial's protocol • The identified need

A description of each of the initial themes (with illustrative quotes) follows:

Theme 1: The 'culture' of care homes

Care homes have a 'culture' which can impact on all aspects of patient care. Each of the care homes included in the OTCH study had a particular way of working and managers understood the role of their staff in different ways.

As explained by OTs, staff at the care homes often followed a way of working that led towards 'safety of patients' and a more compensatory approach. This impacted on how OTs carried out their work and how much of their intervention plans were implemented and followed through. In regards to this an OT explained:

> *"They had actually decided these patients were going to be hoisted right from the very beginning. And they had actually got them into that routine and it did restrict me working with them, which was a shame really. If there had of been an OT there when they first came into that home we could have stopped that and worked with doing transfers rather than hoisting". (OT 4, line 345)*

Another OT gave the following example when referring to the care home staff:

> *"They're almost just on automatic pilot. You know, they pick up the*

washcloth and they just wash. But they kind of, they're stopping and I am going 'oh actually you could do that' but it just doesn't even seem to enter their heads I don't think". (OT 7, line 1245)

Theme 2: Patient allocation to the OTCH study

Interview data showed how OTs dealt with patients with co-morbidity in different ways. Cognitive impairments were reported as the most difficult to address when trying to implement the OTCH interventions. As one OT explained:

"I mean… severely cognitively impaired, I'm talking about … they won't even make eye contact with you. So… you know, some of the nursing homes I had residents who were completely bedbound… didn't make any eye contact, had no speech or recognition or anything like that, you know". (OT 3, line 564).

Another OT described a similar experience:

"O*ne lady that had got severe cognitive problems and severe communication problems […] and really I think that was an inappropriate referral because she was getting immensely distressed by us being there, because obviously we couldn't explain to her why we there, she didn't know us, she saw us as a sort of stranger. So I think that was a very difficult time to come across". (OT 4, line 144)*

Patient allocation to the OTCH trial impacted on the work of OTs. OTs explained that in some cases they limited their role to 'reviewing' patients' management and maintaining their physical condition. As one OT put it:

"*It was really just a matter of… you know, making sure that their needs were met, and that whatever independence they still had they maintained. So really I saw my role more as maintenance and review… because they had already had the rehabilitation input". (OT 1, line 77).*

OTs explained that the 'time since stroke' was a factor that had a negative impact in their ability to work at promoting patients' independence and pushed OTs towards a more 'compensatory approach'. One OT explained:

> "*I think the compensatory approach has definitely been the main approach and the main focus for the therapy, because of the clients that were coming through. […] Some of the clients that we've picked up are sort of fourteen years post Stroke; well we're not going to get any improvement from a Stroke perspective after fourteen years." (OT 5, line 971)*

Theme 3: 'Small interventions' versus 'costly interventions'

OTs reported a feeling of satisfaction linked to the success of what they described as 'small interventions'. These small changes such as installing handrails were equally welcomed by care home staff, as one OT explained:

> *"They were very, very grateful for handrails because I was paying for them. They were 'Oh yes, fine' that will look good when the inspection people come round (laughs)". (OT 7, line 1301)*

These small, free of charge changes often involved the issuing of small pieces of equipment and often had a clear and direct positive impact on patient's independence. One OT described the following experience with one patient:

> "S*he'd been struggling to cut up food and to get food onto her fork so and I had a plate surround and an adapted fork for her to try and she seemed a lot happier, you know, she wasn't making a mess which was bothering her before" (OT 5, line 744).*

On the other hand, funding limitations were often mentioned by OTs as an important factor affecting their ability to implement proposed intervention plans, particularly those involving costly specialized seating and positioning equipment. OTs were often not able to provide appropriate seating "*because they (care homes managers) say that health should provide it and health say*

that the homes should provide it and there's that conflict between who's funding it". (OT2, line 302).

Theme 4: Challenges in OT/care home staff joint working

OTs had to 'get to know' care home staff in order to blend into the care home. Care home staff members were often suspicious of OTs and their role which they perceived, at times, to be a judgemental one. One OT explained:

> *"In many instances the carers were quite defensive, because I think they thought you were examining their work… rather than trying to do the residents and it didn't matter how much you tried to explain it…[…] I do think some of them felt defensive… that I was checking up on them and that obviously wasn't the case at all." (OT 1, line 177)*

During the interviews OTs expressed the importance that building rapport and communicating with care home staff had during their time working in the care homes. Some OTs were aware of the need to spend time conversing with staff:

> *"An awful lot of sort of… chatting and explaining and also trying to not just focus on work, you know, trying to have normal conversations as well and… spending time in the tea room with them and things, you know". (OT 1, line 449).*

Also, OTs explained that they made an effort to include care home staff in their discussions in order to work towards common goals, this was often achieved through both, written and verbal feedback. As one OT explained:

> *"I got to work with individuals and I got to talk to them the whole time that I was working with them, and sharing my thoughts and reasons why I wanted to do things in a particular way and… and because I was actually doing the dirty work with them and actually getting hands on I think that they had more respect for me than just going in and saying 'This is what I want you to do'' (OT 6 line 103).*

OTs took time to feedback the results from their interventions to care home staff and often did so via a number of ways such as regular verbal feedback, documenting their work on the patient's records or even via poster displays in patient's rooms. However, most OTs found communicating their work challenging and as one OT expressed "*well, I think out of sort of duty that I always document what I've done but yeah, I would be very surprised if anyone's read it" (OT 1, line 229).*

OTs applied their communication skills in order to maximize the chance of success in the delivery of the OT intervention. As one OT explains:

> *"I would ring them sometimes the day before to remind them; like if I wanted to dressing practice and I was going in early specifically to see someone… to remind them that I didn't want them to get dressed I would ring them up the day before just double check and confirm" (OT 4, line 1229).*

One OT described another example were she had to work hard at communicating the needs of one of her patients:

> "S*he was sort of… not very strong and she needed a small glass to drink from, and they always gave her a big glass. And I kept saying to staff… I've said verbally to staff, kitchen staff, everybody, and I put it in the notes, still she's sometimes getting a big glass. So then I just did a poster" (OT 7, line 1844).*

Theme 5: Impact of the characteristics of the care home

OTs worked in residential and nursing homes as part of the OTCH trial. This variability strongly influenced the work of the OTs. Whilst residential homes' patients were often able to engage in therapy sessions, many of the residents in nursing homes were severely impaired and their engagement in the OTCH intervention was extremely challenging. One OT explained:

> *"I think it's very different between residential and nursing homes… I think the nature of client groups in residential homes, people tend to be*

a little more mobile, more energy, and they are… I guess there's less… heavy intervention required from care staff, whereas I think in nursing homes there is… such a high level of care required, and there is a high turnover of staff, that… so I think… my impression was that the homes were coping with meeting basic needs. And therefore rehabilitation is not really a priority in that environment" (OT 4, line 775).

The size of the care home and the number of patients that OTs had in a care home was described as impacting in their interventions with OTCH participants. OTs found that if they had a high number of patients in one care home, regardless of the size of it, they could easily establish themselves as a member of the team. As an OT explained:

"I had one care home that had a ridiculous number of clients and it was a very big care home and it was divided into four different units, but within that care home I had twenty-four clients I think. And so I was there an awful lot because of the fact that I had so many clients there. And certainly, because I had so many I think in one unit I had every single client, so I just sort of went in and just became one of the members of staff initially, because it was the only way I could observe and work with that many clients, and so in that care home I found it very easy to establish myself because I was there two or three times a week". (OT 3, line 119)

This same OT went on to explain: "*when I moved to another unit within that establishment, where I only had one client, it was a very different you know, the staff were very much more 'Oh who are you and what are you up to?".*

Overall small care homes with a small number of residents and an accessible manager were described as the 'ideal' in terms of OTs fitting in. One OTs explained:

"The home that I felt that I achieved the most was in a residential home where there was a very small amount of people in there. The manager wasn't in a room separate, her office was actually in the living room so she was very present, she was involved in everything, it's a very… it

was an extended bungalow, it was very, very homelike. And I found that a really responsive environment to be in". (OT 3, line 1178)

Theme 6: Impact of care home's postcode

During their time in the trial OTs dealt with the variability of available services and referral systems linked to the care homes they worked at. These were highly dependent on the care homes postcode. OTs had to learn what referral procedures were in place for each care home and what outside services they could make us of. OTs who worked in care homes that were in areas which they knew well reported feeling more comfortable and having to spend less time 'researching' options. One OT explained:

"I think we were very lucky because we did know the extent of what we could get from our service, because they were in Wolverhampton… and we were working in Wolverhampton we knew which agency to go to, which services to approach. […] So they were quite lucky from that point of view, that we had, again, the knowledge base to refer to somebody more appropriately after our input". (OT 4, line 201)

Other OTs explained how, at times, they had faced complex decisions due to the lack of available services in particular geographical areas:

"If I were in Birmingham I'd be asking a spasticity clinic in Birmingham to review him. In Coventry they don't have such a service. Not for over sixty five's unless he comes to Birmingham. And then you have to balance, well okay he's an end stage dementia patient, how is it going to be transporting him to and from Birmingham? Is that great for him? I don't know!" (OT 3, line 1344)

Referring patients to external services was often time consuming and complex. OTs expressed being frustrated by the referral process which often involved unclear paperwork and time delays. Experiencing these challenges helped OTs understand why at times care home staff felt frustrated and 'just gave up':

"So that was it, they just kind of gave up. I think that's what happens, the people that do care, and they try to find out, but then they make so many different phone calls and get so many kind of doors shut in their face that they just eventually give up and think 'Oh its hopeless". (OT 5, line 178)

Another OT explained:

"I've found out that… some of it just seems like a massive sort of paperwork exercise for the sake of it. So you could put something in writing, or explain it in great detail over the phone to the person, and then they'll want you to still fill in their referral form. Then I'll send it, and then it's not always even possible to complete it. […] So they want all these loads of different bits of information, and it's really hard to get, you know, height and stuff like that, and you can't... so you'll fill in the form and you'll send it back, and say there's one bit that it's just not possible to get the measurements… they'll send it back to you; so you'll send it off and a week later it will come back to you". (OT 7, line 2012)

Theme 7: Challenges of being both, an OT and a researcher

OTs dealt with the challenge of being an OT and a researcher at the same time. This meant that OTs had to understand their role as researchers and modify their OT practice accordingly whilst assuring best quality care for their patients. OTs with previous research experience, who for example were familiar with outcome measures, found this easier than those working in a research project for the first time. Also, a number of OTs carried out their research job whilst retaining their everyday full time job, this has meant visiting the care homes on a weekly basis or arriving out of normal work hours. These OTs expressed that if they had been able to go to the care home on a daily basis and be consistent enough they would have been able to influence a change in patients more easily. OTs reported that "*because sometimes it's been a couple of weeks between visits and in the meanwhile the staff have just kind of… you know, quietly forgotten about it all" (OT 5, line 153).*

Some OTs reported that this influenced their ability to make an impact and possibly show improvements in outcome measure scores. As one OT explained:

> *"I think initially it was difficult for myself and my other colleague because we were doing it as overtime we were doing it after normal work hours. So we were tending to get to the care home and the care staff were trying to toilet everybody, or get everybody ready for teatime, so it was more difficult to coordinate the intervention from that perspective". (OT 2, line 698)*

During the interviews OTs were able to explain the reasoning behind their decision making and it became apparent that those OTs with prior research experience were aware of the importance of influencing outcome scores in the limited time available. As one OT expressed: "*you've only got limited time; maybe choose the thing that you're most likely to get a change in outcome score for" (OT3, line 145).*

Finally, OTs identified the benefits of their role as researchers but it was those with years of OT experience that explained how they had enjoyed the freedom linked to her research role. For example one OT stated:

> *"I've worked in various different departments from hand clinics to stroke patients, to the elderly, physical and mental health. You know I've practically been there and done it. I have felt confident and I have been happy. Yes I thoroughly enjoyed being like my own boss in a way. I have really enjoyed it". (OT 6, line 25)*

Theme 8: The challenges of following the trial's protocol

The OTCH protocol was mainly targeting the promotion of independence in activities of daily living. Therefore OTs were aware of the fact that one of their challenges was to focus their proposed therapy plans accordingly. OTs aspired to remain client centred throughout the duration of the trial whilst following the study protocol. This proved challenging, since at times, activities

of daily living were not what patients were interested in doing. One OTs explained the following:

> *"I wouldn't normally have just concentrated on things like washing and dressing, it would be very much client driven, so… what would be important to them. And it may not be that washing and dressing are the most important things to them because they might be wanting to conserve their energy to do something different. It might be that they want to engage in some kind of leisure activity that has much more meaning to them than doing their personal care." (OT 5, line 145)*

All OTs were happy to discuss the ways in which they carried out their job whilst being aware of the OTCH intervention protocol. A number of OTs chose to remain within the limits set by the protocol, but others 'accepted' that although some of the interventions they were implementing were out of the scope of the trial, they were meaningful to the patients and as one OT expressed "*may have made their lives more comfortable" (OT6, line 559)*. At times and justified by the client needs, OTs made a conscious decision to carry out interventions that were out of the scope of the trial.

Theme 9: The identified need

OTs were aware of the lack of occupational therapy available to care home residents. Therefore they believed there was a need to assess the impact that regular OT input could have on these residents. OTs, especially those who had prior experience of working in care homes were able to identify specific positive impacts that could be made on the level of independence of care home residents and how this would also impact on staff's understanding on what their role should be. When discussing OT interventions one OT explained:

> *"It has better time implications for them because it frees them up for… to do other things, it increases the dignity of that patient. And they feel it's more rewarding as well because the carers get to see the actual resident's personality, they get to see the resident as a person as opposed to a patient or a client". (OT 7, line 210)*

Other OTs explained how they felt that those participants taking part in the trial were lucky since "*they get so much intervention and so much more time that… the NHS would never have been able to look at some of the things that we've been able to". (OT 1, line 77)*

In summary, the researcher was able to collect rich and in depth information by interviewing this subsample of seven OTs. The interview schedule proved to be a useful tool in order to guide the conversation and allow for information to flow. OTs engaged in discussion and were happy to share opinions, both positive and negative regarding their involvement in the project. Although all OTs faced different challenges, they often reported having enjoyed working around them and finding ways forward.

4.3.3 Initial Programme Theory - Identifying potential 'areas of interest' and initial hypothetical CMO configurations - Results from 'a realist workshop'

Following the research process outlined in Figure 3.1 and as a result of the interim analysis carried out during a realist workshop with research team members (please see details in Chapter 3) the following four theory areas and hypothetical CMOs were identified. These reflected aspects of fidelity and directed the remaining analysis (Table 4.3). The identified areas of interest that led to the Initial Programme Theory were:

Trial factors: Working in a research study brings about changes in the way OTs made decisions. OTs working in the OTCH project potentially felt like they were being monitored and this could have generated anxiety. Also, OTs needed to be aware of the trial's protocol at the time of identifying intervention goals and this could have potentially affected the reasoning behind their proposed intervention plans.

The OTCH team put in place a number of support mechanisms such as online peer group discussion forums, email and telephone communication and clinical supervision. OTs worked towards reaching a balance between 'keeping with the protocol' and having free decision making.

Therapist factors: OTs working on the OTCH trial had different backgrounds, different sets of skills and previous experience, preconceptions regarding care homes and different levels of support. Witnessing success of their proposed interventions could have impacted on OTs motivation and enthusiasm levels. On the other hand experiencing challenging situations could have led OTs to re-evaluate their reasoning and work with a more creative 'thinking outside the box' attitude.

OTs that had a 'realistic attitude' when implementing the OTCH intervention were able to target goals in line with patients' characteristics, 'keeping it simple' and understanding that success can be linked to small/simple interventions.

Making changes: OTs faced care homes where the owner and staff had different degrees of willingness to put in place proposed environmental adaptations due to a number of reasons (e.g. funding issues, staff availability, understanding of what OT is, and availability of external services). Also, some OTs came to OTCH with or without previous experience carrying out environmental adaptations. OTs worked at re-engineering the components of the environment via adding/removing equipment and via taking into account the value attached to the environment (resident's home).

OTs potentially achieved a greater 'fit' between environment and both, patients' 'capacity' and staff availability. This could have resulted in OTs suggestions impacting on the care home as a 'whole' rather than at a patient level.

Organisational factors: Care homes have very frequent staff turnover and this can generate low continuity. As a result OTs could have struggled to effectively communicate with staff the reasoning behind proposed intervention plans. Also, staff had a 'risk aware' attitude that could strongly influence their decisions.

OTs have to work alongside staff, getting to know them and familiarizing themselves with care home's routines via effective feedback procedures. As a result staff became more knowledgeable regarding the purpose of OT and

this potentially increased their engagement in the process. Ultimately this could have led to care home staff being more aware of patients' rehabilitation potential.

Table 4.3 Hypothetical CMOs identified for each 'area of interest' – Initial Programme Theory

Area	Context	Mechanisms	Outcomes
Trial factors - OTs working in a research study	• OTs feeling that they are being monitored – this generates anxiety/stress • OTs very aware of 'outcome measures' – these influencing their decision making	**Support in place for OTs:** • Peer group – discussions and meetings • Internet communication • Clinical supervision – preparation	**Alignment with OTCH protocol:** • OTs being able to carry out their job finding a balance between 'keeping with the programme/protocol' and having free decision making
Therapist factors - Expectations of OTs	• OTs having different backgrounds • OTs having a different set of skills and previous experience • OTs might have preconceptions regarding care homes • OTs receiving different levels of support whilst working for the OTCH project	• Seeing success - OTs increase their motivation and enthusiasm • OTs being creative and thinking *outside the box* • OTs experiencing challenging situations – this can lead to them re-evaluating their working methods/thinking – *stepping away from a de-sensitized attitude*	**Realistic attitude** • Realistic goal setting due to increased confidence – changing goalposts • Positive attitude towards treatment – '*keeping it simple'* • Realistic intervention plans – higher rate of success • OTs understanding that success can be linked to small/simple interventions.
Making changes (to the environment)	• Care home owner's willingness to engage • OTs previous experience carrying out environmental adaptations	– Locating this work – Re-engineering components of environment: • Adding/removing equipment • Considering the value attached to the environment (resident's home)	**Greater 'fit' between environment and:** • Resident 'capacity'. • Staff availability – Increase safety – OTs suggesting/making environmental changes for the benefits of all patients.
Organizational factors - Changing staff attitudes	• Very frequent staff turnover – low continuity • Communication problems • Risk aware attitude – strong impact on staff's decisions	• OT feedback to care home staff: purpose of OT • OT working alongside care home staff • OT getting to know shift patterns – familiarizing themselves with care home staff routines	• Care home staff aware of what OT is – increase engagement • Care home aware of patients rehab potential

4.3.4 Identifying patterns across iCMOs and quantitative data

Following the results from the workshop, all remaining qualitative and quantitative data were analysed and tested against the initial programme theory and hypothetical CMOs (Table 4.3). A complete list of the identified iCMO for each 'area of interest' in the form of contingent narratives, including units of meaning (quotes) supporting them is available in Appendix 4.6.

A total of 38 iCMOs were identified for all areas of the initial programme theory. Of these, 11 were linked to Trial factors (OTs working in a research study), 13 to Therapist factors (expectations of OTs), 5 to the area of interest regarding Making changes (to the care home environment) and finally 9 to Organisational factors (changing staff attitudes). A number of iCMOs overlapped between two or more identified areas of interest.

In accordance with the thought process described in Chapter 3 (Figure 3.3), the researcher applied realist enquiry principles to the initial programme theory. As a result it was possible to identify patterns across all iCMO configurations and quantitative data. After reading and re-reading all iCMOs and synthesizing quantitative data in the search for patterns, the researcher was able to describe a number of mechanisms which were often present. Figure 4.12 is an example diagram which illustrates in detail how one of the refined CMOs (OTs learning over time) was identified by synthesizing initial programme theory iCMO configurations and quantitative data. The same thinking process was followed in order to identify the remaining three refined COMs which constitute the refined programme theory.

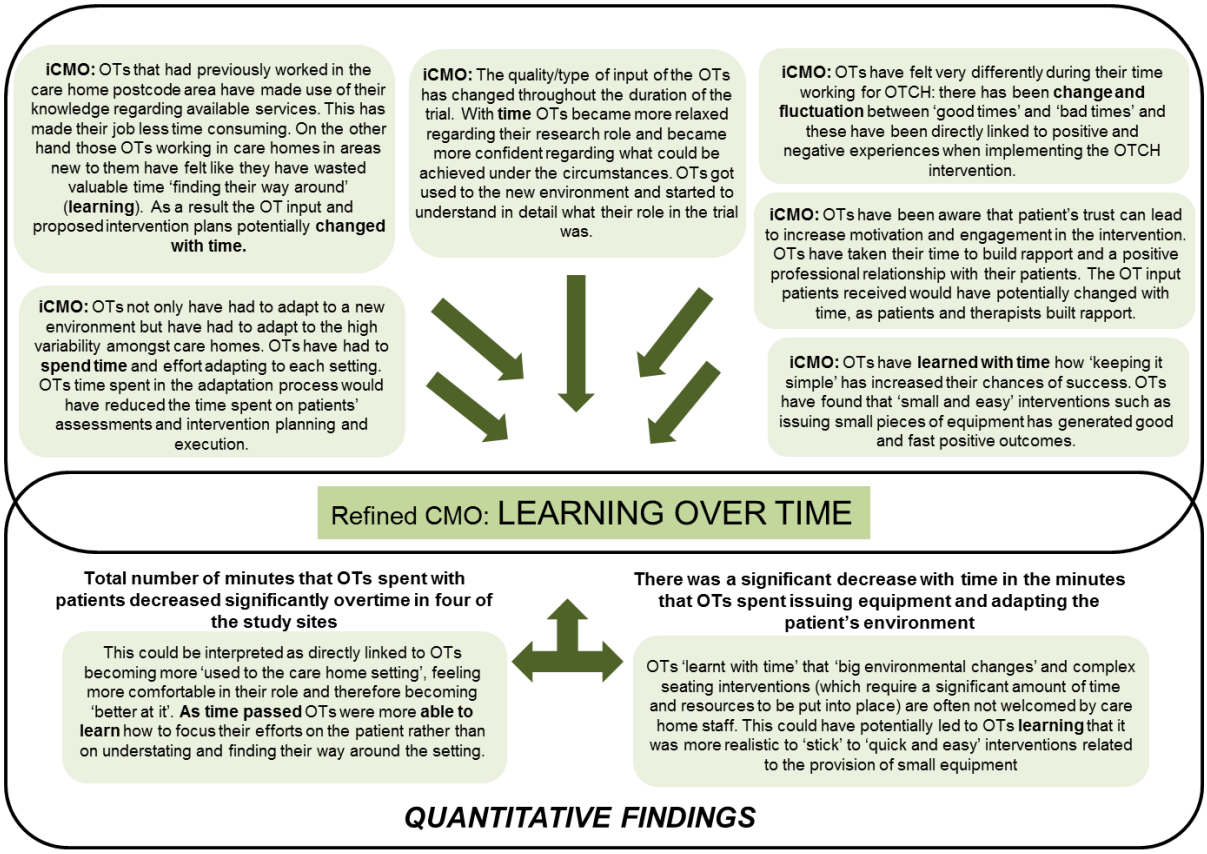

Figure 4.12 Diagram representing the generation of the 'learning over time' refined CMO

4.4 Refined programme theory

The four refined programme theory areas are reported first by presenting the structure of their refined CMO followed by explanatory narrative. The mechanisms that underpin the refined programme theory areas which characterise the fidelity of the OTCH interventions are described, with exemplary evidence from interview transcripts and critical incident reports. These highlight the contingencies and consequences of therapists' activities within these areas, and the complexity of implementation processes.

AREA 1 - OTs balancing act

Context	Mechanism	Outcome
Experienced OTs working on the OTCH trial were aware of the study protocol and what their professional and research role entitled	…this prompted a need for **balancing requirements** in order to be able to work according to protocol. A number of balancing acts took place: – Resource availability versus proposed intervention – Research independence versus sources of support – Standardized approaches versus OTs knowledge of the area where care home is – Broad holistic focus versus targeting interventions – OT proposed treatment versus patient's motivation levels – Stroke rehabilitation versus patient's co-morbidity	…which resulted in changes in the way OTs implemented the OTCH intervention including: • Producing realistic intervention plans targeting all aspects of patients' needs. • OTs carrying out interventions outside the scope of the trial. • OTs making use of trial's support systems in place in order to make inform their decision making.

Participants described a shift from their role as OTs, to their 'new' role as experimental OTs within a clinical trial. This shift can be characterised as balancing work where, over time, they developed to a greater or lesser extent, a sense of equilibrium between their professional responsibility as therapists, and the tightly defined therapy outlined within the study protocol. The specification of interventions was, although broad, reported to constrain attempts to be client-centred. The OTCH intervention had a strong focus on promoting independence in ADLs. Some therapists reported difficulties focusing on the functional remit of the trial intervention: "*I don't think many would say it's the self-care issues that I'm struggling with'." (OT11, line 351).*

Results from quantitative data analysis support this 'balancing exercise' and have shown that the choices that OTs made in terms of how to spend their time with patients varied with time and between sites. In particular, OTs changed the percentage of time they spent on ADL related interventions as the trial progressed and the same happened in regards to OT time spent 'in other activities'. This supports the idea that OTs worked on balancing

requirements and made the necessary changes to their practice, this could, at times, lead to OTs carrying out interventions outside the scope of the trial. Therapists appeared to be able to find a balance between their research and therapy expectations where patients were unclear about therapy goals, by guiding patients' interests towards relevant components of the OTCH intervention:

> *"When you ask questions about goal setting and what they'd like to be doing… and they go 'Oh, I don't really know', you kind of… you lead them in a way towards self-care… and mobility… Whereas I would have probably opened up the discussion wider if… if it hadn't been for… for the OTCH guidelines." (OT14, line 1231)*

Therapists with prior experience of clinical research appeared to find it easier to achieve this balance:

> *"I knew it was important to target an intervention. That was a research bit rather than an OT bit… that was previous experience. I think actually saying "yes we want you to be an OT, but bear in mind that these are … the things that we'd like you to influence" would be helpful". (OT15, line 352)*

Drawing on communication and negotiation skills, therapists reported that where intervention plans were 'balanced' between the demands of the trial and individual patients' wishes, patients appeared to have been more motivated and engaged in the rehabilitation provided: "*when you start working with them, actually it becomes more and more important." (OT11, line 356).* However, this balancing exercise was challenging for those therapists with extensive clinical experience who, at times, proposed some intervention goals that were potentially out of the scope of the trial intervention, as reported by OT4:

> "*It's not going to increase anything on the Barthel, but I know for this lady … what's important to her is that she does something that she's going to enjoy during the day. She has something to fill her time".*

Additionally, the study participants presented a complex mix of co-morbidities, mainly related to cognitive impairments, which compounded the functional consequences of stroke. In this way, therapists reported considerable challenges in balancing rehabilitation treatment plans around individual patient co-morbidities: "…*they all had dementia as well as their stroke diagnosis. I just thought 'I don't even know where to start here'" (OT15, line 266).* Those therapists with previous experience of practice in related care settings, who demonstrated creativity, and reported commitment to the trial appeared to have been more successful in achieving a sense of balance in this respect. They produced realistic intervention plans, targeting all aspects of patients' needs, whilst addressing patient's post stroke rehabilitation:

> *"I think… what's influenced it; experience. Just general experience, and probably experience of working with older people, experience of working with different clinical teams and looking at how they respond and how they react." (OT15, line 1671)*

Therapists also balanced the freedom their research role provided, with feelings of 'loneliness'. They considered there were limited opportunities to 'bounce ideas' with team members in real-time through the various supports for therapists offered by the trial, including supervision and an internet-based discussion forum.

AREA 2 - Building rapport

Context	Mechanism	Outcome
When OTs were aware of the benefits of utilising knowledge from care home staff and developing shared goals	… this prompted **rapport building -** OTs spending time and energy in: – Finding appropriate ways to feedback and communicate to patients and staff their proposed plans and reasoning behind these. – Training care home staff to understand the purpose, benefits and reasoning behind OT – Engaging and involving care home managers in their decision making	…which resulted in a positive increase of care home staff's engagement in the trial. Care home staff's attitude towards the trial shifted from being 'defensive' to being 'accepting' and 'understanding'. This led to a higher chance of OT proposed intervention plans to be followed through.

As both, quantitative and qualitative data show, a considerable amount of time was spent by some therapists building rapport with care home staff. This remained consistent throughout the trial. Developing an organisational context was thought to be more conducive to rehabilitation in general, and the trial intervention in particular. This was felt to be important in establishing the foundations on which trial interventions could then be established. One strategy through which this mechanism operated was through therapists *'mucking in'*, and working as a team with care home staff:

> *"I try and work alongside people rather than…rather than kind of… leading the situation, trying to learn from them… and, you know, creating almost a therapeutic relationship with the carers as well as with the clients." (OT13, line 100)*

Sharing patients' goals with care home staff was used to boost their engagement in the trial. In this way, therapists attempted to address any *'defensive'* attitude by demonstrating that their role did not include judgement or *'examining'* of care staff work, but cooperation for the benefit of the residents. Furthermore, regular feedback of therapists' reasoning behind intervention plans, to members of care home staff, was also used to build rapport. OTs attempted to do this in the way they believed to be the most efficient and in line with the way care homes were run. As an OT explained:

> *"I'd go in and say what's happening with this person? Anything happened? Anything I need to be aware of? And then I'd always try and give them a little bit of feedback at the end so either personally or sort of jot something down, certainly writing sort of, you know their care plans. And again there's often kind of staff that would be working with those patients each day so particularly for the people who had more sort of cognitive problems or kind of dementia-wise I'd be looking at kind of the daily stuff and say well this is what I've done or this is what's happened today just to give them a quick sort of feedback as to what I was doing. So that tended to be more of a kind of a verbal kind of catch up really." (OT11, line 599)*

In many cases, therapists perceived an organisational importance attached to organisational routine and scheduling of caring activities. Consequently, there was a view that this importance was demonstrated by some care home staff where attention to efficiencies ran the risk of loss of residents' independence in functional activities. Quite simply, sometimes it was quicker to 'do for', rather than work with residents: "*And they (staff) were saying 'Well, if we let them wash themselves it will take all day, it will be lunchtime by the time we get them down for breakfast'." (OT4, line 1203)* Some therapists, through their previous experience, approached their work with care homes aware of this risk. In these cases, it was evident that they were able to build a positive rapport with staff by proposing interventions that melded with the care home organisational routine and usual patterns of work.

> *"Because certainly in the homes you know, things can be, not can be, they are quite rigid mostly and, you know, this is when we get people up and washed and dressed and this is when we give them their afternoon tea and this is when we give them their dinner or. You know, and you've got to kind of play a game, you've, you've got to work around that a little bit. But I think as long as you do, you know, there's not too much of a problem. Yeah you've sort of got to incorporate that into what you're doing really." (OT11, line 683)*

Inevitably, data show that engaging some care homes in the trial was problematic, and a lack of managerial engagement was a particular concern:

> *"The deputy manager and I were discussing the outcome of a dressing assessment that we had conducted together, both feeling positive as the participant had exceeded our expectations functionally and cognitively. We were discussing how to document and monitor a regime change that promoted independence and made most effective use of medication timing. Care home manager came into the office and on hearing our conversation stated the plan was not justifiable giving staffing implications (time required to facilitate independence was too long)" (OT15, CIR 1)*

Engagement of care home staff appeared to be associated with a positive cycle of reinforcement around the potential benefits of the trial interventions. Those therapists that were successful at gaining rapport with staff appeared to increase the chances of positive implementation of their proposed interventions as they faced less opposition.

AREA 3 - OTs promoting independence via re-engineering the care home environment

Context	Mechanism	Outcome
When OTs were aware of the vital role that a patient's environment plays in promoting independence but also aware of the 'risk aware' and often financially driven culture in care homes	…this prompted a need for **re-engineering** the care home environment. This meant that OTs had to work towards re-thinking patients' environment not only at and individual level but also considering the care home as a 'whole'.	…which resulted in OTs changing and adapting their practice in order to: • Utilize available resources and funding in a creative way ("thinking outside the box") whilst training staff on the benefits of adapting the environment to patient's needs.

The work that therapists undertook, to re-engineer the care home environment around their rehabilitation plans for patients, was completed to different degrees of detail, depending on local circumstances. Generally therapists were careful to propose realistic intervention plans that could be carried out within available resources such as funding, skills availability, and access to external services. Through careful assessment, the provision of aids and minor environmental adaptations, the trial interventions intended to provide patients with an environment that best matched their needs. During the trial, therapists were able to issue small pieces of equipment (e.g. helping hands and adaptive cutlery) free of charge. This equipment was readily available and easy to use and set up; this type of intervention appeared to be welcomed both by patients who achieved greater independence, and staff who were able to see a reduction in workload around support with some ADLs.

"Any intervention that requires minimal additional… outlay from them is going to be well received. Pressure cushions or grab rails, or anything that is static and will just support somebody… without any regular intervention I think is always going to be well received." (OT13, line 815)

Through the implementation of these small scale interventions therapists have been able to show care home staff where to find, and how to make best use of a variety of pieces of adaptive equipment about which they had little awareness. Increased knowledge of this type of resource was positively associated with patients' ability to do more for themselves, and was used by care home staff in other contexts.

Therapists often reported that the physical environment of care homes was rarely configured or utilised to promote opportunities for social interaction for their patients. A lack of appropriate seating and moving and handling equipment was identified by some therapists as one of the reasons for this:

"Residents don't go into the dining room to eat and they don't have the opportunity to have much social interaction and be in communal areas because most of them are nursed in bed. And the staff found it difficult to find the time to… hoist them out of bed, take them through to the communal areas and then hoist them back into bed. They haven't got the right equipment to enable a lot of people to sit out, because they don't have the right chairs." (OT14, line 347)

The provision of seating equipment was consistently identified as a particularly contentious issue for therapists, due to a lack of designated funding: "*commissioners completely obviously forget that there are people in care homes." (OT4, line 2094).* Therapists reported that they had not been able to acquire the specialized seating that their patients required, and this may have negatively impacted on the success of the proposed interventions:

"...they weren't happy if I made recommendations for seating because that would be a cost implication for them. I found I got blocked most of

the time with seating recommendations, even though they'd have made such massive differences." (OT15, line 1433).

Quantitative data showed great variability amongst sites and waves in terms of the time OTs spent engaged in equipment provision and environmental adaptations. In three of the sites, time spent in these interventions showed a significant decrease over time. This can be explained by qualitative findings describing the challenges faced by OTs when attempting to implement these types of interventions.

AREA 4 - OTs learning over time

Context	Mechanism	Outcome
Where OT interventions were delivered by trial OTs throughout a period of time	… this prompted OTs and care home staff to **learn over time.** Therapists' personal engagement and work in the trial appeared to be closely linked to the observation of success or failure of their proposed interventions and to the time they required in order to learn 'how things worked'	…which resulted in OTs learning with time how to be 'better at their role'. OTs were able to acknowledge how their motivation, confidence levels, reasoning and way of working had changed throughout their time in the trial. With time OTs learnt how to modify the way they worked, adapting to new situations and being more effective.

Therapists' personal engagement in the trial appeared to have been very closely linked to the observation of success of their proposed interventions. When therapists saw an improvement in a resident's quality of life, for example by increasing the confidence and or increased independence in activities, therapists reported feeling motivated and energized about the purpose of the trial.

"And its… it has its peaks and troughs; sometimes you can have a real success and you feel really good and you think I'll really make difference for that person. Other times I've felt that I haven't made a difference at all and you know, you just have to keep going really." (OT1, line 49)

The data clearly demonstrate that therapists have not been passive participants in the delivery of trial interventions. Therapists appeared to have learned through their experience of the interventions over time with individual patients, and across waves of recruitment within the trial. Therapists modified the way they work with care homes and patients, adapting to new situations, learning how to carry out their work more effectively. This was important in enabling therapists' confidence in their work within the trial to grow with time:

> *"When I look back I… I feel a little guilty that maybe I didn't… do enough, or do as much as I could have in my very first home. When I look at what I'm doing now in the homes towards the end of the study I feel I'm doing a lot more. I think part… part of that is confidence, because you're in a new area and you don't know the systems and how things work, and what's available and what's… what's not." (OT4, line 598)*

> *"Because I feel like only now, only in the last sort of (pause) maybe three months or so do I feel like now… oh yeah, now I know what I'm doing, now I'm up and running, now I know how things work. How to do… and now it's nearly over." (OT4, line 3636)*

Therapists reported feeling motivated and energized about the purpose of the trial when they perceived an improvement in a resident's quality of life: *"Sometimes you can have a real success and you think I'll really make difference for that person. Other times I've felt that I haven't made a difference at all and… you know, you just have to keep going really." (OT1, line 49).* Importantly therapists reported that some care home staff also gained confidence and started applying working methods learned during the trial in their everyday contact with other patients: "…*they said 'Oh that would be really good to try with somebody else', who actually wasn't on the trial."(OT2, line 354).* This was also felt to be important factor in sustaining impacts of therapy for individual patients within the trial.

> *"Certainly that worked, I noticed the staff actually make a bit more effort before teatime. That they would sit people upright before giving them a drink rather than leaving them as they were. I think they started*

questioning things more, so they'd see things… they started saying things when I appeared like 'Is that seat right for her? Do you think maybe we need to use a different seat because of this? Would you advise me?' which was certainly a change over the weeks." (OT15, line 1206)

The impact that learning over time has had on the way OTs carried out the OTCH intervention is clearly present in both qualitative and quantitative data analysis findings. Quantitative data analysis results are in line with the mechanism of 'learning over time'. For example, the total number of minutes that OTs spent with patients in the OTCH trial decreased significantly over time in four of the study sites. This could be explained by qualitative findings regarding OTs becoming more 'used to the care home setting', feeling more comfortable in their role and therefore becoming 'better at it'. As a consequence, as time passed, OTs used their time more efficiently and no longer had to spend time 'learning how things work'. As time passed OTs were also more able to focus their efforts on the patient rather than on understanding and finding their way around the setting.

Another example of quantitative data which shows the impact of learning over time on the OTCH intervention can be found when looking at the significant decrease with time in the minutes that OTs spent issuing equipment and adapting the patient's environment. These significant decrease can be explained by qualitative findings showing that OTs 'learnt with time' that 'big environmental changes' and complex seating interventions (which require a significant amount of time and resources to be put into place) are often not welcomed by care home staff. This could have potentially led to OTs deciding to 'stick' to 'quick and easy' interventions related to the provision of small equipment which, as qualitative findings showed, was positively accepted by care home staff.

4.5 Discussion

Overall realist evaluation was a very helpful methodology in order to guide the process evaluation of the OTCH trial. This research supports what Salter and Kothari (2014, p.9) report regarding the application of realist evaluation:

> *"there is no standardized framework or structured guidance on how to conduct a realist evaluation and no agreed-upon criteria available by which to judge the quality of a completed study that are specific to RE".*

This chapter has reported on the findings of the OTCH process evaluation and the generated refined programme theory. The identified refined programme theory and its mechanisms have strongly informed the development of hypothetical explanations that helped bridge the understanding in terms of fidelity of implementation, the impact of the OTCH intervention and resident outcomes. Furthermore, this refined programme theory was tested across different data sources within the trial, both qualitative and quantitative. The findings presented in this chapter present a narrative that is embedded in the trial's context and helps understand the trial's findings.

As a complex, multi-component intervention delivered across many care homes by different therapists, it was anticipated that the fidelity of implementation of the OTCH intervention, and consequently its impact, would be equally complex to untangle. Although the trial interventions were explicitly defined and training provided, therapists were evidently tailoring their practice to the needs of individual care home patients and the practical realities of work in a challenging context. As anticipated, implementation was an active process, as therapists translated protocols and training to the practical realities of work in a challenging context. The four identified mechanisms (balancing, building rapport, re-engineering environments and learning) comprise a programme theory to drive the evaluation of fidelity, which melds hypotheses embedded within the therapeutic components of the intervention and from the broader implementation. Drawing on realist principles, the refined programme theory incorporates potential mechanisms through which fidelity within complex interventions trials could be investigated, including: the balancing of

research and professional requirements; building a positive rapport with staff involved; working at re-engineering the environment in which the intervention takes place; and learning about the intervention and its impacts over time.

The tailoring of OTCH interventions was characterised by therapists as balancing work, where they tried, over time, to find a middle-way between resident preferences and the requirement to focus on resident function. More up to date research needs to be carried out in order to gain a better understanding of this issue since it is a reality that the demands of work context tend to push the balance towards a more pragmatic approach that can often reduce client centeredness (Law et al. 1995, Finlay 2001). The data presented in this chapter shows that this balancing work was also evident across a number of aspects of the OTs practice, including reconciling the intervention purpose with their personal beliefs around occupational therapy, the cognitive capacities of residents, capacities to sustain intervention plans within resource constraints, and the need for professional support within an autonomous research role.

The results presented in this chapter show that the potential impact of the OTCH intervention was closely linked to the dissonance OTs experienced between their roles as researchers and practitioners when trying to follow a standardized protocol. The implementation literature (May and Finch 2009) acknowledges that the scope of change required of implementation, for example in a shift in a therapist's holistic clinical paradigm towards a functional approach, may mediate success, and is neglected in current fidelity frameworks. These results show that the prior experience of trial therapists was important in shaping their ability to 'balance'. For example, whilst clinical experience appeared to be helpful in supporting residents with co-morbidities within the trial, it also prompted some therapists to focus on goals very much on the periphery of the proposed intervention. OTs that came to the trial confident of their extensive clinical experience may have, at times, appeared to have found it more difficult to resist tailoring the study interventions to their clinical worldview, with consequences for fidelity (Kerns and Prinz 2002, Bellg et al. 2004). These results raise important issues for the conduct of research

rehabilitation trials, especially those, such as OTCH where OTs were required to focus on a particular aspect of rehabilitation (in this case ADL) and follow a protocol whilst addressing individual patient's complex needs. Those recruiting therapists to deliver similar trial interventions may want to give this closer attention: What should the essential requirements and optimum experience level of practitioners in charge of implementing a new intervention be? It is obvious that careful recruitment of practitioners is very important and that their training and on-going supervision is paramount to the success of implementation (Dumas et al. 2001). Those recruiting therapists to deliver similar trial interventions may want to give greater attention to how they anticipate their clinical or research experience to influence fidelity.

This chapter presents clear evidence that therapists worked closely with care home staff in a collegiate way. In this respect, therapists invested time in building rapport and creating positive working relationships, and so spent less time on other interventions more directly related to care home patients. A number of studies have reported on the impact that client-practitioner relationships can have on treatment outcomes (Cole and McLean 2003, Leach 2005) and how these take time and skill (Kennedy 2000). The rapport that OTs and care home staff developed was evidently important in sustaining therapeutic intent for individual patients, and spreading therapeutic learning across the care home more broadly. However, some therapists felt that care homes required a lot of development work before they were able to start implementing the OTCH intervention. Consideration should be given to the optimum structure and staffing characteristics and organization required for an experimental evaluation and the running of an RCT (Ross et al. 1999). The degree to which these should be addressed prior to the start of the intervention implementation process needs to be subject of further debate. However these data reinforce the potentially dynamic nature of implementation context which should be accounted for when evaluating fidelity.

The results from this chapter explain that re-engineering the care home environment can be an important aspect of the work that occupational therapists do within the care home setting. Illuminating the scope and scale of

the environmental work that therapists did within the care home setting complements other research which highlights a commitment to interventions such as splinting and those targeting practicing of ADLs (Fletcher-Smith et al. 2013). In addition, this theory area has demonstrated that making small changes to the environment could bring observable benefits for patients, which in turn enhanced therapists' commitment to the trial intervention. The potential impacts of observed success (or failure) on practitioners' commitment, conduct and performance at the time of implementation may further add to the evaluation of fidelity.

The OTCH trial interventions were of three months duration, and delivered across waves of recruitment, providing multiple opportunities for therapists to reflect on what was working, or not. Data analysis described the important role that learning over time played when trialling this type of complex intervention which is neglected in published frameworks for fidelity. A number of studies have looked at learning curve effects in RCTs (Ramsay et al. 2002, Cook et al. 2004). However the bulk of these studies are primarily focussed on surgical trials (clinical health technologies) and the implementation of new surgical procedures. Learning curve effects can be defined "*as an improvement in performance over time"* (Cook et al. 2004, p.421) which indicates that changes over time generally lead to higher quality implementation of the tested intervention (Ramsay et al. 2002).

In regards to the chosen methodology, this chapter presents the development of a programme theory guided by principles of realist evaluation. Realist evaluation differs from potentially more reductionist approaches, such as the development of logic models, which hypothesise the links between intervention components and programme outcomes, and perhaps sit more comfortably with the experimental context of the OTCH trial. Whilst these models can be helpful in explaining required inputs and resources for change to occur (Helitzer et al. 2010), they fail to provide explanatory information of how these antecedents affect change, or the contingencies upon which change is dependent. This is particularly important in the case of the implementation of the OTCH complex intervention, which included activities

directed at both care home staff and patients, across functional, environmental and organisational domains of action and impact. By drawing on principles of realist evaluation to guide this process evaluation the research has been able to identify what it is in the OTCH intervention that might have worked, for whom, and in what contexts.

4.6 Conclusion

The refined programme theory presented in this chapter contributes to the development of conceptualizations of fidelity for research evaluating the implementation of complex interventions, specifically, by paying attention to the learning effect on staff delivering these interventions. Other implications for research include the importance of considerations about how previous clinical or research experience may influence the practice of intervention staff, and where organisational development is positioned in the research programme. The researcher found that in line with what a number of authors have already argued, there is a lack of consensus in terms of how to carry out process evaluations. As a result process evaluations are being carried out following different approaches and methods. Whilst carrying out this process evaluation the researcher identified the strong need to review how other researchers were approaching this type of evaluation. The following chapter investigates this matter via a systematic review on the current state of process evaluation research.

CHAPTER 5:

Process evaluations in neurological rehabilitation research: a mixed-evidence systematic review

5.1 Introduction

The MRC guidance (2008) highlights that process evaluations alongside clinical trials provide insights into why a complex intervention fails unexpectedly, how it can be optimised and whether the trial intervention was performed as planned. There is currently a lack of information regarding how process evaluations are being carried out alongside neurological rehabilitation research, such as OTCH.

This chapter reports on the design and results from a systematic review investigating how process evaluations are currently designed and carried out alongside neurological rehabilitation research. The reported systematic review had two evidence streams: stream I, including studies reporting process evaluations alongside neurorehabilitation research and stream II, including methodological guidance on process evaluation design and methodology. A search strategy was designed for each evidence stream. Data regarding core concepts and design issues were extracted using a bespoke template. Findings across the two evidence streams were synthesised in a narrative reporting on the diversity in research practice.

Good quality process evaluations alongside neurological rehabilitation intervention research can advance the evidence base for therapy by identifying Type III errors of implementation, ensuring that potentially effective interventions are not rejected. In addition, they can highlight strategies that will ensure patients have access to interventions that are shown to be effective (Please see Chapter 1 for further details). The results from the systematic review described in this chapter provide a valuable insight into the design and quality of process evaluations alongside neurological rehabilitation research.

These findings have the potential to inform the development of best practice guidance for carrying out process evaluations which will positively impact on the quality of the research underpinning rehabilitation.

5.2 Background

It is widely accepted that in order to make evidence based decisions, health and social researchers and policy makers should not rely on one single published study (Gough et al. 2012). As a consequence, there is a strong need for high quality systematic reviews. As Gough et al. (2012, p.4) argue "their *development can be considered to be one of the turning points in the history of science"*. Firstly, they say that although there are many social and healthcare science studies that are excellent quality there are others which under review will show methodological flaws or conceptual limitations, or might not be able to be assessed because they are not reported in enough detail. Secondly, even when a study is high quality it might report 'atypical findings' which 'stand-alone' and subsequent research decisions should not rely on it. As an example of this it is worth mentioning the famous case of the one research paper (Wakefield et al. 1998) based on 12 children, which made the world doubt the safety of the MMR vaccine and its possible cause of Crohn's disease and autism. Although the researchers retracted their published results due to potential bias it still caused a reduction in the uptake of the vaccine (Murch et al. 2004). It was a systematic review by Demicheli et al. (2005) which concluded that the link of the vaccine with Crohn's disease and autism was unlikely.

As Gough et al. (2012, p.3) further explain "*reviews can inform us about what is known, how it is known, how this varies across studies, and thus also what is not known from previous research"*. They argue that not reviewing available information might lead to an unnecessary waste of resources and that it is unethical for an ill-informed researcher to start new research since it can lead to irrelevant and inappropriate results.

Systematic reviews are themselves 'pieces of research' (Gough et al. 2012) and therefore their design and chosen methods are paramount to them. As authors such as Gough et al. (2012) and Oakley (2012) recommend, a systematic review should clearly describe its chosen methods and should provide:

- Detailed description of published research relevant to the review question.
- A systematic critical appraisal of the research.
- A synthesis of the findings and coherent discussion.

In the same way, if a systematic review is in itself a 'piece of research' that aims at answering a research question, then in the same way as in primary research, this research question will need to be taken into account at the time of choosing the appropriate approaches and methods to answer it (Gough et al. 2012, Thomas et al. 2012).

5.2.1 Brief history of systematic reviews

As Oakley (2012, p.vii) explains, carrying out a systematic review is:

> "*The art and science of collecting and pooling information from primary research studies and their aim is to arrive at a more comprehensive and trustworthy picture of the topic being studied than is possible from individual pieces of research".*

The search for evidence to influence policy has been around for a long time. However, looking for evidence in a systematic way using systematic methods for appraising and collating available evidence is a more recent approach (Gough et al. 2012).

The term systematic review is a relatively new concept. Barbara Wootton was one of the first social scientists to carry out a systematic review of research on antisocial behaviour (Wootton 1959). She triggered the fury of many, since her results reported that the studies she had reviewed were not sound and therefore their findings could not be used by policy makers. Years later, Smith

et al. (1980) critically appraised and synthesized research findings in the area of psychotherapy and class size using a systematic method. However, although these were conducted in social interventions and public policy areas, originally systematic research was applied exclusively to medicine and health. It was Archie Cochrane who, in his seminal work *Effectiveness and Efficiency: Random Reflections on Health Services* (1972) initially argued the need for practitioners to make evidence-based decisions in their everyday medical practice

In the early 1980s, inspired by Cochrane's work and his call for the critical summary of all RCTs (1979), a group of researchers in Oxford began producing and collating systematic reviews on the effectiveness of health care interventions. By the 1980s systematic reviews of RCTs were being published and, in 1992 the first Cochrane centre opened in Oxford. In 1993 'The Cochrane Collaboration' was founded as an international network committed to make healthcare knowledge based evidence accessible to all, assuring its quality.

During the 1990s the work carried out by Ann Oakley and her team at the Social Science Research Unit in the University of London developing a database of interventions in the field of education and social welfare led to the creation of The Evidence for Policy and Practice Information and Co-ordinating Centre (EPPI-Centre). Since the year 2000 its remit has widened to include reviews in social care and employment. Additionally, it has contributed strongly to the methodological aspect of systematic reviews by producing widely used tools (Oakley et al. 2005).

5.2.2 Mixed methods systematic reviews – methodological approaches

Systematic reviews are an important tool for generating evidence informed policies and practice since they combine findings from multiple studies (Oliver et al. 2005). As widely discussed in this thesis there is an ongoing debate regarding comparative usefulness of quantitative and qualitative evidence synthesis. A systematic review often identifies several studies, both qualitative and quantitative addressing the same question. The results of these studies

need to be synthesized and interpreted. Synthesizing only one type of evidence would lead to "a *very short sighted conclusion which is out of tune with reality"* (Joanna Briggs Institute (JBI), 2014, p.6). Review methods for identifying, appraising and synthesizing 'quantitative' findings on the impacts of interventions have greatly developed over the past twenty years (EPPI Centre 2010). However, the field of mixed methods systematic reviews is still in early development and to date there is no consensus with regards to the best possible methods to follow (JBI, 2014). According to Harden (2010), the continuous debate on this matter can at times diminish the usefulness of these reviews, since it is not the conclusion around the topic of interest that takes priority but the critique of the method employed.

Harden (2010) identified three methods for mixed methods systematic reviews which are conducted at the EPPI-Centre:

1. Systematic reviews of mixed methods studies – this by default will lead to a mixed method systematic review.
2. Systematic reviews using mixed synthesis methods – two or more separate syntheses are performed on quantitative and qualitative data.
3. Systematic reviews were two or more syntheses are conducted (as in method 2) and then combined in an overall synthesis (Oliver et al. 2005). The first synthesis (thematic synthesis of qualitative data) is used to critique and assess results from the second quantitative synthesis and this results the overall third synthesis.

According to the JBI (2014) the first two methods are not viable and have limited utility since they clearly delineate evidence types which are not combined at any stage.

As already mentioned new approaches to mixed methods synthesis are continually being published. Amongst the most dominant ones is Realist Synthesis (Pawson et al. 2004), which is theory-driven and follows an unstructured highly iterative process that focusses not on whether a particular program works but on the 'program mechanisms'. Realist synthesis attempts to explain how an intervention works, for whom and under what circumstances.

This approach has not been free of criticism. For example, Curnock et al. (2012) argue, firstly that realist synthesis lacks transparency regarding the choice of evidence selected and secondly that it does not provide clear guidance on how to address contradictory evidence.

5.2.3 Process evaluation in neurological rehabilitation research – the context for this review

At present ten million people in the UK are affected by a neurological condition that impacts on their everyday life and requires rehabilitation. Due to improved survival rates and improved diagnostic and healthcare services this number is expected to grow in the next two decades (The neurological alliance 2003). In terms of research, although the number of RCTs of rehabilitation interventions has risen dramatically in recent years, rehabilitation research lags behind other sciences in providing conclusive evidence of its beneficial impacts. As a consequence the development of innovative interventions and programmes is being slowed down (Tate 2006). As a 'broad based discipline' the impacts of rehabilitation interventions are difficult to evaluate and therefore its multidisciplinary nature needs to be addressed when designing research studies (Hart and Bagiella 2012). The challenge relies in working towards defining, in detail, rehabilitation treatments in terms of what are their 'active ingredients', what is their individual impact and what is the impact of the intervention as a whole (Clark 2013). Furthermore rehabilitation research is context specific and often defined as the interaction between the individual and the environment (Townsend 2002). Thus, identifying contextual factors (physical, psychological, social, etc.) and acknowledging that researchers bring their own personal values into situations is of great importance when thinking about the science of rehabilitation.

A number of models to assist with the development of complex interventions and improve their quality have been published. The UK MRC (MRC 2008) has proposed an approach to the evaluation of complex interventions which includes developing theory-based explanations of how interventions work. This framework has already been used in a number of neurological rehabilitation research projects (Robinson et al. 2005, Tilling et al. 2005 and

Redfern et al. 2006). It describes five phases for intervention development which the research process should follow. Although this framework does not provide details as to which research methods should be used, it provides guidance in terms of what research questions need to be addressed in each phase. The MRC (2008) framework highlights that a process evaluation, including qualitative data gathering methods, can provide insight into why an intervention fails unexpectedly or has unanticipated consequences, or why a successful intervention works and how it can be optimised (Oakley et al. 2006). It is widely accepted that process evaluations serve a very important role, not only when checking whether the trial intervention was performed as planned but also in providing detailed insight into the experiences of those exposed to the intervention (Steckler and Linnan 2002, Oakley et al. 2006). By evaluating processes, an intervention can be improved either during its application, or afterwards, at an implementation stage (Hulscher et al. 2003). Finally, trials which include a process evaluation will produce higher quality results that can help clarify the potential generalizability and optimisation of the proposed intervention in routine practice (Bonell et al. 2006). However, to date, process evaluations alongside trials are very scarce and they are even rarer in multidisciplinary therapy research on neurological rehabilitation.

As described in detail in Chapter 1 in recent years there has been a large increase in published research on theories and frameworks driving process evaluations for complex interventions. Steckler and Linnan (2002) proposed a framework for carrying out process evaluations which included a series of program components that should be measured and evaluated: recruitment (how were participants attracted into the study), context (social, political and environmental factors that could have influenced implementation), reach (proportion of targeted patients that participated in the intervention), dose delivered (proportion of the intervention components that was provided), dose received (level of participant's engagement in the intervention), fidelity (to what extent was the intervention delivered as had been intended by the researchers) and implementation. However, there is still very limited guidance to help researchers design process evaluations (Grant et al. 2013); as a consequence, researchers can find the prospect of carrying out a process

evaluation daunting and this could lead them to discard the idea of embedding one alongside their proposed trials, especially when looking at complex interventions.

5.3 Design and methods

5.3.1 Research questions

To our knowledge this constitutes the first systematic review that applies a two stream mixed evidence synthesis to investigate process evaluations in neurological rehabilitation research. The overarching aim of this systematic review was to answer the following question: *How are process evaluations currently designed, what methodologies are used and how are they developed alongside or within neurological rehabilitation research?*

A number of more specific research questions have been identified:

1. What methodologies and methods have been used to carry out process evaluations when undertaken alongside neurological rehabilitation research?
2. What are the theoretical underpinnings (if any at all) of process evaluations alongside neurological rehabilitation research trials?
3. How have the results from process evaluations alongside neurological rehabilitation research trials been used to understand and clarify trial results?
4. What are the potential barriers and facilitators to carrying out process evaluations alongside neurological rehabilitation research?
5. What terminology is currently being used in process evaluation research?

5.3.2 Research design – mixed evidence synthesis

The review followed the University of York Centre for Research and Dissemination (York CRD) guidelines for conducting searches and extracting

data (York CRD 2009). The Evidence for Policy and Practice Information and Co-ordinating Centre (EPPI-centre) published methods for conducting systematic reviews (EPPI-centre 2010) was used to guide the synthesis of mixed-evidence findings.

The aim of a process evaluation is to investigate how and why an innovative intervention fails or succeeds at producing the desired outcomes (Byng et al. 2008). According to Steckler and Linnan (2002) it achieves this through identifying and measuring a variety of intervention components such as adherence to protocol, fidelity, dose delivered, dose received and participants' perceptions amongst others (refer to Chapter 1 for more information). In order to do this, process evaluations may make use of both qualitative and quantitative methods (Braun et al. 2010).

Following the CRD's guidance for undertaking reviews in health care (CRD 2009), an initial review of published literature was carried out in order to identify key terms and types of studies reporting on process evaluations. This review identified a variety of quantitative, qualitative and methodological literature. This provided an indication of the multi levelled nature of the current state of process evaluation research in neurological rehabilitation research.

As a result, the researcher decided that this review would benefit from including not only published mixed methods research studies reporting on process evaluations, but also studies discussing methodological and design issues around process evaluation. The researcher considered that a range of study designs and study types would be needed in order to be able to address the review questions (CRD 2009). Thus, the decision was made to segregate studies (evidence) into two different streams of evidence which would include a variety of study designs (Popay et al. 2006, Gough and Thomas 2012). This would address the need to answer different layers of the systematic review questions (CRD 2009). Studies included in each evidence stream would be analysed and synthesised separately, and following from this, results from each evidence stream would be 'bridged together'. This would be done by attempting a narrative (interpretative) synthesis (Harden et al. 2004, Oliver et al. 2005, CRD 2009) which is defined as a textual approach that looks into the

relationships within and between studies developing new concepts (recommendations in this case) whilst being grounded on data extracted from the selected studies instead of "*floating free of any empirical anchor"* (Dixon-Woods et al. 2006, p.37).

As mentioned above, in a review like this one, with two evidence streams, it was likely that included studies would be heterogeneous and variable, since they would be addressing process evaluations from two perspectives: how are they being carried out and what methodological guidance and frameworks are informing it. In this review, heterogeneity is "*seen as a strength and an opportunity for analysis rather than as a problem"* (Gough and Thomas 2012, p.55). Informed by Cochrane guidance (Jackson 2004) the researcher identified the following potential sources of variability amongst selected studies for both evidence streams:

- *Variability in interventions and settings*: studies in stream I would report on process evaluations alongside research studies targeting a wide range of innovative interventions, often complex and therefore multicomponent.

- *Variability in measures*: studies included in stream I evidence would be likely to include and measure a range of heterogeneous outcomes. Outcomes could be investigating physical change or physiological change, short term, long term, etc. Process evaluation measures would therefore be potentially variable depending on the studies outcomes.

- *Variability in study designs and methodologies*: studies in stream I evidence will be likely to represent a wide array of designs, purely quantitative, purely qualitative or mixed. Studies in stream II would also be likely to discuss a wide range of methodological factors in different ways.

- *Variability of population under investigation*: studies in stream I are likely to focus on a range of study populations of all age groups, gender, race and socioeconomic position and with a wide range of physical and cognitive disabilities.

The following streams of evidence were agreed (Figure 5.1):

Research evidence (stream I)

This research evidence stream will aim to identify how process evaluations have been carried out alongside or linked to neurological rehabilitation research trials. This type of evidence will provide data to answer the specific objectives of the proposed systematic review which aim at identifying terminology used in process evaluations, how results of process evaluations are used to understand the trials overall outcomes and what particular methods are mostly used by researchers. The researcher aimed at collating extensive and exhaustive evidence that would provide a complete data set. This evidence should, ultimately be a complete representation of *what is taking place.*

Inclusion criteria:

Qualitative and quantitative primary research studies that reported on process evaluations linked to neurological rehabilitation research trials conducted around the world. Articles had to report on one or more process evaluation components (Steckler and Linnan 2002). Descriptive studies without any process evaluation component or papers that only reported on impact evaluation were excluded. Studies that reported on results from the assessment and monitoring of one or more process evaluation components (Steckler and Linnan 2002) were included regardless of the study type.

Methodological guideline/resources evidence (stream II)

This research evidence stream targeted research studies which were not necessarily primary research. Stream II sought to include studies that would include rich data to help answer methodological and theory related research questions and aimed to explore frameworks and theory behind process evaluations. It was anticipated that the data would be heterogeneous. The researcher made the decision to further search for studies focussing on methodologies for identifying 'learning curve effects' (when linked to implementation fidelity research). The researcher was aware of the need to select studies which would provide richness of data in order to develop and explore the existent theory and methods. Thus, although an inclusion criteria

was specified from the start, the researcher was aware that these criteria might need to be modified or altered through the process of the review (Gough and Thomas 2012).

Inclusion criteria:

Studies and reports exploring methodologies, guidance and opinions regarding process evaluation research methods were included, as were studies reporting on frameworks for fidelity of implementation in health research and its components.

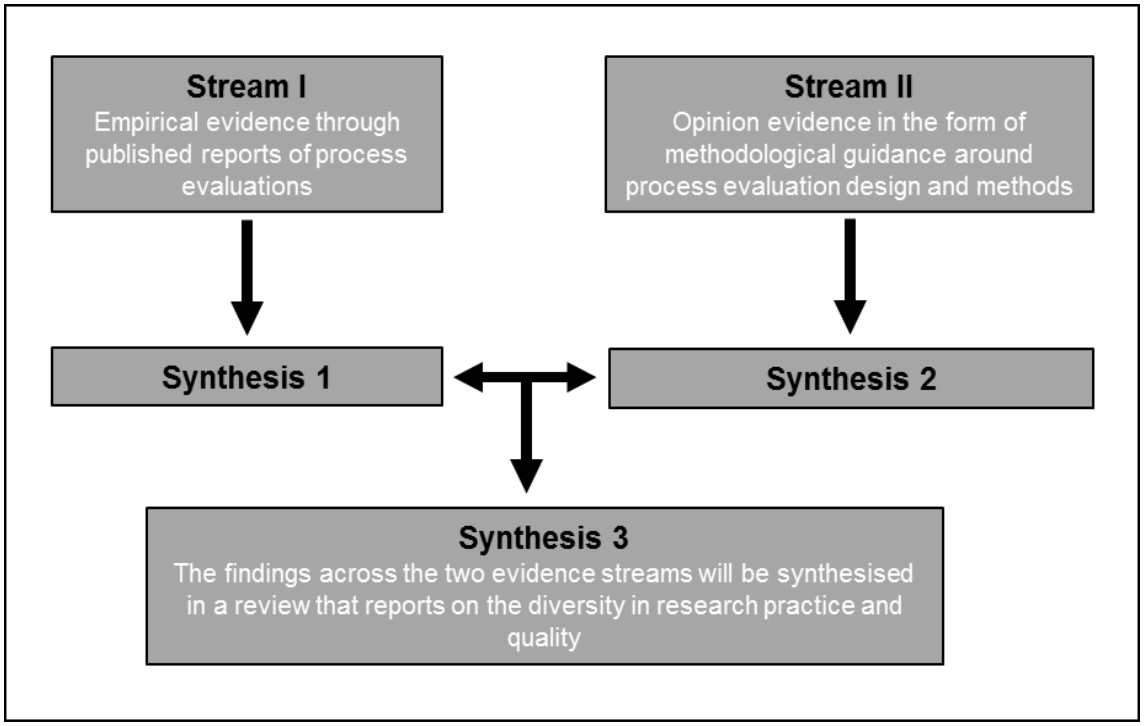

Figure 5.1 Mixed evidence systematic review - design flowchart

5.3.3 Search methods

Stream I searches:

As explained above, stream I evidence was attempting to collate as much relevant research as possible in order to avoid bias. To achieve this, the researcher considered varied sources, including not only electronic databases but additional ones (CRD 2009).

Relevant articles to be included in stream I were identified through conducting electronic database searches (Table 5.1). The researcher regularly recorded all search details (date, search strategy, hits) in a 'search log'. All search results were managed using Refworks. In line with the CRD (2009) advice in regards to the choice of databases, the following were searched: CINAHL, Web of Science, Medline, PEDro, SSCI, PsycINFO, ClinicalTrials.gov, HTA Database, Cochrane Central, EPPI Centre Database, ASSIA and DORIS. The data searches were carried out using search terms and keywords that were a mixture of Medical Subject Headings (MeSH) and non-MeSH terms.

The researcher contacted experts in the field, carried out manual reference list checks (citation tracking) and hand searched key journals and trials registers websites as well as other specialist websites and internet search engines such as Google Scholar.

Table 5.1 Details of the databases and specialist registers searched

Database	***Time period of search***
CINAHL (Cumulative Index to Nursing and Allied Health Literature)	January 1977 – February 2015
WoS (Web of Science)	January 1977 – February 2015
MEDLINE (via Ebsco-host)	January 1977 – February 2015
SSCI (Social Science Citation Index)	January 1985 – December 2014
PsycINFO (via Proquest)	January 1985 – November 2014
ASSIA (Applied Social Sciences Index and Abstracts)	January 1985 – November 2014

Specialist registers	***Date searched***
ClinicalTrials.gov	September 2014
Health Technology Assessment (HTA) Database	September 2014
PEDro (Physiotherapy Evidence Database)	September 2014
CENTRAL (Cochrane Controlled Trials Register)	September 2014
EPPI Centre databases (BiblioMap, DoPHER and TRoPHI)	September 2014
DORIS (Database of Research Into Stroke)	September 2014

Following the advice from an experienced librarian and informed by three published systematic reviews on process evaluations (Murta et al. 2007, Cooper Robbins et al. 2011 and Yeary et al. 2012) searches for stream I were carried out considering three different search arms:

Process evaluation: At the time when the searches were being carried out, and to this date, the term 'process evaluation' is not a MeSH in any of the databases that were searched. The researcher developed a careful selection of terms around process evaluation (e.g. 'process evaluation', 'program* evaluation', 'outcome evaluation' and 'evaluation study'). Although the concept of process evaluation as we define it is fairly new, a number of its components that are of interest to this review have been investigated for longer. Thus the terms 'adherence' and 'fidelity' which are frequently linked to process evaluation research and frameworks were included as search terms.

Neurological conditions and rehabilitation: In order to limit the results only to studies reporting on neurological rehabilitation interventions, searches based on MeSH terms for neurological conditions and rehabilitation were carried out separately. Search strategies for 'neurological conditions' and 'rehabilitation' were informed by published Cochrane searches accessed through the following sources: Cochrane Movement Disorder Group, the Cochrane Dementia Group, the Cochrane Multiple Sclerosis Group, the Cochrane Stroke Group and the Cochrane Collaboration's Rehabilitation and Related Therapies (R&RT) Field.

Finally, the three search arms (process evaluation, rehabilitation and neurological conditions) were combined. An example of the search strategy used for the MEDLINE database is available in Table 5.2. The online bibliographic management program Refworks was used in order to manage all results. A wide time period was chosen; searches were restricted to studies published between 1977 and 2015.

Table 5.2 Example of the search strategy for the MEDLINE database

Database: MEDLINE (EBSCOhost) Limiters: Date (Jan 1977- Feb 2015), English Language	
Search arm	**Query**
Process Evaluation	["outcome evaluation" OR "adherence" OR "fidelity" OR "process evaluation" OR "programme evaluation" OR [(MH "Program Evaluation+") OR "program evaluation"] OR (MH "Evaluation Studies")] **AND**
Rehabilitation	["function* recovery" OR (MH "Recovery of Function") OR "rehab*" OR (MH "Activities of Daily Living+") OR (MH "Rehabilitation of Speech and Language Disorders+") OR (MH "Rehabilitation Nursing") OR ["vocational rehabilitation" OR (MH "Rehabilitation, Vocational+")] OR [(MH "Rehabilitation+") OR "rehabilitation"]] **AND**
Neurological Conditions	[[(MH "Guillain-Barre Syndrome+") OR "guillain-barre"] OR [(MH "Poliomyelitis+") OR "poliomyelitis"] OR [(MH "Meningitis+") OR "meningitis"] OR [ictus] OR ["brain tumour*" OR "brain tumor*"] OR [(MH "Muscular Dystrophies+") OR "muscular dystrophy"] OR [(MH "Dementia, Vascular+") OR (MH "Dementia+") OR "dementia"] OR [(MH "Huntington Disease") OR "Huntington"] OR [(MH "Motor Neuron Disease+") OR "motor neurone disease"] OR ["cerebro-vascular accident" OR "cerebrovascular accident"] OR [(MH "Stroke") OR "stroke"] OR [(MH "Alzheimer Disease") OR "Alzheimer's disease"] OR [(MH "Cerebral Palsy") OR "cerebral palsy"] OR [(MH "Hemiplegia") OR "hemiplegia"] OR ["Traumatic brain injury"] OR [(MH "Brain Injuries+") OR "brain injury"] OR ["head injury"] OR [(MH "Amyotrophic Lateral Sclerosis") OR "Amyotrophic lateral"] OR [(MH "Multiple Sclerosis+") OR "multiple sclerosis"] OR [(MH "Parkinson Disease") OR "parkinson's disease"] OR [(MH "Neuromuscular Diseases+") OR "neuromuscular disease"]]

Stream II searches:

Searching for stream II evidence was purposeful and inclusive in order to minimize the risk of relevant studies not being identified; since this type of evidence is often targeted at a very broad audience, the researcher did not

think it was appropriate to limit the inclusion criteria to a particular discipline or field. It is important to point out at this stage that the aim of this search was to identify a quality representative sample of relevant studies to be included in stream II rather than identify all possible studies meeting inclusion criteria (Gough and Thomas 2012). The researcher was aware that studies to be included in stream II would not necessarily be available in electronic academic databases and that some would feature outside mainstream research literature. Thus, searches were carried out using a wider approach.

Overall, relevant literature was identified through the use of search engines such as Google Scholar and snowball sampling. Thorough manual reference checking of studies included in stream I was carried out. Specialist websites were searched and experts were contacted in order to assure that relevant studies were not left out. Searches were not limited to the UK, international guidelines and methodological resources were included when considered relevant to the review.

5.3.4 Screening of results

The screening of the results was carried out in different stages and it was adapted for each of the evidence streams:

- In the case of **stream I** evidence firstly, all duplicates were removed from all identified studies and subsequently titles and abstracts were screened against the inclusion/exclusion criteria. When in doubt, full texts were read and reviewed. Secondly, screening of full text documents of all remaining studies was carried out and a final list of studies was selected. In order to reduce bias a second researcher joined the process at this stage and reviewed each study independently. When necessary, agreement on inclusion was reached through discussion.

- In the case of **stream II** evidence, duplicates were removed, all identified studies were collated and full texts read and reviewed. The researcher then briefly summarized the content of each study in a document which was shared with the rest of the research team members. Following this a

meeting with a sub-set of the research team was held where agreement on reasons for inclusion/exclusion for each of the studies was reached. As a result of this meeting a final list of studies was selected.

5.3.5 Data extraction

Stream I

As previously explained, one of the objectives of this research was to unpick how process evaluation components had been identified and measured as part of or alongside each study. Thus, due to the nature of the research questions that this study aimed to answer, studies included in stream I were expected to include both qualitative and quantitative studies of different designs, not only RCTs. Extracting and synthesising this type of mixed information constituted a big challenge for the researcher since, as it became apparent, methods for doing so are much less developed and thus there are few completed reviews which could have helped guide and inform the process (Popay et al. 2006).

Furthermore, as previously discussed by other authors (Kavanagh et al. 2006, Kavanagh et al. 2011) although work is being carried out (for example MRC guideline, Harden et al. 2001) there are currently no established methods for assessing the quality of process evaluations as such, partly due to the wide variation in the reporting of process evaluations (Grant et al. 2013). Thus, the researcher decided the systematic review would not formally review the methodological quality of the process evaluations. This is in line with the systematic review research questions.

Firstly, basic information (publication year, author, title, discipline) was collected from all stream I studies. Secondly, data on process evaluation components was extracted. Decisions on appropriate methods for doing this were informed by three published systematic reviews on process evaluations (Murta et al. 2007, Cooper Robbins et al. 2011 and Yeary et al. 2012) and a systematic review which included a set of studies that were process evaluations (Kavanagh et al. 2006). A bespoke template for data extraction

was prepared including components identified in published frameworks on process evaluation such as the one proposed by Steckler and Linnan (2002). Summary information of data extraction components is provided in Table 5.3. As recommended by the CRD (2009) the data extraction form was piloted on a sample of 10 included studies in order to guarantee that the relevant information was captured and resources were not being wasted on extracting irrelevant data. Furthermore, a quality check on data extraction from a random 10% sample of studies included in stream I evidence was undertaken by two reviewers.

Table 5.3 Data extraction components and definitions for stream I evidence

Data extraction components	Definition
Basic information	Author, publication year, study design, study intervention, target audience, discipline and study focus
Recruitment	Procedures used to attract participants to be part of the research study, including barriers and facilitators to the process. Procedures used to retain participants for the duration of the study.
Dose delivered	The number or amount of units (e.g. session) or components of the intervention that were delivered. It is directly dependent on the work of staff providing the intervention.
Participant attitudes	Participants' opinions and perception of the quality and usefulness of the intervention, including their opinion regarding possible outcomes. The term 'participant' includes both, people recruited to receive the intervention and staff delivering it.
Adherence/fidelity	Measure of how the content, frequency, duration and coverage of the intervention was delivered as planned.
Implementation	It is an overall indicator of the extent to which the intervention has been delivered and received by the study participants.
Context	Aspects of the larger social, economic and political environment that may impact on the implementation of the intervention.
Intervention protocol	Information regarding whether the trialled intervention was described in detail in a study protocol (content, format, frequency, duration, etc.). Information regarding implementation of an available protocol (e.g. tailoring to patient needs).
Aims and objectives	Information regarding clarity and specificity of aims and objectives of both, the outcome and process study.
Process evaluation study design and rationale	Details on strategies and methods used in order to carry out the process evaluation linked to the research study.
Mechanism to assess adherence to the intervention protocol	Procedures and methods in place in order to assess how well are providers keeping to the protocol at the time of delivering the intervention.

Description of intervention providers	Details regarding level of relevant experience, set of skills and professional grading of staff in charge of delivering the intervention.
Training of intervention providers	Details regarding the training of staff delivering the intervention prior to or throughout the research study: providers, level of standardization, structure, frequency, post-training skill acquisition assessment.
Learning over time	Procedures in place to monitor and measure changes to providers' capability of delivering the intervention over time. Measures in place to assess how these changes might have influenced study outcomes.
Theoretical model or clinical guidelines informing the process evaluation	Details on theoretical models, frameworks or guidelines used by the study team in order to both, design the process evaluation and interpret its results.
Process evaluation findings	Information regarding how the results from the strategies in place to measure process evaluation components have been described and presented.
Linking process evaluation and outcome results	The extent to which results from the process evaluation have been used to explain the success or failure of the intervention. Methods in place to link outcome and process results.

Stream II

Basic information was firstly extracted on type of publication, topic, aims, objectives and target audience. The primary goal of the stream II data extraction phase was to identify the overall statements and ideas that were implicit in each of the studies and that referred to the process of evaluating what takes place at the time of designing and carrying out a process evaluation within a research trial. The researcher aimed at collecting information on how methodological and opinion publications had addressed the following aspects (or a number of them) of process evaluation research: theory development, context, recruitment, staff characteristics, staff training, learning over-time and adherence to protocol.

As Sandelowski and Barroso (2002) explain, identifying the findings in qualitative research can be complex since there are a number of reporting styles and often data is misrepresented as findings. In line with this and with work by Thomas and Harden (2008) the researcher found that it was often difficult to identify key concepts and 'results' in stream II included studies. In order to resolve this problem the researcher interpreted 'study findings' as all

text sections which directly (or at times indirectly) referred to 'results' or 'discussions' on how to carry out process evaluation research. Since included studies ranged from being a few pages to complete book chapters, the extracted sections were equally variable in size. For those documents in electronic form, extracted sections were copied and saved as a word document. When only hard copies were available, the extracted sections were scanned and then saved as word documents. As with studies included in stream I, a quality check on data extraction from a random 10% sample of studies included in stream II evidence was undertaken by two reviewers.

5.3.6 Synthesis of extracted data

The findings from this review were arranged to answer the proposed research questions. The review aimed at exploring the way in which process evaluation components are being assessed and which existing theories or frameworks are being used in different research contexts. In order to achieve this, this review was carried out by configuring the findings from each included study in order to understand the 'whole' (Gough and Thomas 2012).

As expressed by Thomas et al. (2012, p.180) a synthesis "*is not just a list of the findings of individual studies, it also involves a transformation of the data from the primary studies in order to build a 'connected whole''*. They further say that a synthesis '*is more than simple the sum of its parts'* (p.180). For a synthesis to be such it needs to generate some innovation or new knowledge which is grounded in the data of all studies.

In line with CRD (2009) recommendations, any synthesis should begin with a clear descriptive summary of included studies. The researcher used descriptive statistics in order to do this and map studies included in both streams of evidence.

5.3.6.1 Stream I – Synthesis 1

A narrative synthesis was chosen to carry out the synthesis of studies included in stream I evidence. This decision was based on the likelihood of considerable heterogeneity amongst included studies (Popay et al. 2006). Narrative

synthesis methods have long been considered useful when attempting to understand the heterogeneity across studies (Petticrew and Roberts 2006, CRD 2009). As previously discussed, due to the complex nature of rehabilitation interventions, heterogeneity was likely to be present in terms of types of participants, health discipline, type of intervention and characteristics of the population being studied. Also in terms of the type of findings which had the potential to be both, qualitative and quantitative.

Data extracted from studies included in evidence stream I was analysed and themes were identified using a modified method described by Kavanagh et al. (2006). The first step in this process involved establishing patterns within particular components of process evaluation (data extraction components). These were then further evaluated by the researcher in order to establish events across the whole data set which constituted the emerging themes (Figure 5.2). During this process the researcher analysed identified patterns in regards to how they could contribute to answering the review questions.

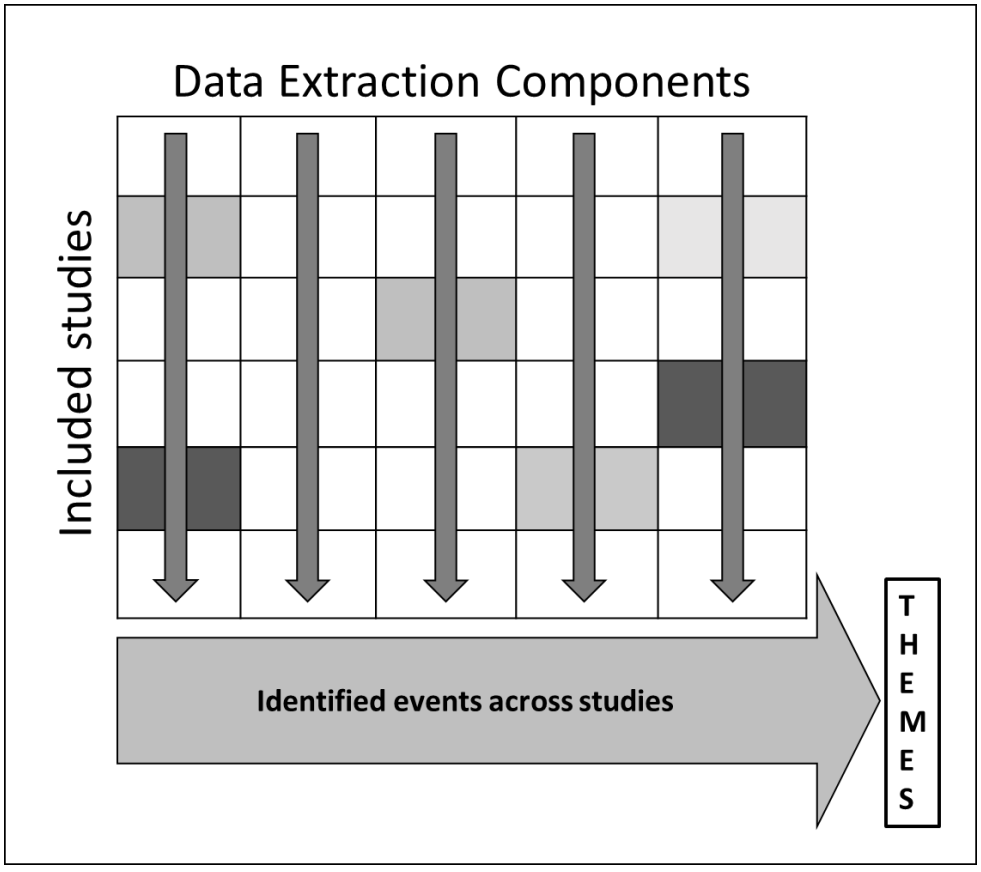

Figure 5.2 Thinking framework for synthesis of stream I studies

Results from this analysis are presented in the form of overarching narrative descriptive themes (synthesis) which were inductively generated (Popay et al. 2006, Thomas et al. 2012). In other words, themes were not identified a priori to guide the data extraction, they were generated afterwards and reflected main events across studies (Popay et al. 2006). As an example, Figure 5.3 illustrates a summary of this process for the identification of Theme 7. The researcher considered that, in line with what other authors have reported, themes were a clear and effective way of organizing and synthesizing findings in a large and heterogeneous data set such as the one this review was expected to generate. For quality assurance, initial patterns and subsequent themes were independently reviewed by another member of the research team. Finally emerging themes were then opened to debate, and disagreements amongst researchers were solved via discussion.

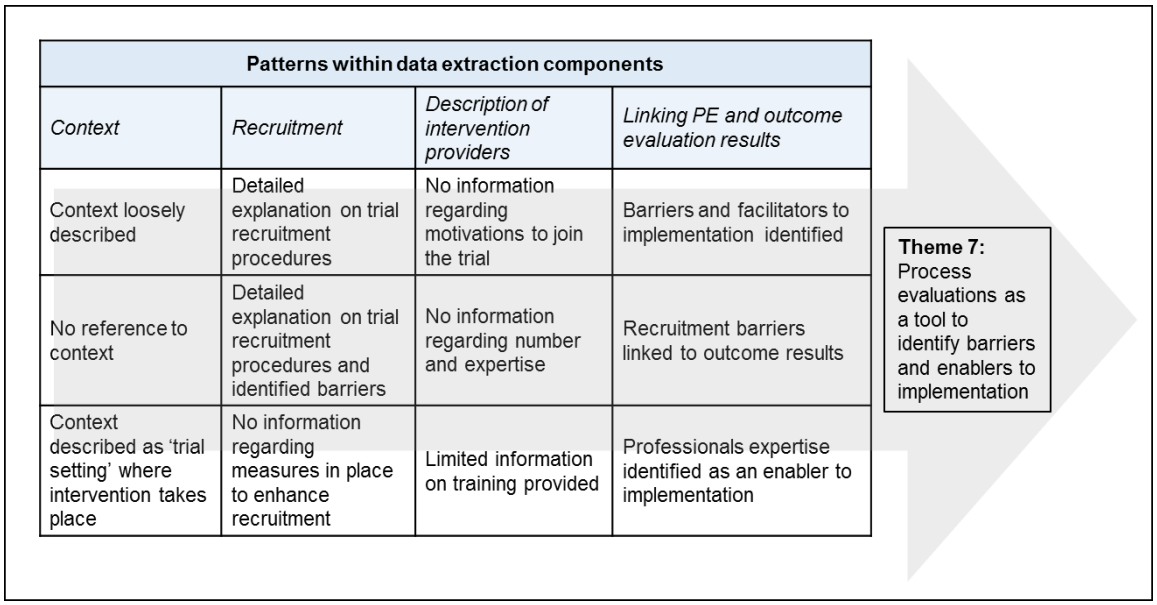

Figure 5.3 Illustrative example of the process the researcher followed in order to describe Theme 7

5.3.6.2 Stream II – Synthesis 2

Thomas and Harden's (2008) method for carrying out thematic qualitative synthesis on primary qualitative research was adapted, as required, in order to carry out the synthesis of methodological evidence included in stream II. The researcher had to modify this method in order to apply it to this particular data set, which comprised methodological reports and guidance. The following steps were followed:

Finding ‘descriptive themes’: key components and specific recommendations expressed in each of the methodological studies were identified in each of the documents. This would constitute the ‘descriptive themes’ which in this research were often presented as opinions and recommendations. These themes were close descriptions of what each of the included studies reported. Due to the nature of stream II included studies, it was unrealistic to undertake coding of each line of text. Thus, the researcher read each of the sections which had been extracted during the data extraction phase and coded sections according to its purpose and content. As the coding progressed, a ‘bank of codes’ was generated and new ones were created when necessary. The researcher carried out this coding by hand, assigning a colour to every extracted section belonging to the same identified code. The researcher followed an inductive process and looked at similarities between codes in order to group the initial codes. This process resulted in a number of descriptive themes (Figure 5.4 is an example of how one of the descriptive themes, *intervention staff factors*, was generated). Before completing this stage, all sections which had been given the same code were examined by a different member of the research team in order to check consistency of interpretation and to see whether additional codes were necessary.

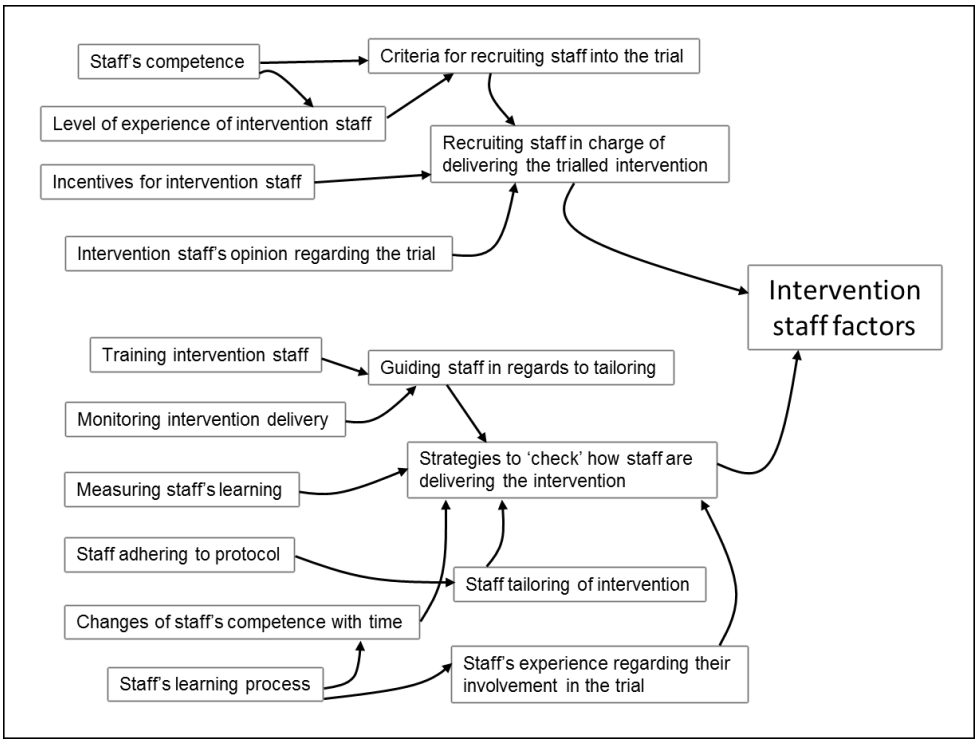

Figure 5.4 Example of grouping of initial codes to form broader descriptive themes

The generation of ‘analytical themes’: during this stage of the qualitative synthesis the researcher aimed at moving beyond identified descriptive themes and creating higher-level analytical themes. This was done by using the descriptive themes that emerged from the inductive analysis to answer the systematic review question. The researcher inferred aspects of how process evaluations are currently being carried out alongside neurological rehabilitation research that were captured in the descriptive themes. She then considered the implications for process evaluation research development. The researcher did this independently, and then, through discussion with the rest of the members of the team, more analytical (abstract) themes began to emerge. These final analytical themes constituted a number of broader ‘list of recommendations’ regarding the undertaking of different aspects of process evaluation research.

5.3.6.3 Bringing findings together (in depth review) – synthesis 3

Guided by the main aim of this systematic review, the findings across the two evidence streams were synthesised in a narrative that reports on the diversity in research practice, identified gaps and quality. The method described by Oliver et al. (2005) and Harden et al. (2004) was used to structure, compare and bring together findings from both research and the methodological guideline streams of evidence (over-arching narrative synthesis). The themes that emerged from synthesis I provided a picture of how neurological rehabilitation researchers are currently carrying out process evaluations. These themes were then mapped on to the recommendations (analytical themes) identified in the synthesis of stream II studies. As a result of this process the researcher was able to identify potential gaps and strengths defining neurological rehabilitation process evaluation research (Figure 5.5).

This overarching synthesis (Synthesis 3) is presented as a list of identified potential statements regarding how to best carry out and report process evaluations in neurological rehabilitation research.

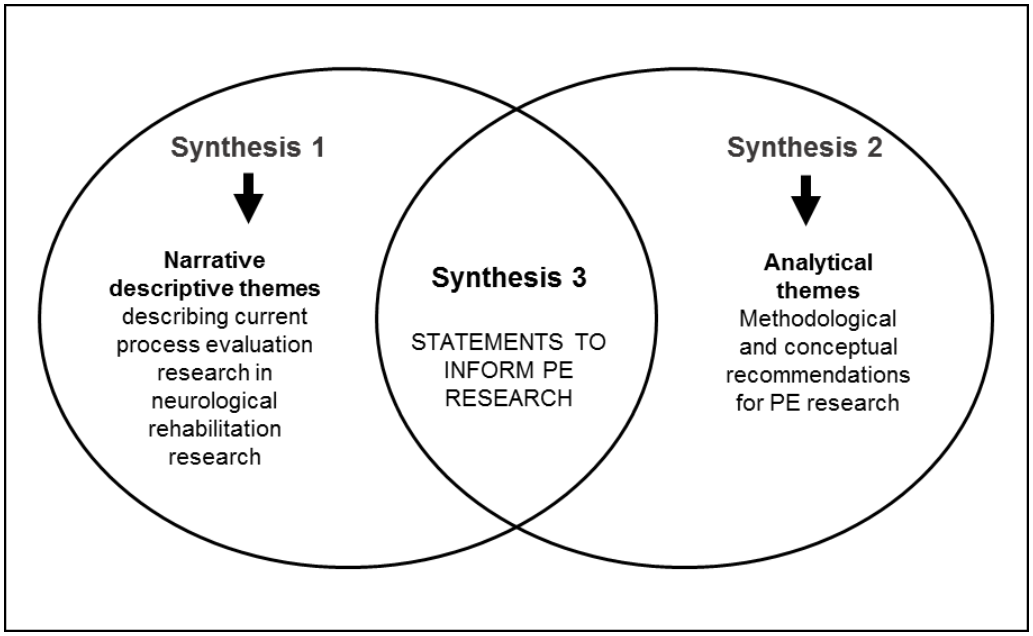

Figure 5.5 Summary of the synthesizing process

5.4 Results: identifying, describing and synthesizing studies

5.4.1 Included studies

A total of 3316 studies were found for stream I searches. 1281 duplicates were removed and after screening titles and abstracts, 1680 were excluded on the basis of not meeting inclusion criteria. The full text of the remaining 257 studies was screened and upon complete reading, 118 studies were left (Figure 5.6). The main reason for exclusion at this stage was studies not including any reference to one or more process evaluation components. This final screening stage was challenging due to the varied nature of pre-selected studies. Some researchers published a separate process evaluation result paper in addition to an outcome evaluation paper and a process evaluation protocol paper; articles describing one intervention were combined and considered as one unit for the purpose of this review. After this grouping, a total of 118 studies reporting on 103 interventions remained for analysis. A list of all included studies in stream I evidence, ID number and summary information is available in Appendix 5.1.

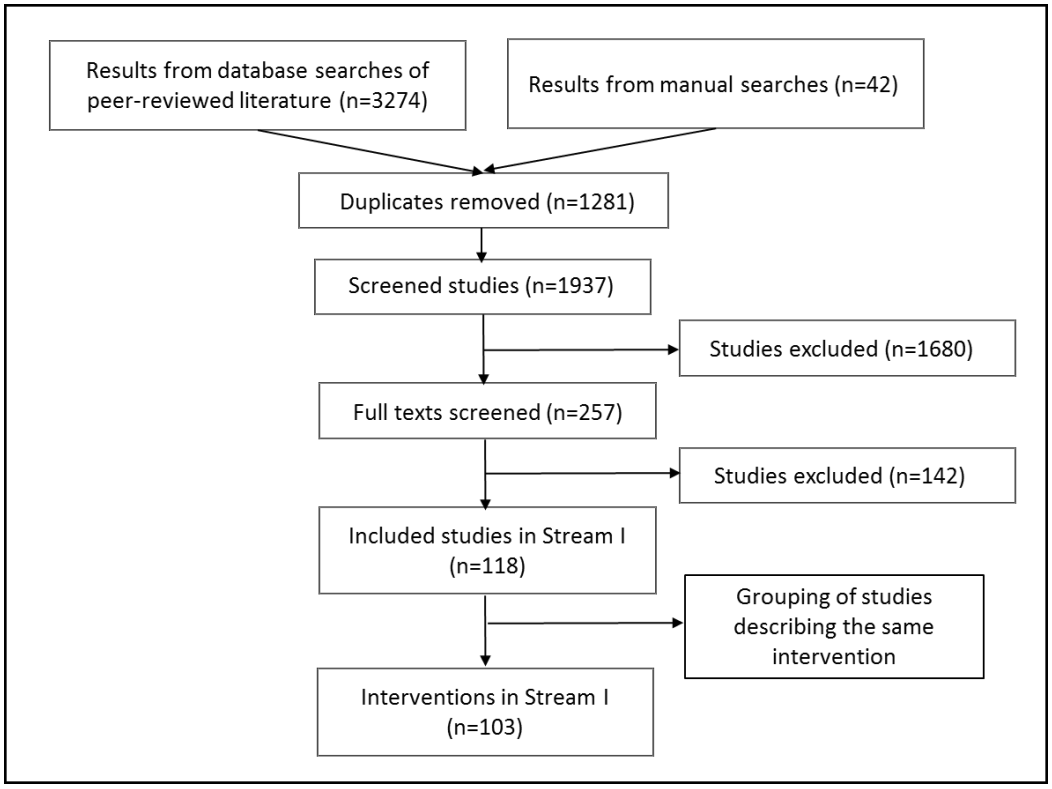

Figure 5.6 Search results for stream I - Flow diagram of screening stages and review process.

Search strategies for stream II led to a total of 45 studies. Full text of these was screened and finally 30 studies were deemed eligible for inclusion (all included studies in stream II evidence and summary information is available in Appendix 5.2). Reasons for exclusion were failure to include opinions or guidelines on how to best carry out process evaluations (or measure one or more of its components) in complex intervention research.

5.4.2 Results from stream I – Research evidence

5.4.2.1 Mapping of included studies

The majority of studies (89%) included in stream I were published between 2001 and 2014. Only 4 and 8 studies were published during the 1990s and the year 2000 respectively. Studies included in stream I were varied in terms of content, design and approach to process evaluation research. This further contributed to the variety of the sample.

In terms of rehabilitation disciplines, 33 (32%) interventions were multidisciplinary, 20 (19%) involved occupational therapy, 21 (20%) were physiotherapy and 9 (9%) psychological interventions (Figure 5.7). A total of 14 (13%) were interventions involving alternative forms of exercise or therapy (e.g. yoga, Tai chi, treadmill training).

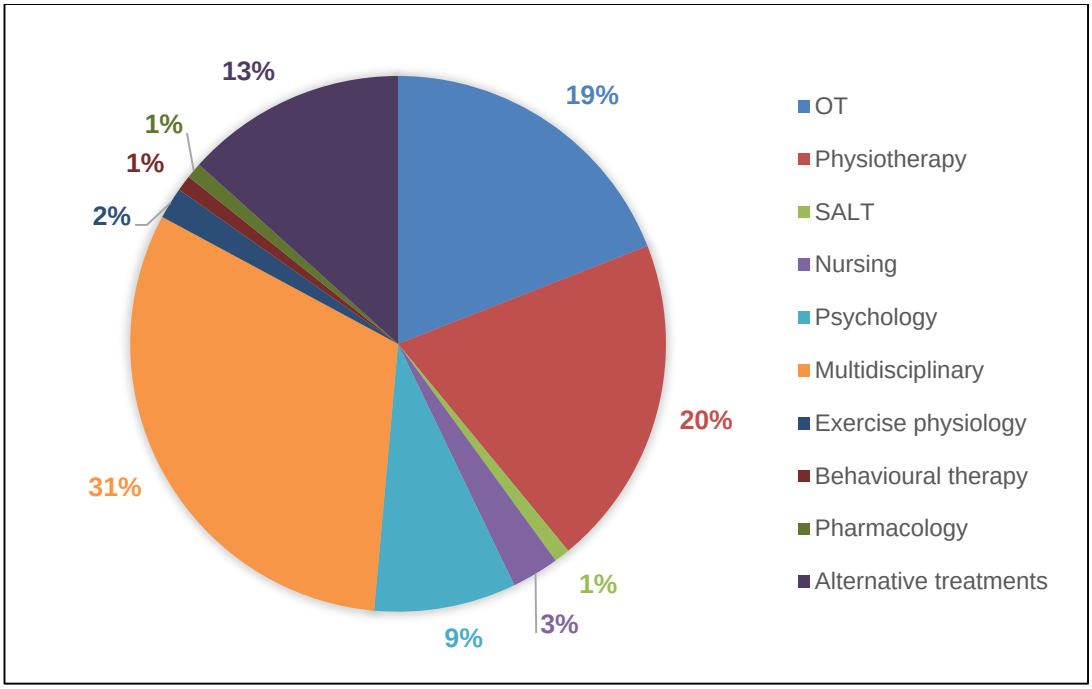

Figure 5.7 Distribution of studies according to health discipline

In terms of methodologies, a great number of interventions (50%) were investigated via RCTs, including pilot, multicentre and cluster RCTs. The remaining studies used a range of methodologies to investigate interventions, including pre-post one group design, repeated measure three group design and two group non-randomized design. Out of the 118, 9 studies were purely qualitative research studies. Amongst all 118 included studies, 47% (56 studies) reported results from a research trial (2 of those studies were reports which had not been peer reviewed), 10 (8%) were protocols and 19 (16%) reported specifically the results of a process evaluation (or fidelity research). 29 (25%) studies reported results of exploratory, pilot and feasibility research studies (Figure 5.8).

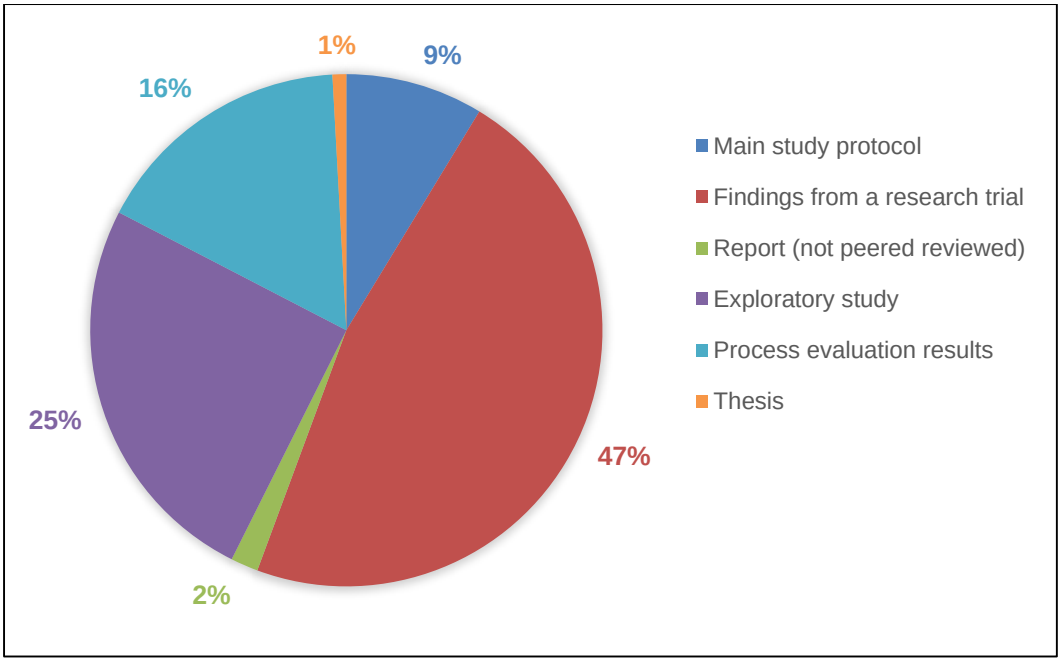

Figure 5.8 Distribution of included studies according to type of study

All 103 interventions described in the 118 studies were being investigated for their effectiveness in treating a range of neurological conditions, such as stroke (28%), Parkinson's disease (PD) (10%), multiple sclerosis (MS) (8%) and traumatic brain injury (TBI) (7%). A total of 24 interventions (23%) were targeting cognitive impairments including Alzheimer's disease and dementia (Figure 5.9).

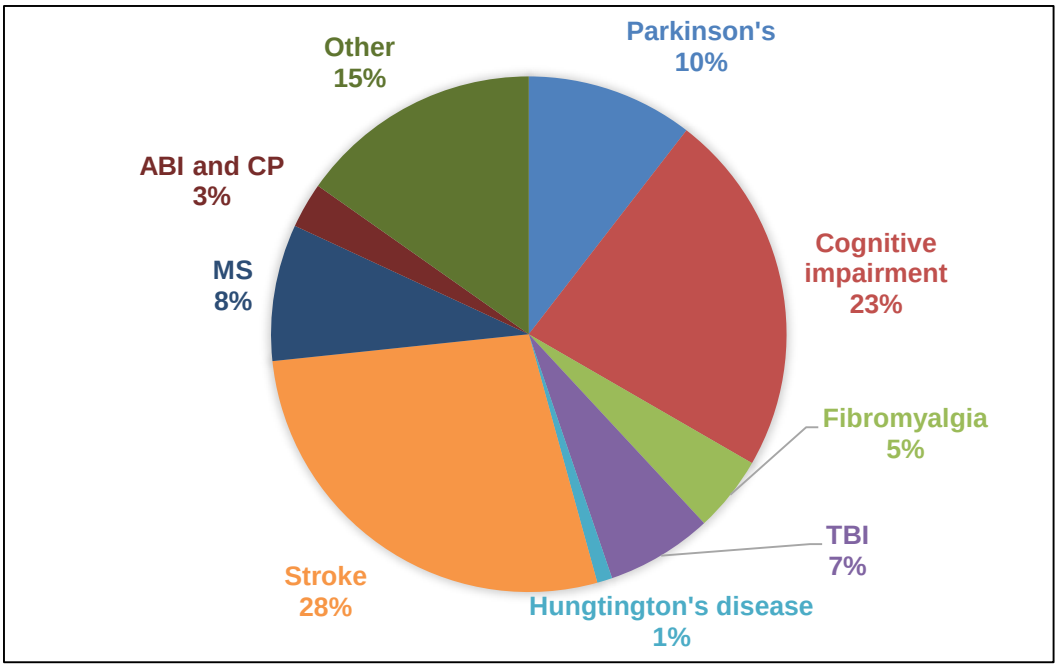

Figure 5.9 Distribution of interventions included in the review according to targeted condition

5.4.2.2 Synthesis 1

As expected and as described above, evidence included in the final 118 studies of stream I comprised a very heterogeneous data set. Following the method previously described, a number of themes, including descriptions and narrative summaries were developed. The researcher firstly identified patterns within data extraction components (Figure 5.2). Further in depth analysis was then carried out by mapping these patterns onto the review question; the researcher looked for patterns across the data in order to identify potential answers to review questions. The following themes emerged:

Theme 1 - Addressing context

The context in which the neurological rehabilitation intervention implementation and research trial took place was described for 48 (45%) of the included interventions; however, this description often lacked detail and was focussed solely on information regarding the trial's setting [e.g. 1, 9, 57, 64] without accounting for the wider physical, social, economic, organization and political environment. Only 11 studies (10%) described in detail the provision (with respect to the trialled intervention) that already existed and how contextual factors had experienced change over time. 5 studies [16, 17, 18, 93 and 108] described the strategies in place to explore how changes in contextual factors had possibly affected the implementation and/or impacts. Sturkenboom et al. (2013) [93] in a RCT looking at the impact of a home based OT intervention on adults with Parkinson's disease used interviews in order to investigate participants' personal context (e.g. openness for change and possibility of change). In the TRACS study [16, 17 and 18] which looked at the impact of a structured training program for caregivers of stroke inpatients context was fully investigated via observations, questionnaires, and interviews with intervention staff, patients and caregivers. The results from their process evaluation showed that contextual factors such as organizational history and team relationships, external policy and service development initiatives impinged on the implementation of the TRACS intervention.

Theme 2 - Barriers and facilitators to recruitment

All trials investigating the 103 included interventions described the main trial's recruitment procedures, including chosen sites, participants' inclusion/exclusion criteria and diagrams describing the flow of participants throughout the research process; only 21 of them (18%) provided a detailed description of identified barriers and facilitators to both initial recruitment and consequent retention and engagement of individuals during the running of the neurological rehabilitation trials. Scianni et al. (2012) [80] provided a detailed account of recruitment procedures and identified lack of transport as the main barrier to patient participation in a gait training study. Taylor-Piliae and Coull (2012) in their study looking at the feasibility of community-based Tai Chi for chronic stroke rehabilitation [100] described a number of retention strategies such as personal encouragement, appropriate incentives, clear communication and personalized feedback which were reported to positively impact on retention results. Other studies used regular phone calls and text messages for the same purpose [87, 110 and 112].

In relation to recruitment of participants for the process evaluation, 13 studies provided an explanation of what subsample was selected and why. Döpp et al. (2013) and Döpp et al. (2011) [21 and 22] in their Community OT in Dementia (COTiD) programme provided a brief explanation of how all intervention staff had been recruited for the process evaluation. Lavoie et al. (2005) [47] carried out the process evaluation of an RCT trial looking at the impact of a psycho-educational group for caregivers of persons with dementia. They reported on saturation as the measure used to limit the chosen subsample of participants. The authors also provide reasons why a minimum attendance rate of 60% had to be reached by trial participants in order to be recruited into the process evaluation.

Theme 3 - Describing those in charge of delivering the trialled intervention

29 studies (comprising 23 interventions) (22%) investigated what were the providers' motivations for joining the research programme or what were their perceptions regarding treatment effects and possible impacts. This was mostly achieved by carrying out in depth interviews and questionnaires (including both ranking items and open questions) and less often through focus groups

(5 studies). Scobbie et al. (2013) [81] carried out a process evaluation to evaluate the implementation of a theory-based action planning framework (G-AP) to guide goal setting practice. In their study, interviews were chosen as a data collection method in order to investigate the experiences of intervention providers and the difficulties they faced. The study by Döpp et al. (2013) [21] is a clear example of the use of a variety of methods in order to achieve this; the authors used web-based questionnaires which included a number of statements regarding barriers to implementation which the OTs had to rate in terms of how much they agreed. They carried out further focus groups and semi-structured telephone interviews.

Information about providers' previous skills and experience related to the research topic was often not provided or lacked detail and therefore it was not acknowledged as part of the process evaluation. Of those studies included in stream I, only those looking at 10 (10%) of the interventions provided details in regards to the level of experience of intervention staff. A number of studies referred to health professionals experience using expressions such as 'experienced health professionals' [51 and 95], 'multiple years of clinical experience' [58] or 'had prior experience' [75] without providing any further detail. Some studies reported on the years of experience that health professionals had [28, 32, 49, 60, 71, 100, 103, 107, 108 and 110], the grade of intervention staff [17], or level of education [58 and 101].

Theme 4 - Training and assessing intervention staff competence in delivering the intervention

Out of the 103 interventions included in stream I studies, 37 (36%) were delivered by staff who had attended training workshops regarding the neurological rehabilitation intervention, prior to the start of the trial. This training was delivered using a variety of methods such as lectures, role play [14 and 107], practical sessions, group discussions and it varied in length from 2 hours [58 and 81], 2.5 hours [60], 4 hours [92], 16 hours [107], 40 hours [89] to ½ day [57], 2 days [45], 3 days [23 and 93] and 5 days [50]. A study looking at the impact of a structured training programme for caregivers of inpatients

after stroke (TRACS study) [16, 17 and 18] relied on ‘cascade training’ as a method of transferring knowledge from one health professional to another.

King et al. (1998) [42], in their feasibility study evaluating the effects of paediatric therapy services in the school setting, and Voigt-Radloff et al. (2009, 2011) [107 and 108] in the process evaluation of the RCT looking at the impact of evidence based community on dementia patients (WHEDA study), both provided a detailed description about the training and expected learning outcomes of staff. However, amongst the studies that included a training component, only 7 defined a performance criteria and measured (mainly via observations) the skill acquisition post training to a minimum standard, that would allow the provider to be involved in the delivery of the intervention. Chung (2009) [15] and Döpp et al. (2011) [22] used quizzes and questionnaires respectively to assess intervention staff’s knowledge on the trialled dementia intervention. Researchers on the TRACS trial (Forster et al. 2013, [16, 17 and 18]) defined a list of mandatory training components for intervention providers. In Hutchison et al. (2006) [39], intervention staff, in charge of delivering hypothermia therapy to children and adolescents with TBI, underwent training, and only when they had met the pre-trial adherence criteria were they able to take part in the RCT. In Morris et al. (2009) [63], all personnel that had undergone training were required to achieve a score equal to, or greater than, 90% of items correctly executed. Failure to meet this criterion required the tester or trainer to withdraw from the project and to resubmit standardization videotapes for rating until the 90% or higher criterion was achieved.

Only 11 studies (reporting on 8 interventions) [16, 17, 18, 25, 28, 37, 39, 42, 45, 81 and 92] reported on methods in place to regularly ‘refresh’ intervention staff knowledge on the neurological rehabilitation intervention (e.g. due to staff turnover throughout the research process). In the TRACS study [16, 17 and 18], local training sessions were arranged, if necessary, to provide feedback and support. Additionally all centres involved in the trial were offered a local refresher course midway through the trial. A total of 22 studies (reporting on 17 interventions, 16%) described methods in place to maintain intervention

staff's skills over time. This was achieved mainly via individual or group supervision (set or available when necessary), led by an 'expert' in the field or an advisory group [87] and delivered via a number of ways: meetings, telephone conversations, emails or blogs amongst others.

Only 14 studies (regarding a total of 7 interventions) [7, 8, 21, 22, 23, 49, 52, 53, 54, 55, 63, 70, 93 and 94] discussed changes on how intervention staff delivered the neurological rehabilitation intervention over time. However, this was not described in detail. Morris et al. (2009) [63], in the process evaluation of an RCT looking at an extremity constraint induced therapy intervention, and Østensjø et al. (2008) [70], in a trial of a goal setting rehabilitation programme, discussed how health professionals improved their standard performance over time. On the other hand, Sturkenboom et al. (2013) [93] in the process evaluation of a multicentre trial looking at the impact of a home based OT intervention for adults with Parkinson's disease, explained that due to the high number of health professionals recruited to the trial the number of patients that each one treated was low and this could have limited their chances of increasing their expertise with time. Although these studies referred to learning over time none of them acknowledged learning curve effects at the time of evaluation.

Theme 5 - Tailoring and adherence to intervention protocols

88 studies (comprising 77 interventions) (74%) reported having protocols/manuals which provided a description of the intervention with a varied level of detail. However, 36 of included studies (30%) also discussed how the intervention remained flexible throughout the research period in order to be tailored to the needs of individual patients. Studies included in this review failed to investigate and report whether the research team had reached a consensus regarding standardization of the intervention, or if health professionals were provided with a brief rationale to help them assess which was the 'right' amount of tailoring that should take place. Mayo et al. (2013) [56] and McGinley et al. (2012) [60] both describe two different exercise programmes for patients with stroke and Parkinson's disease respectively. Both studies explain how exercise programmes were tailored to individual

needs whilst remaining within the limits established by the study protocol. Although none of the studies in stream I discuss whether intervention staff were provided with specific guidance and advice on tailoring, 72 of studies (82%) which described a protocol, reported results and described a variety of strategies in place to monitor and measure adherence to research protocols. Adherence was assessed via a number of methods: reviews by experts of audiotaped/videotaped sessions of intervention staff with participants [4, 7, 8, 49, 58, 62, 63, 89 and 110] and also life observations [7, 8, 16, 17, 18, 38, 65, 67, 74, 100 and 101]; treatment log books (16 studies comprising 13 interventions); intervention staff reflexive accounts (5 studies comprising 5 interventions), therapy evaluation forms (2 studies comprising 2 interventions); diaries (8 studies comprising 7 interventions); field notes/case notes (8 studies comprising 8 interventions); and various standardized scales and checklists for fidelity (9 studies comprising 8 interventions). Finally, 5 studies (comprising 5 interventions) had a 'group steering committee' that acted as an evaluation team.

Theme 6 - Investigating participants' opinion

81 studies (76 interventions) reported the experience, motivations and opinions of those exposed to the neurological rehabilitation intervention. Out of these, 44 gathered this information via evaluation questionnaires that included either itemized scaled questions, open ended questions, or both. 30 studies used in depth interviews and 7 studies carried out focus groups amongst other methods.

Of all the studies that investigated patient's opinions, 29 described the use of enquiry tools and methods specifically designed to investigate whether participants understood and comprehended the intervention (e.g. goals, outcome measures, rationale) or not. Leuty et al. (2013) [49] and Macht et al. (2007) [51] assessed comprehension by adding related questions to the participant opinions questionnaire. Others such as Li et al. (2007) [50] enquired about the level of comprehension during the 'exit interview'. Whiting et al. (2012) [110] assessed participants' comprehension of an Acceptance and Commitment Therapy (ACT) intervention for TBI by getting them to

complete tasks and review intervention sessions throughout the research process. Observations of intervention implementation sessions were also reported to be used as ways to assess participants' comprehension. This was the case for Taylor et al. (2004) [99] who looked at the impact of home based strength training for young people with cerebral palsy and for Resnick et al. (2011) in their RCT looking at the impact of an exercise training intervention for patients with stroke (Treadmill Study) [74].

Theme 7 - Process evaluation as a tool to identify barriers and facilitators to implementation

Studies included in stream I often provided details about how identified contextual and implementation issues had impacted on the overall result of the research trial. 20 studies (18 interventions) described and discussed barriers and facilitators (facilitators and inhibitors) to the implementation of the trialled intervention. Several studies [e.g. 40, 41, 57, 75, 81, 96 and 109] used tables or appendices to present data about barriers and facilitators. Van't Leven et al. (2012) [23] and Döpp et al. (2013) [21] used focus groups and telephone interviews with occupational therapists and managers to explore barriers and facilitators to the implementation of an OT guideline for older people with dementia and their carers. Scobbie et al. (2013) [81] carried out in depth interviews with both, health professionals and participants in order to identify views on implementation and acceptability of a framework for goal setting in community based stroke rehabilitation.

Theme 8 - Intervention dose planned vs. dose received

73 studies (reporting on 68 interventions) provided details on the planned intervention dose (measured by number, frequency, and length of contact) within a particular treatment condition. The amount of 'intervention received' by participants is also reported throughout (85 studies reporting on 82 interventions). However, there was no consensus on terminology used to describe what was measured. 26 studies used the term 'adherence', 8 'dose received', 6 'fidelity', 19 'attendance', 5 'compliance' and the terms 'level of participation' and 'exposure and participation rate' were each used in 1 study.

Finally, 18 studies reported results on intervention dose but did not assign a term to it.

Theme 9 - Use of theory to design and to understand results from process evaluation – linking trial outcomes to process evaluation findings

Only 24 studies (21 interventions) reported the use of a theoretical framework or a research framework to inform the decision making and design of the process evaluation. As a result, reasoning behind used approaches and methodologies was rarely described. The MRC guideline for reporting complex interventions (MRC 2008) was the most mentioned amongst neurological rehabilitation trials included in stream I evidence [16, 17, 18, 40, 81, 87, 93, 94, 103, 114 and 117]. Vroomen et al. (2012) [109] used the Adaptive Implementation Model whilst Whiting et al. (2012) [110] used Borrelli et al. (2005) fidelity framework. Vluggen et al. (2012) [106] applied the method of Saunders et al. (2005) which recommends a number of themes to investigate as part of a process evaluation.

41 studies (reporting on 37 interventions) presented and discussed relationships between the results of process evaluations and trials; these studies used the results from the process evaluation to make sense of what had been taking place during the implementation process and for building explanations about the impact on outcome measures. However, only 11 of these studies made use of theoretical frameworks and behavioural theories such as Normalization Process Theory (TRACS study [16, 17 and 18]) to guide the 'explanation building' process. One example of this is Letts and Dunal (1995) [48] which developed, through consensus, a logic model in order to plan the implementation, and integrate information about process and outcomes of a community rehabilitation intervention for adults with brain injury. Resnick et al. (2011) [74] used a fidelity component framework in order to demonstrate that the Exercise Training for Hemiparetic Stroke Intervention Development Study had been carried out as planned.

Finally, near half of the studies (59; 53 interventions) used process evaluation results to generate suggestions and develop recommendations to counter

balance the limitations of the research study. These recommendations were regarding aspects of the intervention that could be adapted or modified in order to increase chances of success at the time of future implementation and further neurological rehabilitation research work.

Theme 10 - Process evaluations aims and strategies

49 studies (reporting on 42 interventions) amongst those included in stream I, identified process evaluation specific aims and research questions. 47 studies reported on strategies in place at times referred to as 'feasibility' [12 and 42] or 'fidelity' outcomes [67 and 89] to answer those research questions. However, most studies provided a very broad description of these strategies, without much detail. Two studies provided details on specific tools used to investigate a process evaluation component; Alwyn et al. (2007, 2013 [2 and 3]) described the Patient Perspective on Care and Rehabilitation Process (POCR) instrument to investigate the significance of an assistive technology intervention for the relatives of people with dementia. Khalil et al. (2012, 2013) [40 and 41] used the Intrinsic Motivation Inventory (IMI) to assess how individuals with Huntington's disease perceived (e.g. enjoyment, value, usefulness) the activities included in a home based exercise intervention.

Theme 11 - Terminology

The term 'process evaluation' is yet to be widely used to describe the assessment and evaluation that takes place at the time of carrying out research on the implementation of a new or innovative intervention. Only 30 studies of those included in stream I used the term 'process evaluation'.

More specifically, amongst all studies included in this review there was a clear lack of consensus regarding terminology used to describe processes that were being evaluated and their components; this led to confusion and lack of clarity. The term 'adherence' was a clear example of this since it was often referred to as 'dose', 'attendance rate', 'compliance', 'fidelity' or 'exposure'. Neurological rehabilitation studies failed to define terms in a unique and non-interchangeable manner. The term feasibility was widely used; however, it was defined differently across studies. McGinley et al. (2012) [60] in their pilot RCT

study looking at the impact of a physical therapy intervention for patients with Parkinson's disease defined it in terms of safety, retention, adherence and compliance measures. Stephens et al. (2008) [91] in their pilot RCT investigating the potential benefits of an exercise intervention for children with fibromyalgia defined it as comprising adherence and recruitment data.

5.4.3 Results from stream II – methodological guidance/resources

5.4.3.1 Mapping of included studies

Searches produced a total of 45 studies and reports; upon screening of the full texts a total of 30 studies were included in stream II (Appendix 5.2).

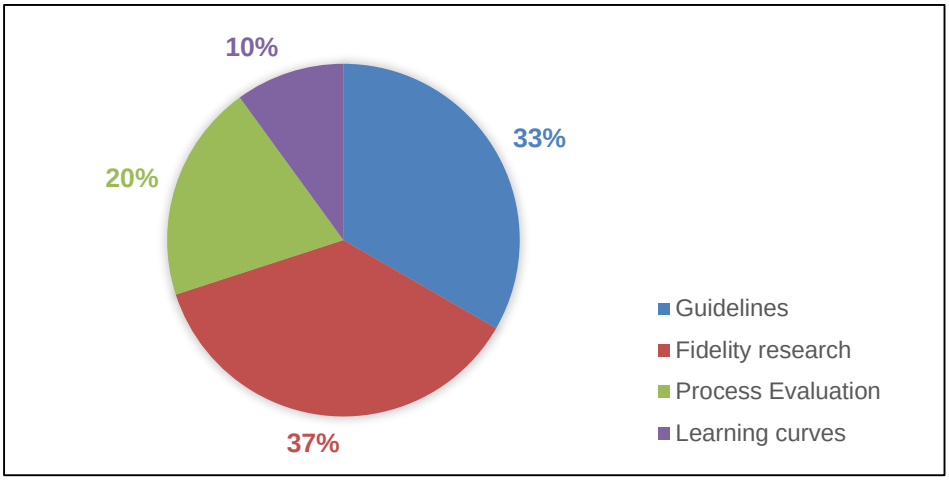

Figure 5.10 Distribution of included studies in stream II according to research area

Amongst included studies (Figure 5.10):

- 10 (33%) were guidelines and guideline related studies (G). These studies discussed relevance, applicability and usefulness of published guidance for the evaluation and reporting of complex interventions.
- 11 (37%) were published studies describing and providing useful resources in order to investigate fidelity alongside research trials (F).
- 6 (20%) were specifically related to process evaluation research and design (P).
- The final 3 (10%) provided information regarding the assessment of learning curves in health research (L).

5.4.3.2 Synthesis 2

As in evidence in stream I, evidence included in stream II was heterogeneous and mostly qualitative (Appendix 5.2). Complex interventions were widely discussed amongst studies included in stream II. The importance of defining 'active ingredients' was defined as paramount to complex intervention research (MRC guidelines 2001, 2008) since it helped researchers to identify how the intervention worked and why. Furthermore, making explicit use of theory to develop an intervention and its further evaluation was considered vital at the time of designing a research study. Craig et al. (2008) [G5] explained that developing a theoretical understanding of the likely process of change by drawing on existing theories and conceptual models is a vital initial step. Saunders et al. (2005) [P3] specified that this should be the starting point when planning a process evaluation.

MRC guidelines required evaluations to be able to describe contextual factors which include wider socioeconomic background and underlying cultural assumptions. In the revised version of the MRC framework (MRC 2008, [G2]) more emphasis was given to this issue at both the designing stage and the evaluation stage. Campbell et al. (2007) [G4] reported that context would also shape the theories regarding how interventions work. Furthermore understanding and acknowledging changes of context with time was described as extremely important. Hasson (2010) [F6] for example, also discussed that by identifying local conditions, interventions can be better adapted to the real world.

The importance of understanding recruitment factors is widely addressed in the MRC guidelines (2001, 2008) [G1 and G2] and their related studies included in stream II; barriers and facilitators to initial recruitment and retention are reported to require close analysis and understanding. Those studies which were mainly focussed on fidelity research acknowledged the importance of understanding recruitment, but did so in a superficial manner.

The synthesis of studies included in stream II revealed the importance of acknowledging and providing details about who was in charge of delivering the

trialled intervention within process evaluations. The background of intervention staff, their level of experience, motivations and further details such as description of incentives are the factors reported and identified in stream II studies.

Those studies included in stream II identified the vital importance of investigating the following processes:

- the ‘quantity’ of intervention that was delivered throughout the research process, secondly,
- the quality of the intervention implementation (via the use of intervention protocols and fidelity assessments) and
- the ‘quantity’ of intervention that was received (enacted) by participants recruited into the trial.

Training of intervention staff on how best to adhere to the protocol whilst facing the need to tailor their work to patients’ needs was often mentioned in stream II evidence. However, there was a lack of specific recommendations on how to best address this challenge.

Following the method previously described, the researcher undertook the coding of all extracted sections from the 30 included studies. Firstly a complete set of 72 codes was generated (Appendix 5.3) and following the same procedure that is shown in Figure 5.4, codes were grouped into a total of 8 descriptive themes. Secondly, by using these themes to answer the systematic review question, 8 analytical themes, in the form of *recommendations*, emerged (Figure 5.11). These recommendations were developed in order to include a number of potential strategies, measuring tools and methods to address process evaluation research.

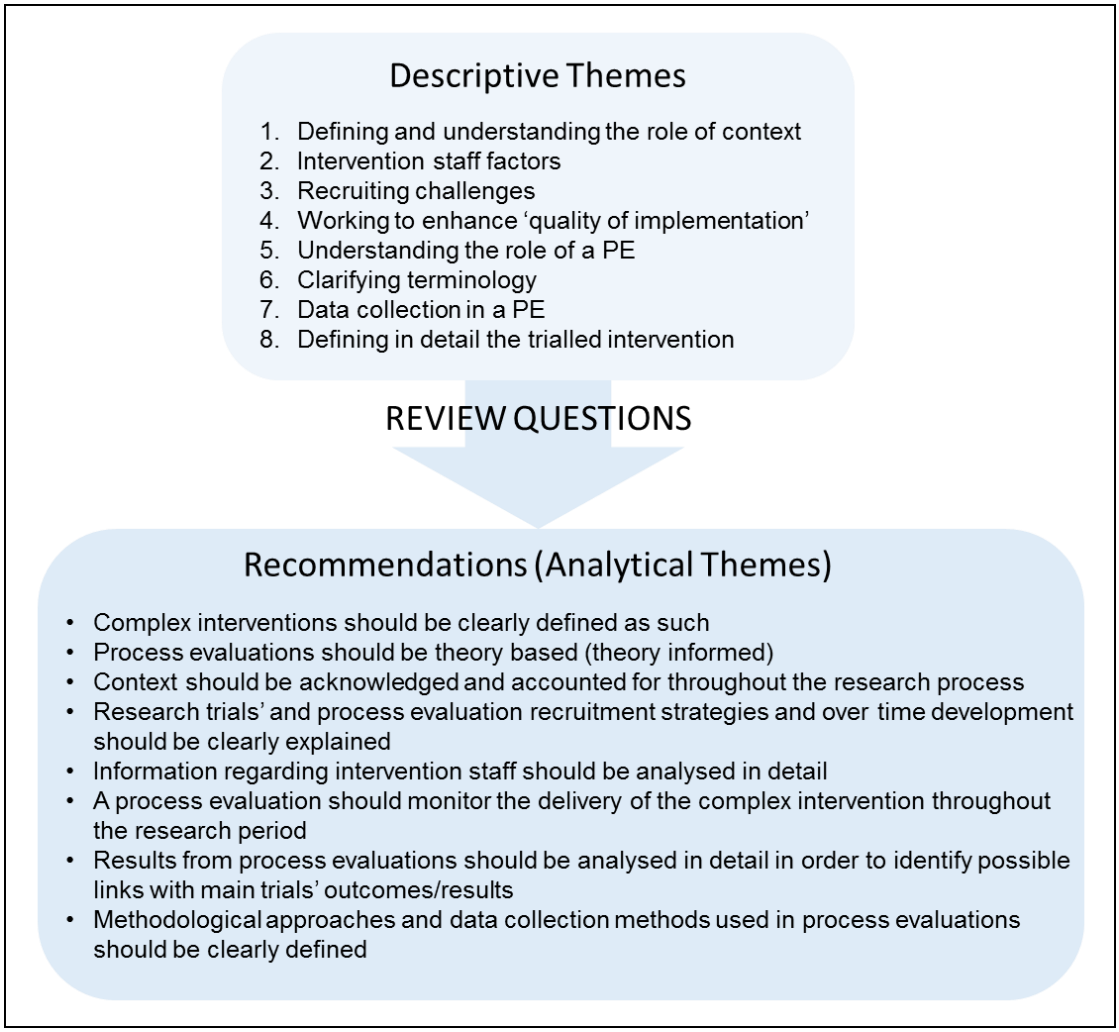

Figure 5.11 Descriptive themes and emergent analytical themes for stream II

A brief summary of the recommendations is presented below (for full details please refer to Appendix 5.4):

Recommendation 1: Complex interventions should be clearly defined as such. Complex interventions should be described in terms of their 'active ingredients'. By defining these the researchers can identify how the intervention works and how these 'active ingredients' are exerting their effect. Creating a steering group of experts (e.g. researchers, practitioners, and stakeholders) is one of the recommended strategies in order to achieve a clear understanding of the intervention and its characteristics.

Recommendation 2: Process evaluations should be theory based. The researchers must draw on existing evidence, guidance and frameworks in

order to understand and theoretically explain what processes they expect will be taking place.

Recommendation 3: Context should be acknowledged and accounted for throughout the research process. The context in which the intervention was developed, implemented and finally evaluated should be clearly defined. It would be necessary to describe and monitor changes in the social, physical, economic, political and organizational context in which the intervention is embedded. Understanding context will help the researchers identify its potential impact on implementation and outcomes.

Recommendation 4: Recruitment strategies and changes in recruitment over time, of both the main trial and the process evaluation, should be clearly explained. Researchers need to identify and assess the strategies in place to approach and recruit participants for both the research trial and the process evaluation. Barriers and facilitators to recruitment will require close investigation. Interviewing staff involved in the recruitment process, or completing logbooks and questionnaires recording reasons for withdrawal, could be a potential strategy in order to address this issue.

Recommendation 5: Information regarding intervention staff should be analysed in detail. A detailed description of their characteristics should be provided: numbers, background experience, incentives and motivations to join the research and their opinions regarding the potential need for the intervention under investigation.

Recommendation 6: The delivery of the complex intervention should be closely monitored. It is necessary for complex interventions to be described in a study protocol/manual. This protocol should be a tool that intervention providers can use in order to understand the level of tailoring that is considered appropriate. Furthermore staff delivering the intervention should be trained in order to increase the chances of standardization and to brief staff regarding the performance criteria. Process evaluations should have strategies in place to investigate if the interventions are delivered as planned in terms of dose and content.

Recommendation 7: Results from process evaluations should be analysed in detail in order to identify possible links with main trial's outcome results. Data collected and analysed during the process evaluation will be of vital importance in order to avoid Type III errors when analysing complex intervention's trials' outcomes.

Recommendation 8: Methodological approaches and data collection methods used in process evaluations should be clearly defined. Chosen terminology and clear aims and objectives should be clearly stated at the start of the process evaluation.

5.4.4 Overarching findings - Synthesis 3

The last step in this systematic review involved collating emergent themes (synthesis 1) and *recommendations* (synthesis 2) (Figure 5.5). By doing this the researcher was able to identify gaps and links between how process evaluation research in neurological rehabilitation is currently being carried out, and, to what extent it is following, or in accordance with, proposed theoretical and methodological recommendations.

Following the methods previously described, synthesis 3 resulted in 57 statements divided into the following 9 areas. Narrative themes from synthesis 1 and *recommendations* (abbreviated as 'R') from synthesis 2 were collated to generate the following statements:

AREA 1 – *Complex interventions and theoretical approaches*

The use of theory to inform and guide process evaluations is recommended. However, to date most process evaluations fail to do so. Theory should be used to get an in depth understanding of the neurological rehabilitation under investigation and to identify its components. Researchers working on neurological rehabilitation research, currently fail to draw on methodological guidance at the time of designing how they will evaluate the processes taking place.

Theme 9	**R2**	**Statements (4):** ▪ There should be a clear description of the theoretical base behind the structure and delivery of the neurological rehabilitation intervention ▪ The structure of the neurological rehabilitation intervention should be clearly described in terms of its components ▪ Process evaluations should draw on methodological guidance ▪ There should be a clear explanation of how the methodological guidance is applied to the process evaluation

AREA 2 – *Context*

Little attention is currently being given to the in depth exploration of the contextual systems in which the neurological intervention is embedded. Evaluation literature discusses context extensively with regards, not only to the need to describe it in detail, but also the need to understand how it can impact on implementation at different stages of the research process. Neurological researchers are required to strive away from the narrow definition of context as the 'setting where the research takes place'.

Theme 1	**R3**	**Statements (3):** ▪ The context prior to the neurological intervention being implemented should be clearly described through the use of both, qualitative and quantitative methods. ▪ Contextual changes over time should be reported and accounted for. ▪ Researchers should aim at clarifying possible impacts that contextual factors could have had throughout the research process.

AREA 3 – *Recruitment*

Recruitment has been identified as one of the main challenges of rehabilitation research. Understanding the barriers and facilitators that take place during the recruitment period is of vital importance for those attempting to evaluate processes taking place and their potential impact on outcomes. To date, process evaluations alongside neurological rehabilitation research have rarely

investigated recruitment with this purpose. Finally, recruitment strategies into the process evaluation should be carefully thought through.

Theme 2	**R4**	**Statements (10):** ▪ Process evaluations of neurological rehabilitation research studies should clearly describe the trial's recruitment procedures. ▪ Reasoning behind participants being recruited for the trial should be provided ▪ Barriers and facilitators to recruitment for the trial should be clearly investigated. ▪ Strategies to recruit participants to the process evaluation should be clearly described. ▪ Criteria for selecting participants for the process evaluation should be clearly identified. ▪ Barriers and facilitators to recruitment of participants into the process evaluation should be investigated. ▪ Process evaluations should investigate measures in place to attract participants and encourage them to remain involved in the trial. ▪ The involvement of participants recruited for the process evaluation should be monitored. ▪ Process evaluations of clustered trials should clearly describe the site recruitment procedure in place (e.g. minimum quality standards, funding, incentives). ▪ How withdrawal from sites was carried out should be clearly explained.

AREA 4 – *Describing intervention staff*

A number of emergent themes from synthesis 1 identify how, to date, process evaluations are not focussing enough on understanding issues such as intervention staff's motivations for joining research or their perceptions on the potential benefits of the intervention under investigation. The role of intervention staff's level of experience in shaping potential outcome results is equally neglected. Researchers designing process evaluations alongside neurological rehabilitation research should attempt to record and investigate these.

Theme 3 **Theme 4** **Theme 6**	**R5**	**Statements (4):** ▪ A detail description of who (and how many) delivered the neurological rehabilitation intervention should be given. ▪ Intervention staff previous relevant experience and skills should be recorded. ▪ Motives for the participation of intervention staff in the study should be explored. ▪ Intervention staff perceptions regarding the research study and possible impacts of the intervention should be investigated.

AREA 5 – *Describing the intervention*

To date, process evaluations often fail to investigate and report whether the research team had reached a consensus regarding standardization of the intervention, or if the health professionals were provided with a rationale to help them assess which was the right level of tailoring that should take place. Study protocols should be detailed enough and guide intervention staff through the research process.

Theme 5	**R1** **R6**	**Statements (5):** ▪ The study intervention should be detailed in a protocol/manual. ▪ All structures and processes involved in the intervention should be fully described. ▪ The protocol should state how much tailoring and flexibility of the intervention is allowed. ▪ A guide for tailoring should be provided to all professionals implementing the intervention. ▪ The degree of tailoring should be investigated within the evaluation.

AREA 6 – *Preparing and assessing intervention staff*

Process evaluations should attempt to have a clear understanding about how intervention staff were trained in order to start their research role. Although training is often provided it is important that it includes well defined performance criteria to guarantee the correct delivery of the intervention. At present this is rarely the case. Furthermore, staff's competence should be

assessed at different time points in order to identify any potential changes that could ultimately impact on outcomes.

Theme 3 **Theme 4** **Theme 6**	**R5** **R6**	**Statements (7):** ▪ The training provided to intervention staff involved in the research should be clearly described ▪ Training provided should have a defined set of goals to achieve. ▪ There should be well-defined performance criteria associated with the intervention. ▪ Skill acquisition/competence of intervention staff should be measured post training as the basis for participating in the study. ▪ Competence of intervention staff should be monitored over time in order to identify learning curve effects. ▪ Methods should be in place in order to maintain skills over time ▪ Any additional implementation strategies to improve/support the fidelity of the intervention should be evaluated

AREA 7 – *Delivering the trial intervention*

To date, process evaluations of neurological research trials often provide information which will help identify barriers and facilitators to the implementation process. However, there is a need for PEs to 'go deeper' in order to generate a complete understanding of the quality of intervention delivery. This can be achieved by defining clear strategies to monitor not only the quality but also to measure how much of the intervention was delivered (dose delivered) and how much was 'received' by participants.

Theme 4 **Theme 5** **Theme 7** **Theme 8**	**R6**	**Statements (10):** ▪ Process evaluations should investigate barriers and enablers to the implementation of the intervention. ▪ Process evaluations should clearly define quantitative indicators that reflect acceptable adherence to the intervention dosage across constituent components. ▪ Process evaluations should clearly define what strategies were in place in order to measure 'dose delivered'. ▪ There should be well defined strategies in place to be able to measure 'dose received'. ▪ Process evaluations should clearly define quantitative and qualitative indicators that reflect acceptable quality in the delivery of the study intervention.

		▪ Process evaluations should clearly explain the strategies in place in order to assess quality of intervention implementation. ▪ Process evaluations should assess the quality of the strategies in place to monitor adherence to protocol ▪ Participants' understanding of the intervention should be assessed. ▪ There should be strategies in place to monitor participants' utilisation of the intervention provided. ▪ The process evaluation should collect data regarding participants' experiences of the intervention, and the level of acceptability that was achieved.

AREA 8 – *Understanding and interpreting process evaluation results*

One clear theme that emerged from synthesis 1 was that at present results from process evaluations are often not used to make sense of what has been taking place during the research process. PE results are required to build explanations about the impacts of the trialled intervention on outcome measures.

Theme 7 **Theme 9**	**R7**	**Statements (4):** ▪ There should be a detailed description of the synthesis of process evaluation findings with trial results. ▪ Theoretical frameworks should be used in order to build explanations that link process and outcome evaluations. ▪ Process evaluations should provide evidence surrounding the chances of Type III errors (implementation failure) at the time of analysing trial's results. ▪ Plans to develop a theory as part of the process evaluation research results should be clearly described

AREA 9 – *Thinking about methodology*

A process evaluation should be a piece of research in its own right and therefore should be described in a protocol. It should have a clear purpose and clear aims and objectives. To date process evaluations alongside neurological rehabilitation research rarely provide detailed information regarding design and chosen strategies. Ultimately process evaluations

should aim at answering a research question by making use of a variety of methods in order to gather sufficient data.

Theme 10 **Theme 11**	**R8**	**Statements (10):** ▪ The design of the process evaluation should be reported in detail. ▪ Ethics and other approvals for process evaluations data collection should be included in the trial approval process. ▪ A process evaluation should use a clear set of measures and evaluation criteria that will need to be described and reasoning behind them provided. ▪ Methods used to investigate the different components of the process evaluation should be reported. ▪ Reasoning behind timing for data collection should be clearly stated. ▪ Process evaluation data should be collected from all intervention and control sites. ▪ Process evaluations should use a variety of methods and strategies to gather data, including both qualitative and quantitative approaches. ▪ Details regarding the triangulation of the data within the process evaluation should be clearly reported. ▪ Process evaluation protocols should be clearly described and made available. ▪ Process evaluation results should be published alongside trial results.

5.5 Discussion

This mixed-evidence systematic review has resulted in the identification of a number of gaps in the evidence informing the undertaking of process evaluations in neurological rehabilitation research. The findings reported in this chapter therefore have the potential to significantly impact on the way that process evaluation research alongside trials of neurological rehabilitation interventions is designed and conducted in the future.

Like other authors (Hulsher et al. 2003, Carroll et al. 2007, Hasson 2010) this research has found an overlap between the concepts of process evaluation and implementation fidelity, which at times, appear to be used interchangeably. However, the basic goals behind each of these concepts and

their interacting factors are the same: to evaluate the quality of the intervention's implementation, how well it was delivered and what factors influenced its implementation according to an intended protocol. Results reported here show that this overlap can lead to confusion and a lack of clarity at the time of understanding how processes were evaluated. In line with work published by Grant et al. (2013) the lack of consensus regarding terminology meant that extracting and synthesising the findings from selected studies became a major challenge. Furthermore, the lack of clear, consistent definitions for each of the process evaluation components under investigation in included studies is one of the gaps this review has identified. It is clear from these results that at present there is no consensus amongst researchers carrying out and reporting results from process evaluations, regarding which terminology (and definitions) to use. These findings are in line with previous work by Steckler and Linnan (2002) or Carroll et al. (2007). They identified a considerable overlap in how terms like fidelity or dose are defined. Amongst the studies included in this review (both stream I and stream II), a clear overlap of terms like 'adherence', 'dose', 'attendance rate', 'compliance', 'fidelity' or 'exposure', was identified. Taking adherence as an example; although it is simply defined as 'the act of doing what is required' (Wikipedia), from a health research perspective, several authors (Dane and Schneider 1998, Dusenbury et al. 2003) have explained adherence as the component of 'implementation fidelity' that measures to what extent the intervention that has been delivered is consistent with the way the intervention was originally designed or planned. Carroll et al. (2007, p.3) reports that "*the measurement of implementation fidelity is the measurement of adherence"* which includes the subcategories of content, frequency, duration and dose. However, Steckler and Linnan (2002) propose this same definition for 'fidelity' which they consider a process evaluation component in its own right, in the same way as 'dose'. The findings here reported therefore reinforce what others have suggested (Steckler and Linnan 2002); that a clearly defined 'set of terms' for process evaluation still needs to be developed, universally recognized and applied in order to allow the number of neurological rehabilitation research studies which include a process evaluation alongside them, to increase.

Our findings show that context is often acknowledged, with almost half of the studies included in stream I providing details on the social and physical environment in which the trialled intervention took place. Two previous systematic reviews looking at process evaluations in occupational stress management programs (Murta et al. 2007) and church-based health interventions (Yeary et al. 2012) found that only 9% and 34% of the studies respectively included information concerning context. However, context was rarely defined. Neither of these studies assessed the level of detail in which context had been described as part of the process evaluation or which strategies had been used, if any, to assess the impacts that contextual changes over time might have had on outcomes. These findings show that the way context is currently being assessed as a process evaluation component is not detailed enough, and that the impact of wider contextual changes over time are rarely investigated or even acknowledged in neurological rehabilitation research. This is contrary to the general recognition that context is important in the implementation of interventions and needs to be paid attention to (Bate 2014, Dixon-Woods 2014). Process evaluation should not only aim at identifying and describing contextual factors but also investigate their association with variation in mediating responses to intervention components, and ultimately outcomes (Oakley et al. 2006). Campbell (2007) argues that the investigation of context is 'all important' and should include all wider socioeconomic background. He further reports that contextual changes over time can influence how an intervention may succeed or fail to show a significant impact. In other words, describing the context in which an intervention takes place is important, but understanding it is 'crucial', not only to inform intervention design but also to assess if successful ones might, or might not, work when implemented in different settings and conditions.

A further important point identified in this systematic review is the lack of detailed information describing those delivering the trialled intervention in terms of both their previous experience and background and their opinions and perceptions of treatment effects and possible impacts of the intervention. Firstly, although near a quarter of studies included in stream I investigated

providers' perceptions towards the quality of the intervention, its perceived effects and possible impacts, this number is relatively low and therefore we suggest more effort needs to be put into this aspect of process evaluations. This is in line with what other authors have suggested regarding staff's perceptions playing a role in influencing outcomes (Elford et al. 2002, Oakley et al. 2006 and O'Cathain et al. 2014). Secondly, these results have identified that there is a strong need for process evaluations to both, clearly describe intervention staff skills and experience prior to joining the research and investigate how they might influence outcomes. It is obvious that careful recruitment of practitioners with the right level of experience is paramount to the success of implementation (Dumas et al. 2001). However, there is currently a lack of evidence to help researchers decide which should be the essential requirements and optimum experience level of staff in charge of implementing a new neurological rehabilitation intervention. As widely agreed, qualitative research embedded in a process evaluation is needed to understand the role that previous experience plays in shaping the impacts of the trialled intervention (Donovan et al. 2002, O'Cathain et al. 2013).

Training of intervention staff has often been mentioned as a necessary component in order to increase implementation fidelity (Dumas et al. 2001, Santacroce et al. 2004, and Horner et al. 2006). The results from this review show that training of staff often takes place. However, amongst studies included in this review, there is rarely mention of performance criteria or assessments to measure skill acquisition post training and throughout the research program. This limitation further highlights the lack of on-going monitoring of how staff are delivering the intervention. In other words, our results show that process evaluations in this field of research are currently not addressing the role that learning curve effects might play in influencing intervention outcomes. Although a number of studies have looked at learning curve effects in randomized controlled trials (Ramsay et al. 2002, and Cook et al. 2004), the bulk of these are primarily focussed on surgical trials (clinical health technologies) and the implementation of new surgical procedures. Learning curve effects can be defined "*as an improvement in performance over time*" (Cook et al. 2004, p.421) which indicates that changes over time

generally lead to higher quality implementation of the tested intervention (Ramsay et al. 2002). A number of hierarchical factors have been reported as influencing learning (Cook et al. 2004). Cook et al. (2004) reported that 'professional teams', the characteristics of the patients undergoing the procedure and the characteristics of the surgeons carrying out the intervention (e.g. attitudes, abilities and previous experience), will further impact on the learning. Further consideration should be given to how learning effects should be studied within the context of a longer term, complex intervention. The results of the OTCH process evaluation (Chapter 4) described how OTs reported becoming better at implementing the OTCH intervention as time went by. They learned how to overcome challenges linked to, amongst others, resource limitations, institutional context and patient and care home staff engagement. These results provide evidence about how learning over time can impact on the quality of the implementation of neurological rehabilitation intervention(s). Process evaluations need to assist researchers in identifying the mechanisms underlying this possible impact. Ignoring the learning effect could potentially lead to non-conclusive results since often the trialled intervention will only have identifiable significant impacts once adequate experience is gained (Ramsay et al. 2000). Learning curve effects also have implications for the length of the intervention period within the trial timetable, and associated costs.

Several authors (Castro et al. 2004, Morrison 2009) have argued that interventions that have been designed and tested with participants who are all the same in terms of race, ethnicity, economic background or religion will have very limited generalizability. There is more to delivering the intervention than just measuring how many elements were delivered (Harshbarger et al. 2006, Hawe et al. 2008). There is a current need to tailor interventions to patients' limitations and cultural background in order to be able to replicate interventions across settings (Song et al. 2010). However, this can lead to tension between tailoring and the need to have fidelity to the original intervention. Song et al. (2010) further explain that tailoring does not mean that the provider may improvise what he/she does, it means that what is standardized will be contrasted and clearly defined and monitored against what is customized

(including delivery of unplanned components of the intervention). The way in which this can be accurately done remains unclear to date. Our results show that tailoring guides for staff delivering the intervention are very rare. Song et al. (2010) argue that the assessment of fidelity will have to be standardized and tailored to the actual level of standardization and tailoring of the trialled intervention. In line with these suggestions, the results from this review have identified a strong need for process evaluations to have strategies in place to investigate and monitor in detail the level of *tailoring according to patients' needs* that is taking place when providers deliver the trialled intervention. It is only by doing so that researchers can avoid the tailoring process having a negative impact on fidelity of implementation.

Contrary to what process evaluation and complex interventions research guidelines strongly recommend, the results here reported have identified that links between process evaluation and outcome evaluation results are often not being clearly addressed. This finding is supported by previous research (Murta et al. 2007, Yeary et al. 2012 and Grant et al. 2013). In 2006, researchers involved in the RIPPLE study (randomised intervention of pupil peer led sex education) reported on a series of statistical analysis they had used to integrate process and outcome data. Their proposed method maximized the ability to interpret results according to empirical evidence. However, a widely accepted and standardized way to achieve this is yet to be proposed.

5.6 Conclusion

Steckler and Linnan's (2002) framework for process evaluation research has proven to be a useful tool for guiding this systematic review looking at the current state of process evaluation in neurological rehabilitation research. This review identified the following key findings:

(1) There remains no consensus regarding process evaluation terminology, and this provides an excellent opportunity to engage the rehabilitation research community in creating one that reflects the nuances of research in this field;

(2) There is a need for process evaluations to address the nature of context, and the role that contextual factors (and their changes over time) can play in influencing outcomes;

(3) There is a strong need for process evaluations to both, clearly describe intervention staff skills and experience prior to joining the research, and investigate how these may influence outcomes;

(4) Process evaluations to date do not monitor learning over time and investigate how learning curve effects may impact on outcomes;

(5) There is a strong need for process evaluations to have strategies in place to investigate and monitor in detail the level of *tailoring according to patients' needs* that is taking place when providers deliver the trialled intervention;

(6) Further research is needed to develop clear and standardized methods for linking outcome and process evaluation results.

This systematic review has provided a valuable insight into the design and quality of process evaluation research in neurological rehabilitation. Further research is needed to promote the use of process evaluation alongside health research trials and more emphasis on providing specific training in process evaluation research is strongly recommended. The findings presented in this chapter have informed the consensus work, presented in the following chapter, aimed at developing a best practice guidance for carrying out process evaluations in rehabilitation research.

CHAPTER 6:

Consensus work – the generation of a best practice guidance for carrying out process evaluations in rehabilitation research

6.1 Introduction

This chapter will describe in detail the process which was followed in order to generate best practice guidance for carrying out process evaluations in rehabilitation research. The aim of this guidance is to provide rehabilitation researchers, policy makers and research funders with a tool that will assist them at the time of designing, carrying out and appraising process evaluations.

This chapter starts by providing background information regarding the current need for tools that will assist rehabilitation researchers when undertaking a process evaluation. The chapter will then discuss and describe in detail the formal consensus method chosen to carry out the proposed work and will report its results. Finally, the proposed guidance is presented and described in terms of its contents and applicability.

6.2 Background information

Rehabilitation practitioners, like other healthcare professionals are increasingly promoting and embracing a philosophy of EBP (Ritchie 1999, Gibson and Martin 2003) (for more information please refer to Chapter 1). This philosophy which emerged in the 1990s embraces the fact that choices for patient care must be based on the best available and most up to date evidence (Rycroft-Malone 2001). Although not free of limitations, EBP, including rehabilitation practice, is considered the best available model to follow primarily because it is based on the least biased evidence (Herbert et al. 2001). As expressed by Rosenberg and Donald (1995, p.1122) an evidence-

based professional will focus on "*finding, appraising and using contemporaneous research findings as the basis for clinical decisions".*

On the basis of this it is then vital to discuss what forms of knowledge constitute valid evidence (Gibson and Martin 2003) and what should be the nature of the evidence. Upshur (2001, p.7) defines evidence as "an *observation, fact, or organised body of information offered to support or justify inferences or beliefs in the demonstration of some propositions or matter at issue"*.

For example, several authors (Bennett and Bennett 2000, Herbert et al. 2001) have emphasized the importance of using a broader definition of evidence when discussing physiotherapy practice. They argue that evidence in physiotherapy should include not only knowledge acquired via research but also knowledge from clinical practice experience (expertise) and patients' perceptions and preferences. In these same lines, Sackett et al. (1996) state that EBP should not replace clinical experience and judgment, it should build on it.

It is becoming increasingly difficult for health professional to keep up to date with new research. This is mainly due to the fact that in the last decade there has been an enormous increase in the volume of published research studies (Hush and Alison 2011), with millions of health research articles published each year (Bennett and Bennett 2000). Practical barriers such as lack of time and problems accessing publications and databases have been identified by authors in rehabilitation disciplines such as physiotherapy (Maher et al. 2004, Heiwe et al. 2011) or occupational therapy (Law and Baum 1998). Practical resources have been developed to tackle this problem and assist rehabilitation professionals translate the published evidence into their own daily patient management (Hush and Alison 2011). Clinical practice guidelines are one of these resources which according to several authors play a central role in helping health care practitioners in their decision making about services and patients. They provide recommendations that are based on scientific evidence and experts opinions and that explain which is the most appropriate care (Oxman et al. 1994). The use of these guidelines is becoming a normal

occurrence across all health care settings (Oxman et al. 1994). These clinical guidelines are considered to facilitate standardisation of practice but at the same time providing room for manoeuvre due to contextual and other factors (Moore et al. 2014b). Ultimately, a guideline should aim at integrating both expert opinions and evidence in the research literature, thus reducing bias as much as possible. However, this aim can prove challenging (Rycroft-Malone 2001).

6.2.1 Evidence in process evaluation research

Although in recent years there has been a strong increase in published research on theories and frameworks driving and guiding process evaluations for complex interventions, there is limited guidance to help researchers design process evaluations (Grant et al. 2013). As a result, carrying out a process evaluation alongside a complex rehabilitation research trial can be seen as a daunting task, leading researchers to discard the idea of embarking on one.

To date, only one guidance has been published in this matter, the MRC guidance for carrying out process evaluations in health research (Moore et al. 2014a). This guidance aims at providing guidance on how to carry out process evaluations of public health interventions, and is considered by its authors as relevant to complex interventions. It was produced on behalf of the MRC Population Health Sciences Research Network by a group of 11 health researchers based at 8 universities (consultation with a bigger group of stakeholders). The guidance summarizes why there is a need for process evaluations alongside current health research and it then proposes a framework which is highly informed by the MRC guidance on complex interventions (MRC 2008). It discusses process evaluation theory and then presents a practical section on how to carry out a process evaluation. The guidance discusses issues of implementation, mechanisms of impact and influences and role of context. It further discusses how the function and focus of a process evaluation will vary according to the stage at which is conducted and the particular type of complex intervention (Moore et al. 2015). Each process evaluation will be different, but, the MRC guidance was created in order to facilitate its planning and conducting (Grant et al. 2013, Moore et al.

2015). In line with this, this chapter presents the development of a guidance that is tailored to the individual challenges that define complex rehabilitation intervention research and its process evaluation. According to several authors (Graham et al. 2005, Harrison et al. 2010) the tailoring of guidance to particular contexts is of vital importance and can strongly influence the guidance uptake by the target end user.

6.2.2 Consensus work and Nominal Group Technique (NGT) – guidance development

As a result of the current shift towards EBP in healthcare research, the production of guidelines has moved away from discussions amongst small groups of experts which can result in a high degree of bias. Current guidelines are now the result of the integration of experts' opinions and research evidence mostly in the form of systematic reviews in the target area of research (Woolf 1992, Trickey et al. 1998). Although difficult to prove (Trickey et al. 1998) due to the lack of published evaluations on this matter, experts consider that linking guideline recommendations with research evidence maximizes the 'validity' of the guideline. This has been described as one of the vital attributes for a good guideline (Grimshaw et al. 1995). It allows for the recommendations to be graded in terms of the quality of the supporting evidence although defined generally from a particular world view (Mulrow and Oxman 1996).

As Trickey et al. (1998) explain, producing a guideline in this way is not 'without problems', since sometimes there will not be enough evidence available, and even when there is, it can lack in quality or be biased. Also, this way of producing guidelines can be costly and time consuming. Consequently, guideline recommendations are often a mix of evidence based and consensus-based. The National Institute for Health and Care Excellence (NICE) guidelines are an example of documents produced based on the best available research evidence and expert consensus. Furthermore, as stated by NICE (2012) these guidelines should not override professional judgement and the responsibility of healthcare professionals to tailor their decisions to individual patients' needs (NICE 2012).

Gallagher et al. (1993, p.76) describe the nominal group technique (NGT) as "*a structured procedure for gathering information from groups of people who have insight into a particular area of interest*". This group process technique aims at avoiding the challenges often associated with interacting groups such as the dominant personalities taking over. Its aim is to generate ideas, in a highly controlled process, which are then ranked (Gallagher et al. 1993). It must provide an environment where all voices are effectively voiced (Delbecq et al. 1975).

A wide range of potential applications of NGT have been reported, such as in exploratory research, in programme planning, in audit procedures, clinical guideline development (Rycroft-Malone 2001, Potter et al. 2004) and rehabilitation research (Potter et al. 2003, Hutchings et al. 2014). Other group processes such as focus groups and brainstorming (Stewart and Shamdasani 1990) or Delphi groups (Delbecq et al. 1975) which aim also at encouraging creative expression have been described. NGT has been described as having a number of advantages over these because it allows participants to meet face to face and also because of its controlled structure which facilitates the contribution of all those involved, decreasing the chances of the 'eloquent' individuals taking over (Murphy et al. 1998, Trickey et al. 1998, Potter et al. 2004). The NGT is also considered a technique that minimises the chances for researcher bias, since participants are directly involved with the data collection and analysis (Potter et al. 2004). Furthermore, NGT is an interdisciplinary collaborative approach and this can work at enhancing the credibility of a guideline produced using this method. In other words, when end users of a guideline (in this case rehabilitation researchers) have been involved in its creation, this can have a positive influence on the future uptake of the guideline (Grimshaw and Russell 1993, Rycroft-Malone 2001, Francke et al. 2008).

Potter et al. (2004) reported on the degree to which NGT had been applied to health research and physiotherapy in particular from 1966 to 2004. They identified a total of 200 research articles (9 of them regarding physiotherapy research). 45 of them used NGT for the development of policies and guidelines

(27 in general medicine, 5 in nursing and 13 in 'other'). Potter et al. (2004) concluded that NGT has a lot to offer to rehabilitation research, physiotherapy in particular, given that it is not only cost effective but also time efficient and has proven broadly used and widely applied in health research. They argue that NGT can provide an effective means to address the development of guidelines and also identify practice needs and challenges.

On the basis of what has been discussed the chapter continues by providing a detailed description of the chosen methods, including the NGT amongst others, which were used in order to generate the proposed guidance for carrying out process evaluations linked to rehabilitation research trials.

6.3 Design & methods

This consensus work focuses on the challenges of conducting process evaluations alongside clinical trials within rehabilitation. The ambition of this work is to produce best practice guidance for process evaluations within this context. This consensus work will explore the issues which shape rehabilitation researchers decisions around process evaluations. The evidence available for this guidance came from one source: the systematic review on the current state of process evaluation research in neurological rehabilitation research which is described in detail in Chapter 5. This systematic review identified a number of provisional recommendations (statements) for carrying out process evaluations in neurological rehabilitation research (please refer to findings section in Chapter 5).

6.3.1 Formal consensus – study design

A formal consensus development process was undertaken by the researcher based on a modified NGT and informed by previous work carried out by Rycroft-Malone (2001). A formal consensus process was chosen over an informal one since it has been argued that guidelines produced as a result of informal consensus often formulate recommendations without drawing from research evidence (Grimshaw and Hutchinson 1995). Also, according to

Rycroft-Malone (2001) an informal process often follows random criteria and therefore resulting guidelines are not robust and can be highly subjective.

As previously described, formal consensus provides the researcher with a structured process to follow, in order to lead group decision-making via a series of methods (e.g. rating). Furthermore, it is considered a logical and objective pathway to find out the degree of agreement or disagreement amongst participants in regards to a number of predefined statements or topics (Trickey et al. 1998).

A NGT was chosen over other consensus techniques such as *Delphi groups* or *focus groups*. For example, Delphi groups, as argued by Gallagher et al. (1993), can fail to identify personal problems, allow self-disclosure and promote group cohesiveness. Likewise, focus groups do not guarantee the avoidance of 'quick decision making', do not always allow the measurement of important ideas and can generate a high number of comments leading to data which is difficult to manage. NGT was considered to address the limitations of other techniques. It was first developed by Delbecq et al. in the 1970s (Delbecq and van de Ven 1971), and is one of the most commonly used formal consensus methods in healthcare settings (Hutchings et al. 2014). A number of strengths of this method have been identified. First, it allows for participants to discuss recommendations face to face, and, due to its highly structured nature, it can maximize the chances for all participants to contribute in an equal way. Secondly, it is a technique that has been successfully used in the fields of health and rehabilitation research. As Potter et al. (2014, p.126) point out, the NGT "*offers both depths and richness to physiotherapy research"*. By adopting a mixed methods consensus design during consultation the researcher can obtain more in depth information to support the decision making process (Hutchings et al. 2014). Finally, this design can assist in exploring the issues that shaped the consensus process.

The modified formal consensus work was carried out based on a modified NGT which comprised two different phases:

- Phase I: nominal group meeting with expert panel of participants to rate and discuss the proposed recommendations
- Phase II: in depth semi-structured telephone interviews with expert panel participants in order to further discuss the structure and contents of the revised guidance.

6.3.1.1 Expert panel

In order to select participants for this consensus work the researcher carried out purposive sampling. The purposive sample aimed to reflect specialist knowledge and experience in rehabilitation research. Participants were asked to take part due to their status as 'experts in this area'. A group of rehabilitation researchers working in the North West of England/North Wales was selected. Invited participants worked in different universities and covered a range of demographic characteristics and career progressions. Participants qualified for selection based on their expertise on the matter under discussion (Jones and Hunter 1995) but also because they had the seniority in their field to implement the findings. In other words, the findings will directly affect them. Participants reflected the range of people to whom the guidance will apply.

The expert panel was expected to comprise 5-9 participants. Limited research in this area has shown that this range is appropriate, with less than 5 decreasing reliability and more than 9 causing coordination problems (Bloor et al. 2001). However, some researchers have successfully used larger groups (Lloyd-Jones et al. 1999).

In order to recruit participants, the researcher searched relevant websites (e.g. universities rehabilitation departments) and identified experts in the area through reading their publications. Since the researcher had worked in these areas for all previous stages of the PhD she was aware of who 'the experts' were. Once a number of names had been identified the researcher personally emailed potential participants in order to enquire if they wished to be involved. An information sheet and consent form explaining the consensus work was included in the email (Appendix 6.1 and 6.2).

6.3.1.2 Statements under consideration

A total of 57 initial statements around process evaluation research in rehabilitation were developed by the researcher (please refer to Chapter 5 for a detailed account of this process). These 57 statements were grouped in 9 areas of interest (Table 6.1). As mentioned before, these statements were developed from the results from the systematic review described in Chapter 5 which involved a synthesis of both, published process evaluations of neurological rehabilitation interventions and published guidance and methodology on process evaluation (Figure 5.5).

Table 6.1 Number of statements per area of interest

Area of interest	N of statements
Complex interventions and theoretical approaches	4
Context	3
Recruitment	10
Description of intervention staff	4
Description of intervention	5
Preparing and assessing intervention staff	7
Delivery of the trial intervention	10
Understanding and interpreting process evaluation results	4
Methodology	10

6.3.2 Phase I - Nominal group meeting

The nominal group meeting was organized following the standards reported by Rycroft-Malone (2001). In this meeting participants had the chance to discuss face to face, critique and rate each of the proposed statements (Appendix 6.3). Also they could voice their opinions on the relevance of each of the suggested recommendations.

A suitable and convenient place for the meeting was chosen in order to increase the chances of participant's availability. The researcher was the

nominal group meeting facilitator. She can be considered an expert on the topic under discussion due to her time carrying out research for this thesis. As recommended by Delbecq and van de Ven in 1971, prior to the meeting the researcher dedicated time to practice and familiarize herself with the method and the issues under discussion.

Prior to the nominal group meeting all participants received via email a document including all statements which would be discussed in the meeting (Appendix 6.3) and another document including a summary of the results from the systematic review (Chapter 5). Trickey et al. (1998) argue that making this evidence available increases the chances of reducing bias as participants' opinions are then influenced not only by their own personal experiences but also by the evidence provided. The researcher considered that by emailing this information in advance it would help participants realize that this was a research exercise and not merely an opinion based exercise (Rycroft-Malone 2001).

Data collected during the meeting was recorded using flip charts and the complete meeting was audio recorded to assure that all information was captured. The meeting was held in July 2015 and it was anticipated to last 3-4 hours with a lunch break. During the meeting the facilitator carried out the following:

- Brief introduction: including a summary of research evidence and purpose of the consensus work and the NGT.

- Discussion on statements and rating: following a strict order each of the 57 statements and supporting information was considered (Appendix 6.3). Although the scoring paperwork included explanations and supporting information for each of the areas under discussion the chair made sure that the statement was clear and everyone understood it. Firstly participants were encouraged to discuss their opinions regarding the statement. The chair played a major role in allowing all participants to voice their opinion and control the time spent on each statement. Participants were then asked to privately rate the statement taking into

account the research evidence, their expert opinion and the current state of rehabilitation research in this area of the UK. The participants were asked to rate the statement from 1-5 according to the following question: *How important is it for this statement to be included in the future guidance?* This process was followed for the 57 statements allowing participants to take a break when necessary.

- Conclusion: the researcher concluded the meeting by first asking participants if they had been free to express their opinion during the meeting and finally, thanking all participants and explaining the next step of the NGT.

6.3.3 Phase II - Second round of feedback

Once results from the initial nominal group meeting were analysed a summary of results was emailed to all participants. This included a summary of main identified themes and a revised version of the proposed guidance recommendations according to the results from the nominal group meeting.

Prior to the telephone interview, participants were asked to read the revised version of the guidance. This allowed participants to see the spread of agreement and how their response related to the results from the group meeting. Certain items were selected for discussion with the focus primarily on the items (statements) where agreement had not been reached. Participants were then invited to provide further feedback regarding their ratings (via email or during a semi-structure telephone conversation), focusing primarily on those statements that were the source of the most disagreement during the nominal group meeting.

6.3.4 Analysis of data

6.3.4.1 Rating data from the nominal group meeting

Although there is no agreement on what is the best method to mathematically analyse this type of rating response (Trickey et al. 1998) the researcher adhered to suggested principles. The frequency of responses to each

statement was calculated. For each statement the median was calculated using SPSS for Windows. As shown in Table 6.2 if the median score of the statement was 7-9 this meant that consensus had been reached and that the statement would be developed into a guidance recommendation. On the other hand if the median was less than 2.99 then that would mean rejection of that statement. Finally those statements with a median in the middle ground would be retained for further discussion during telephone interviews and post nominal group meeting feedback.

Table 6.2 Status of statements in relation to rating results

Median value	Status
7 ≥ 9	'Consensus' reached – statement developed into a guidance recommendation
6.99 ≤ 3	Need for further discussion
2.99 ≤ 0	Statement rejected

6.3.4.2 Qualitative data (audio-recordings)

Data obtained from audio-recordings during the nominal group meeting and the Phase II feedback sessions (in depth telephone interviews) were transcribed in full. The transcriptions were then checked by the researcher. In order to analyse this set of qualitative data a thematic analysis (TA) approach was taken following the method described by Clarke and Braun (2013). As they describe it "*TA is essentially a method for identifying and analysing patterns in qualitative data" (*p.121). This method has been widely used and was first named as an approach in the 1970s (Merton, 1975). This method was chosen as it provides a rich and detailed account of the data whilst being flexible. It is widely used and it has been described as being suited for a wide range of research fields and therefore can help answer a wide range of research questions (Braun and Clarke 2006).

The researcher followed and adapted the phases of TA described by Braun and Clarke (2006). First the researcher re-read and re-listened to the nominal group meeting data in order to gain familiarity with the data. The researcher

coded the data in order to capture conceptual meanings. Crosschecking by the researcher's supervisor was carried out with 10% of transcribed data to identify codes where there was lack of clarity. All codes were collated with their relevant data extracts. Themes were then identified as meaningful patterns across coded data which would help answer the research questions. Themes were then reviewed and given a name which would be informative and concise.

All collected data was analysed and as a result the researcher was able to produce a final version of the guidance which was in line and modified according to identified themes.

6.4 Results

6.4.1 Expert panel participants

The researcher contacted a total of 23 potential participants. 13 of these were not able to take part in the study due to other commitments. Out of those a total of 10 participants formed part of the expert panel which informed this consensus work. All participants were asked to sign a consent form (Appendix 6.2). Due to difficulty timetabling a mutually convenient date, only 5 out of the 10 participants attended the nominal group meeting (Phase I). The remaining 5 participants provided feedback during Phase II. Table 6.3 provides information regarding the professional characteristics of the participants and their involvement in the research process. 5 of the participants were professors in their field and therefore had high level of expertise. 2 of the participants were working towards completing their PhD studies. They all worked in North Wales and West England. Participants' backgrounds were varied; one was a physiotherapist, three nurses, one an exercise physiologist, one a speech pathologist, one a psychologist and two were medical doctors.

Table 6.3 Professional characteristics and involvement of members of the consensus expert panel

Participant	Current research role	Background	Phase I (Nominal group meeting)	Phase II (In depth interviews)
A	Professor of Clinical Biostatistics	Biostatistics	√	
B	Doctoral Research Fellow	Speech pathology and therapy	√	
C	Professor of Stroke and Older People's Care	Nursing	√	
D	Honorary Research Associate	Nursing	√	
E	Senior Research Fellow	Nursing	√	
F	Professor in Exercise Physiology	Exercise physiology		√
G	Reader in Psychology	Psychology		√
H	Clinical Senior Lecturer	Medical sciences		√
I	Professor of Stroke Medicine	Medical sciences		√
J	Research Officer	Physiotherapy		√

6.4.2 Results from the nominal group meeting (Phase I)

6.4.2.1 Statement ratings and identified themes

The results of the ratings were calculated for each of the statements. The median value for the statement together with the highest score and lowest score were calculated (Appendix 6.4). 5 statements (n.1, n.9, n.14, n.16 and n.17) were excluded since consensus was not reached. The remaining 53 statements met the criteria to be included in the guidance; however, participants expressed these needed further editing, clarifying and grouping in order to reduce the number of recommendations. During the nominal group

meeting these were discussed in depth in terms of how they needed to be clarified and grouped in order to become part of the guidance.

Participants taking part in the nominal group meeting considered that the statement n.1 (*There should be a clear description of the theoretical base behind the structure and delivery of the neurological rehabilitation intervention*) could lead to confusion since it considered both, the intervention and its implementation. Participants agreed that reviewing theoretical underpinnings was necessary but these should be addressed in two different statements dealing with the rehabilitation intervention and its implementation approach separately.

Participants considered statement n.9 (*Reasoning behind participants being recruited for the trial should be provided*) as highly relevant at the time of designing the rehabilitation trial but they considered that it was "*not applicable to process evaluation*". Similarly, statement n.14 (*Process evaluations should investigate measures in place to attract participants and encourage them to remain involved in the trial*), n.16 (*Process evaluations of clustered trials should clearly describe the site recruitment procedure in place*) and n.17 (*How withdrawal from sites was carried out should be clearly explained*) were described as "*a trialist's job*" and scored lower than 2.9, thus were excluded from the guidance.

A number of themes were identified as having a significant influence on participant's ways of thinking at the time of rating statements according to the need for them to be included in the proposed guidance. The data gathered during the nominal group meeting was key in order to understand what the rehabilitation research community think about process evaluations. Participants openly discussed issues around the practicalities and the challenges of process evaluation research. Furthermore, the meeting became a platform for researchers to voice their understanding about what is and what should be the aim of a process evaluation. The difficulties and lack of clarity in terms of 'separating' the roles of the trial itself and of the process evaluation were openly argued. A number of themes were identified:

Theme 1: The practicalities of doing research – being realistic about what 'can be done'

Participants in the nominal group meeting unanimously acknowledged that there are always practical limitations which will strongly impact on the ability of the researcher to carry out a process evaluation. All participants agreed that there is a degree of compromise which impacts on what can realistically be achieved at the time of evaluating processes. Despite participants identifying the importance of a number of the statements in order to support a high quality process evaluation they raised concerns about the real possibility of being able to follow all recommendations. Participants considered that funding and staffing resources are often limited and researchers are therefore constantly making decisions that will try to reach a balance between these limitations and research needs. As one participant explained:

> *"Because some of them would be unaffordable. In reality you know, ideally yes you should do this, but actually practically … But that's the icing on the cake then isn't it, so you could say yes you know they should do this, but actually that's icing… How lovely that would be, have everything… have the context…have all" (Participant D)*

Closely linked to the above, participants explained that although in an 'ideal world' they would follow most of the proposed recommendations, in the 'real world' of research they would very often have to compromise. Participants discussed how today's research's agenda was highly driven by funders' priorities which often regard aspects of process evaluations (e.g. qualitative explorations) as secondary. Thus, participants expressed their desire to not only rate recommendations in terms of the need for them to be included in the guidance, but also to rank these statements in terms of their relative importance. As put by a participant:

> *"You could ask me whether I like muesli and whether I liked carbs and I'd probably would say that I like both okay … […] But if you ask me which I would prefer, then I would definitely not give the same rating to one or the other, if you were giving me a choice of which I would, so I*

think that's the trouble I'm having with this is that really, I'm likely to agree that these things should be in, and probably they'll be some things that I might disagree with, but I'll either agree or disagree and giving a rating I'm not saying it in the context of the other items, I'm just saying in context with that individual, so I just don't think you're getting a ranking, this isn't ranking…" (Participant C)

Participants considered that having the possibility to rank the statements would have given them the chance to distinguish those recommendations which are vital from those which are additional:

"I suppose I'm worrying about in making these ratings is that I'm not making a relative rating and it's an inherent problem with Likert scales that you may not get any idea of what, which things are more important than the other ones, because we're not ranking them. I think maybe that's what we should be doing, because in a way there's some things that you would absolutely have to have and some things that are a bit more icing on the cake" (Participant C)

Participants unanimously agreed in the fact that guidance produced to assist researchers involved in rehabilitation research should reflect the real world of research which is often constrained and highly dependent on outside factors out of the control of researchers.

Theme 2: Starting points - role of theory, concepts and roles

From the offset of the meeting a research culture difference was clear amongst participants taking part in the nominal group meeting. As expressed by one of the participants (E): "*people come at it from different perspectives"*. The participants' epistemological and ontological stance highly influenced their views regarding proposed recommendations and their understanding of the guidance content. Two ranges of views were prominent amongst the participants and this was clearly reflected in the results from the rating of statements (Appendix 6.4). These ratings were often polarized with a number of participants considering that a statement should not be included in the guidance (score of 1) and the rest of participants strongly agreeing with that

statement being part of the guidance (score of 9). Whilst one participant introduced himself as "*coming from a very quantitative stance*" the remaining participants considered themselves as "middle ground", not strictly guided by one particular paradigmatic approach. As one participant said:

> *"How you define everything will depend on where you're coming from fundamentally about the nature of this sort of research […] I don't know what conclusion you reach, but I guess we have to rate this in terms of where we're coming from…" (Participant D)*

Likewise, during the nominal group meeting, participants expressed different views in regards of the role that theory plays at the time of designing and carrying out a process evaluation. The need to understand and account for the theory underpinning the rehabilitation intervention was debated amongst participants. One participant argued the following:

> *"I think there might be a cultural difference here as well; I think qualitative and quantitative research … when I read qualitative grant proposals, an awful lot about the theoretical underpinning framework aint it […] When I read quantitative no one ever says no I'm going to apply statistics because if we work with statistics we define probability in this way, people just do it you know… And just accept that everyone knows what they're doing, and there's not this kind of need to state everything formally and you know it seems like a massive sledgehammer to me". (Participant A)*

However, other participants considered that understanding the complex intervention and using theory to support its effectiveness was necessary in order to avoid impact failure and waste of resources:

> *"I think part of the issue from sort of a neurological rehab context for this is we've got so many trials of interventions which fail and actually where the interventions themselves are poorly described and theorized, so you know very rarely will you see like the logic model for an intervention so that you know how the component are gonna work or the impact of those components might be, how they interrelate […]. I think that*

perhaps is certainly from my perspective a bit of a concern that we have spent, you know quite a few millions on trials of neuro rehab interventions, which then fail." (Participant C)

During the meeting there was strong importance placed on understanding researcher's views and starting assumptions in regards to core concepts and terminology linked to complex rehabilitation interventions. When discussing the terminology used in the proposed recommendations one participant said:

"I think all our terminology seems to be using common words but in completely different ways … There are strict definitions within trials methodology … It seems that those definitions have been half understood, misunderstood, stretched … And taken out by different people in different directions…" (Participant A)

Amongst all participants in the meeting there was a clear lack of consensus when discussing what a complex intervention is and the level of depth in which its multicomponent nature should be investigated. Several participants considered that defining a complex intervention simply as the 'sum of its parts' could potentially lead to a superficial understanding of how the intervention works. However, one participant expressed the following:

"Because that's not what complex means, complex just means multi components, and whether or not you can answer those or not, is just going beyond what complex means… But that's what it does mean in the dictionary […] Complicated means tricky, complex means multiple components, that's as simple as that. You know that's all they mean." (Participant A)

Similarly, participants' research standpoints and background assumptions also influenced their views on what a process evaluation is and what should be its role.

"I mean we're talking about process evaluation of the trial rather than the process evaluation of an intervention within the trial. I was thinking

of a process evaluation of delivery of an intervention. I wasn't thinking of a process evaluation of a running of a trial." (Participant D)

Throughout the meeting participants unanimously expressed their doubts in regard to whether a number of the proposed recommendations should be part of a process evaluation or the main trial itself. The data gathered in the meeting clearly sets out the need for consensus in terms of how should rehabilitation researchers view the links between an intervention, its implementation and its embedded process evaluation. Participants strongly debated how a process evaluation and the main trial are related, in what terms and to what extent:

"So the problem might be for definition of a process evaluation, because for me that's beyond the process evaluation. So process evaluation for me is the…, did the process actually happen?" (Participant A)

Again, participants' paradigmatic and theoretical standpoints highly influenced their opinion in terms of how to understand the links between the process evaluation and the trial itself. One of the participants with a strong quantitative, outcome orientated standpoint strongly argued the need for the process evaluation and the outcome evaluation to be clearly and strictly separated, avoiding any possible connection or integration. In his words:

"My idea of process evaluation is you measure and record what was actually done, how often, by whom, and it doesn't necessarily extend to any connection to outcome data for individual patients. It's just an evaluation of the process. Did it actually happen? Was the intervention delivered as intended? Or near enough as intended? … Whereas your definition, your working definition for this is kind of actually more mechanistic evaluation of and which components were delivered as well as associated with outcomes and mechanistic evaluation which I thinks an entirely separate question and a much bigger thing." (Participant A)

Participants identified the difficulties in attempting to reach a consensus or in trying to 'find a way around' researcher's standpoints and cultural assumptions. They further stated that although the proposed guidance "*might not be able to reconcile points of view, you've just got to say that's where I'm*

coming from". Finally, participants considered that for a guidance to work it needs to clearly explain its underlying assumptions. In this way the rehabilitation researcher can make an informed decision at the time of following a proposed guidance.

Theme 3: Making connections

Participants identified potential connections between aspects related to the recruitment of participants, the tailoring of interventions and the development of a research trial. These connections were identified as highly important and in need of careful consideration when conducting a process evaluation. Rating data showed that participants considered it was the trialist's role, and not the process evaluator's role, to provide the reasoning behind recruitment into the trial. However, participants did consider that identifying barriers and facilitators to recruitment should be an aim for process evaluation. This is clearly reflected in the rating results from statements n.10 to n.13 (Appendix 6.4). Furthermore two researchers attending the nominal group meeting agreed that the recruitment of participants into the process evaluation should be carefully thought through in order to avoid its impact on the recruitment for the trial itself and a risk of attrition. As put by one of them:

> *"The most important thing about in your process evaluation is that it doesn't interfere with recruitment or retention to the main trial. So any additional recruitment to the process evaluation if you're going to interview participants, I was to do that after the event. So after they completed the trial, then ask them if they would also like to give some feedback. If you increase the burden during the trial participation, there's always a risk of attrition". (Participant A)*

Participants discussed in depth the challenges in identifying and assessing the degree of tailoring taking place at the time of trialling a rehabilitation intervention and carrying out the embedded process evaluation. Participants widely agreed on the fact that in the everyday running of a trial it was unrealistic to assume complete consistency in the way professionals deliver proposed rehabilitation interventions: "*But the reality is they will be changing and they'll*

be changing for a reason, it's whether we want to direct that change" (Participant D). According to this view it is the researchers' responsibility to decide to what extent the tailoring is going to be directed. The stance taken by the rehabilitation researchers in this matter will be determined by their assumptions in regards to the links between outcome and process evaluations.

Closely linked to this, participants identified the need for a process evaluation to be able to investigate tailoring, as reflected in the rating results for statements n.24, n.25 and n.26. However, participants expressed that it is often extremely challenging to assess which degree of tailoring can be expected without compromising the purpose and contents of the intervention. As expressed by one of the participants:

> *"So people can say that they're sticking to things or thinking that they're sticking to things, but they've changed it a bit and what should you, what is whatever you have to retain before it becomes a different thing. […] So you focus on those bits where you've tried to change something in a reasonable way, with some theoretical underpinning to how you think that different way of doing its gonna make things better". (Participant E)*

A number of participants debated how the process evaluation should aim to investigate the reasons behind the tailoring, and establish the thinking behind professionals' decisions to adapt a trialled intervention to a particular case.

> *"In practice that no one is there to challenge you whether you're being absolutely consistent, you need them to be absolutely consistent in doing everything as per in a trial … And you need to find out what stops them doing it in the way that you want them to do it, so if you're trying to get people to talk to people and that's part of your strategy, then if people cry, and people can't cope with people crying, then they're just not going to, they're just gonna do some superficial something" (Participant C)*

Participants agreed that providing training to health professionals in charge of delivering the rehabilitation intervention is often an efficient way to address

and attempt to control the issue of tailoring. Thus statements related to training were rated highly (n.27 to n.29). Participants argued that during the training of intervention staff, researchers are able to identify health professionals' competence and underlying motivations. Furthermore, they commented that training provided a platform to discuss the realities of a research context when transferred into a clinical practice setting:

> *"People assume that people can just take a manual, have a bit of training and then that they'll do that without any support and I just don't think that's realistic …..I don't think it's realistic, I think you're right but you can do it like the program I worked on, you know training was delivered to GP practices and there was some selective you know observations and interviews of staff. So looking at could you see when they were consulting, have they incorporated anything in and then interviews with them afterwards. So there, there was obviously some effort to try and see well has that training transferred into practice" (Participant C)*

The challenges linked to recruitment and intervention tailoring were widely discussed by all participants who unanimously agreed on the need for these to be investigated by the process evaluation and therefore addressed in the proposed guidance. However, data presented here shows that there is still the need, as previously highlighted, to reach consensus regarding appropriate links between the trial, its recruitment and intervention tailoring components and its embedded process evaluation.

Theme 4: Who is the end user?

Participants unanimously agreed on the fact that all process evaluations should have clear aims and objectives and that these would differ according to the type of trial under evaluation and the timing of the evaluation. Thus participants considered that the guidance should recommend rehabilitation researchers to clearly state the aims and objectives of the process evaluation. As one participant explained:

"But the answers to these things would be different depending on what sort of study you were doing and what you were doing the study for. So if you're doing the feasibility study, then obviously you have to look in huge amounts of detail at the process of recruitment, why people did and didn't go in, if people followed the things, how people defined you know, I don't know where we have sometimes things in like you know, we can exclude them if they're unstable or something. But you'd want to look at how people were defining that, whereas by the time you get to the trial you should have sorted all that out. You know so you wouldn't really be looking at those things. So really its different types of studies, place the point at which you are" (Participant D)

Participants considered that rehabilitation researchers making use of the guidance would need to be able to identify which recommendations were applicable to the type of study and the proposed timing for the process evaluation. Participants agreed that a process evaluation of a pilot/feasibility trial would be likely to aim at addressing most of the proposed guidance recommendations, whilst an evaluation of the main trial would possibly focus on those areas that have been previously identified as in need of further investigation. Process evaluations can therefore play a role of highlighting to rehabilitation researchers which are the areas that will need to be addressed at the time of running the main trial. In the same way, process evaluations of main trials can build on results from the evaluation of previous pilot studies. This data shows that the proposed guidance needs to state who its end users are; rehabilitation researchers will then be responsible for tailoring its recommendations to best fit their evaluation aim.

6.4.2.2 Revised version of the guidance recommendations

According to the quantitative and qualitative data collected in the nominal group meeting and the identified themes, the researcher was able to produce an updated revised version of the guidance recommendations which accounted for the feedback provided by participants. In summary the new version (Appendix 6.5) included the following modifications:

1. A section briefly stating the ‘starting point’ which the guidance recommendations build on – a number of assumptions about the nature of complexity in complex intervention research.

2. Edited recommendations – a total of 32.

3. A ranking criteria in order to give the participants the chance to weigh the importance of each of the proposed recommendations as ‘essential’, ‘important’ or ‘additional’. Data from this ranking was not intended in order to be analysed quantitatively but to provide an overall impression of participant opinions.

6.4.3 Results from the second round (Phase II)

The researcher emailed all participants the revised version of the guidance recommendations. A total of five participants provided written feedback (via email) regarding the content of the revised guidance. The researcher carried out a total of five semi-structured in depth telephone interviews. These interviews explored those issues which shaped how researchers perceived and understood the relevance of the 32 recommendations and their opinions regarding the ranking exercise. Questions were formatted around the key themes emerging from the nominal group meeting. The telephone interviews were carried out at a time convenient to the participant and lasted an average of an hour.

The researcher carried out the interviews in a semi-structured way and although participants were free to discuss the issues which they found more outstanding the researcher made sure a number of topics were explored:

- Opinions regarding the use of a ranking criteria
- Opinions regarding included recommendations
- Opinions regarding the chosen terminology – clarity of the language
- Overall flow and order and structure of the guidance in sections
- Opinions regarding the clarity of the ‘starting point’ section and its purpose

6.4.3.1 Ranking results and qualitative thematic analysis

Four of the participants ranked the recommendations; these results were only used to provide the researcher with an overall impression of rehabilitation researchers' views but were not a means to assign a label to each recommendation. Out of the 32 recommendations only 6 statements were ranked unanimously as 'essential' (Recommendations 10, 18, 19, 21, 27 and 28) (see Appendix 6.6). These recommended rehabilitation researchers carrying out a process evaluation to review the characteristics of the intervention staff, to review strategies in place to measure 'dose delivered' and 'dose received' and to investigate participants' experiences and acceptability of the intervention. The remaining two recommendations considered 'essential' were those regarding the need for a detailed description and justification of selected process evaluation data collection methods together with a clear reasoning behind chosen timings for them. All remaining recommendations were ranked differently by the four participants. Five recommendations were left 'blank' (not ranked) by at least one of the participants. This was, in all cases, due to the participant not understanding the meaning of the recommendation. Reasoning behind chosen rankings was discussed in depth during the interviews and considered at the time of carrying out the thematic analysis.

A number of themes which appeared to be significant influences on participants' opinions are described. These themes were in line with those identified in Phase I of the consensus work. These themes describe a number of issues in regards to the guidance and its potential use for rehabilitation researchers which participants have suggested needed addressing.

Theme 1: Researchers assumptions and research stances impacting on future use of guidance

Participants expressed how it is important for a guidance to include an explanation of the assumptions that underpin it. A number of participants expressed that current rehabilitation research is being carried out from a number of different standing points. One participant explained:

"I think it's really important because you could take a number of approaches to complex evaluation, you could be very theoretical or you could be more practical and more pragmatic and researchers come at it from different angles, don't they? And so there are some people who are very embedded in the theory and would say that if you don't know the theoretical underpinnings of the intervention that you are looking at you will never get anywhere and there are other people that are more pragmatic and say well this looks like it might work so we'll give it a go or we'll try it out. And I think unless people understand where you are coming from it can sound like a lot of complicated talk around something quite straightforward" (Participant I)

In line with the themes identified in Phase I, participants' opinions throughout the interviews were closely linked to their research stance. This was reflected in the ranking data. Whilst some of the participants described themselves as being 'more quantitative' and described they research as 'purely objective', others were more familiar with the consideration of qualitative methods and their approaches to research.

"I am quite pragmatic in the way I use theory, I think some people are very precious about their theory… I am much more, I have a much more pragmatic way of thinking about it and just using it as a means to an end a means to developing an intervention rather than to justify a particular path of theory" (Participant H)

As in Phase I, participants also expressed an acceptance of the fact that the researcher will have to compromise in some cases and accept that you can't do it all:

"You can't have it all. There is always a compromise between what you want to do and what your subjects are prepared to do and also what your funding enables you to do so there certainly has to be a compromise. We have to look at funding, have we got enough to do all the biochemistry we want to do? Or do we have to rationalize it and just look at A, B and C?" (Participant F)

Participants' research stances were closely linked to a specific terminology. As reflected in the ranking data those participants coming from a more 'quantitative' stance explained how they were not familiar with some of the terminology included in the guidance. To the contrary, other participants used the guidance terms and concepts frequently during their daily research activities. The data presented here shows that there is a need for the proposed research guidance to be tailored, not only to a particular process evaluation, but also to end users' needs.

> *"The only problem I had was actually understanding some of the language and that is because I'm sure all the terms that you use are very familiar to all the people who are doing maybe a lot of qualitative data collection and research, I don't do that so I was unfamiliar with some of the terms that you use so perhaps you have to express things to academics in different research areas of fields in lay terms…" (Participant F)*

Theme 2: Factors in regards to ranking recommendations

As previously explained, the revised version of the guidance included a ranking exercise. Although overall participants understood the ranking exercise, and could see the benefit of it, they expressed a number of concerns in terms of its usefulness. Firstly participants explained that "*rating can be counterproductive*" (Participant G) in regards to funding. A number of participants discussed the fact that the ranking of recommendations can impact on their funding potential since, for example, those classed as 'additional' could have their chances of being funded hugely reduced. As put by one participant:

> *"The rating can turn out to be a little counterproductive because if you publish something from your work saying that 'these things' are not essential then it makes it very hard for people to get funding to do them because of the publication that says they are not essential" (Participant G)*

Another point, which was raised by one participant, is the fact that the rating would be different and will be determined in many ways by the type of study and the stage of the research. Participants argued that for example, recommendations to carry out a process evaluation of a feasibility trial would be ranked differently than those same recommendations in the case of the process evaluation of the main trial. As one participant put it:

> *"There might probably be a point in weighting the recommendations but again I do wonder if the weighting … I thought the weighting might be determined but the type of research design or a weighting that you agree for a RCT might be different to the weighting for a process evaluation of a different type of study but also I am wondering whether the weighting might vary on whether you are at the beginning of the whole system and you are designing a study or putting in a grant application versus you are in the middle of data collection, you are at the end, you are analysing, it might be a little bit different so I think it's not that one is more important than the other is that at different time points there are different things you should be focussing on" (Participant G)*

Similarly another participant argued:

> *"You can certainly see the E, I, A. I can see that makes sense but I can also see that no grant giving body will give you any money for the As, they are really not, they might give you an I, but they are only going to really give you the Es really" (Participant I)*

Theme 3: Who is the guidance for and when should it be used

Similarly to those involved in Phase I, participants in Phase II unanimously agreed that a guidance must be clear in terms of identifying the target audience and its content will have to clearly match the needs of this identified audience. As expressed by one participant:

> *"How are you expecting people to use this then? Are you expecting people to do a checklist when they rate a grant application or are you*

expecting them to use this when they put in an application for funding, or both?" (Participant I)

Another participant explained:

"Well, it's very interesting to think about who will use it in terms of researchers so is it going to be people who do trials and are thinking of doing a process evaluation around a trial will be thinking in a sort of way, in a very trial 'consorty' way but if it's actually aimed at experts who do process evaluations you will pitch it very differently so kind of maybe you almost need in the context of who is this for? And would you be suggesting that there are different versions for different audiences." (Participant G)

Furthermore, participants argued that the timing of events would impact on the use of the guidance. In other words, the guidance would be used differently depending on the stage where the research is at and also depending on the type of study, as already identified during Phase I. As one participant explained:

"People would look at it at different times, it might be that you summarize it into a checklist for people when they are submitting grant applications and then for when they are writing up their results and there may be different things in the two" (Participant I)

6.4.4 The guidance

The guidance for carrying out process evaluations within complex intervention rehabilitation research was produced (Table 6.4) taking into consideration all results from Phase I and Phase II.

The proposed guidance includes:

- A number of clarifying points in regards to: firstly, who is the guidance target audience and how it should be used and adapted by rehabilitation researchers according to the type and the timing of trial under evaluation.

Secondly, a brief explanation clarifying the underlying assumptions underpinning the guidance recommendations.

- Seven sections in which the recommendations are grouped. These sections represent different aspects or stages which the rehabilitation researcher will face throughout the evaluation process. These sections are named as:

  - Theoretical work: addressed issues in relation to the theoretical underpinnings of the trialled intervention
  - Design and methods: this describes a number of steps aimed at treating a process evaluation as a piece of research in its own right
  - Context: this addresses the importance of understanding and accounting for contextual factors.
  - Recruitment and retention
  - Intervention staff: this addresses the need to investigate the characteristics of staff in charge of delivering the intervention
  - Delivery of the intervention
  - Results

Table 6.4 Guidance for carrying out process evaluations within complex rehabilitation interventions research

Section	No	Recommendation
Theoretical work		
	1.1	Review and state the theoretical underpinnings of the rehabilitation intervention under investigation
	1.2	Review and state the theoretical underpinnings of the implementation approach of the rehabilitation intervention under investigation
	1.3	Describe in depth the structure of the rehabilitation intervention in terms of its components and their potential interactions
Design and Methods		
	2.1	Provide a clear definition of chosen terminology (e.g. adherence, fidelity, integrity etc.)
	2.2	Have a defined scope and clear aims and objectives - a process evaluation protocol should be produced
	2.3	Clearly describe and justify the use of a set of measures and evaluation criteria for the process evaluation
	2.4	Provide a detail description and justification of selected process evaluation data collection methods
	2.5	Clearly explain and justify chosen timings for process evaluation data collection
	2.6	Collect relevant /appropriate data from both intervention and control sites
	2.7	Use a variety of methods and strategies to gather data, including both qualitative and quantitative approaches
	2.8	Should aim at publishing its results alongside outcome evaluation results (in order to reduce the chance of biases)
	2.9	Address the interactions between process and outcome evaluations *(e.g. researchers should decide if they take the risk of threatening the outcome evaluation via evaluating processes or if they accept that there will be tailoring which can be guided through the process evaluation)*
Context		
	3.1	Clearly describe and investigate contextual factors and their potential impact on the process and outcome evaluation. *The role of context in shaping both implementation (e.g. how it's done) and impact (whether it works) should be clearly investigated*
	3.2	Account for the dynamic nature of context - investigate contextual changes and their potential impact on the process and outcome evaluation over time
Recruitment and Retention		
	4.1	Review the outcome evaluation's recruitment procedures in order to identify potential recruitment barriers and facilitators
	4.2	Review the strategies that the outcome evaluation has in place to maximize participant retention levels
	4.3	Clearly describe the strategies and criteria informing the recruitment of participants into the process evaluation
	4.4	Investigate the barriers and facilitators to the recruitment of participants into the process evaluation

Section	No	Recommendation
Intervention staff		
	5.1	Review the characteristics of the outcome evaluation intervention staff (e.g. level of skill, experience, number, demographics, motivations and perceptions regarding the outcome evaluation) and identify those potentially impacting on intervention delivery and impact
	5.2	Review the training provided to intervention staff in order to identify possible impacts on outcomes. Explore issues such as: *does the training define a performance criteria and set of goals to achieve? Is skill acquisition/competence of intervention staff assessed post training? Does the training include systems in place in order to maintain and support staff's skills over time?*
	5.3	Review the outcome evaluation's strategies in place to assess competence of intervention staff over time in order to identify possible learning curve effects
Delivery of the intervention		
	6.1	Investigate any strategies in place in order to guide, inform and measure the tailoring of the outcome evaluation intervention
	6.2	Review and assess the quality of any implementation strategies to improve/support the fidelity of the proposed intervention.
	6.3	Investigate, in detail, barriers and enablers to the implementation and delivery of the intervention and evidence surrounding the chances of implementation failure
	6.4	Review the strategies in place in order to measure the 'dose delivered'
	6.5	Review the strategies in place in order to measure the 'dose received'
	6.6	Investigate in detail participants' experiences and acceptability of the intervention
Results		
	7.1	Describe in detail the synthesis of process evaluation and outcome evaluation results
	7.2	The theoretical underpinnings behind both, the outcome evaluation intervention and its implementation should inform the explanations and the synthesis of process and outcome evaluation results

*It is strongly recommended to consider these guideline alongside recommendations on reporting outcome evaluations (e.g. CONSORT statement)
*This guideline is of use to researchers carrying out research on complex rehabilitation interventions and the recommendations will need to be considered and adapted accordingly depending on the research stage/phase or type of study (e.g. feasibility trial, main trial, etc.).
*These guideline recommendations build on the following assumptions about the nature of complexity in complex intervention rehabilitation research:

- Complex rehabilitation interventions are those made up of a number of components which interact with each other, and with patient and other factors to bring about changes in patient outcomes.
- The impact of complex interventions is greater than the sum of the effects of their component parts, and is a product of both the changes embedded in both the intervention hypotheses and the implementation approaches used. In other words, and in order to provide explanations of how a complex intervention works, for who and under what circumstances, this guideline considers that outcome evaluation and process evaluation are inextricably linked.

6.5 Discussion

This chapter has described the steps that were followed in order to create a guidance for carrying out process evaluations within complex rehabilitation research. The proposed guidance builds on published work such as the UK MRC guidance (Moore et al. 2014a) in an attempt to address the difficulties and challenges faced, in particular, by those researchers dealing with complex rehabilitation interventions. Thus, the aim of this guidance is to update and contribute to the published evidence by extending its coverage to rehabilitation research, its processes and theoretical underpinnings. This guidance provides a new lens for rehabilitation researchers attempting to carry out a process evaluation. It does this by working on the assumption that complex rehabilitation interventions are those made up of a number of components which interact with each other to bring about changes in outcomes. Furthermore, it considers that the impact of the complex intervention is greater than the sum of the effects of their component parts and is a product of not only the changes embedded in the intervention hypothesis but also the implementation approaches informing it. In this guidance, outcome evaluation and process evaluation are considered to be inextricably linked. With this in mind, this guidance works towards a consensus in regards to how rehabilitation researchers should go about carrying out process evaluations and how this evaluation should be linked into the proposed trials. Additionally, this guidance is innovative, in addressing the importance of learning effects and contextual changes with time, when evaluating the processes that take place as part of a research trial.

In agreement with Moore et al. (2014b), the researcher considers that there is shortage of guidance to assist researchers in how to design and conduct a process evaluation. This can lead to the risk of process evaluations being organized in an ad hoc manner. This is particularly true in the field of rehabilitation research. Process evaluations are becoming a very common part of grant applications, but the approaches to them are very variable, as other authors have already identified (Munro and Bloor 2010, Grant et al. 2013). Furthermore, as expressed by Lewin et al. (2009) and as identified in

the work presented in Chapter 5, there is often very little integration between process and outcome studies.

As the data presented in this chapter shows, researchers are aware of how their decisions in terms of process evaluation will be closely influenced by the type and stage of the study. As put by Moore et al. (2015), "*the focus of process evaluation will vary according to the stage at which it is conducted"* (p.2). Thus, in line with what other authors (Oakley et al. 2006, Grant et al. 2013) have stated, the researcher considers that the proposed guidance will need to be tailored to rehabilitation researchers' particular needs, since there is no single way to carry out a process evaluation. Issues around the phase, the timing of the study or a number of contextual factors will play a major role at the time of designing and carrying out a process evaluation. Furthermore, as already expressed by Moore et al. (2015), even when the feasibility trial has been under a process evaluation, there will still be the need to carry out another one, alongside the full trial, because it is likely that the intervention, and this is particularly true for rehabilitation interventions, will face new problems and new challenges will emerge when implementing at a larger scale. Finally, the guidance presented here understands that changes in contextual factors, responsible for triggering intervention mechanisms (Pawson and Tilley 1997), are likely to take place throughout the research period and will therefore need to be addressed by the process evaluation.

6.5.1 Addressing rehabilitation research challenges

The appearance of the revised MRC guideline in 2008, which called for the need to "*combine evaluation of outcomes with that of process"* (Craig et al. 2008), accentuated the need for guidance on how to carry out process evaluations of complex interventions (Moore et al. 2014b). The guidance that the researcher presents in this chapter is considered to address the need to target rehabilitation research and its unique challenges. Rehabilitation research, as discussed in depth in all previous chapters in this thesis, presents a particular set of challenges which the proposed new guidance addresses. One of these challenges is in regards to participant recruitment into rehabilitation trials which often follows a criteria that is therapeutically based

and therefore more complex, instead of based on a screening tool (Wolf et al. 2008). The proposed guidance acknowledges this and proposes a number of recommendations that guarantee the close exploration of the trial's recruitment procedures in order to identify potential barriers and facilitators and their impact on outcomes. Furthermore, this guidance recommends in depth review of the strategies implemented during the outcome evaluation in order to maximise participant retention (e.g. transportation to and from research base). A further challenge faced by rehabilitation researchers planning an RCT is making sure that treatment differentiation is kept throughout the study. This can be extremely hard considering the role that tailoring often plays throughout the delivery of the trialled intervention. The proposed guidance addresses this need by advising on the need to firstly, investigate strategies to guide, inform and measure the tailoring, and secondly, assess the quality of any implementation strategy aimed at improving or supporting the fidelity of the rehabilitation intervention. Finally, this guidance understands the further challenges that rehabilitation trials face in terms of recruiting intervention staff. The skills, previous experience and knowledge of those administering the intervention can influence intervention impacts (Hart and Bagiella 2012). This is particularly addressed in this guidance with a number of recommendations focussing on what the process evaluation should investigate in regards to intervention staff characteristics, training provided and possible impact on outcomes.

As already mentioned in Chapter 1 and throughout this thesis there is growing expectation for rehabilitation professionals to develop and use evidence-based treatment methods. In order to do this, rehabilitation researchers need to be provided with the right tools in order to be able to design and carry out high quality clinical trials (Hart and Bagiella 2012). The rigor and strict focus on efficacy, which comes hand in hand with carrying out a clinical trial, can be disadvantageous to complex rehabilitation intervention research (Whyte et al. 2009) since these interventions are often delivered during periods which can last weeks or months. This can challenge, for example, guidelines for implementation amongst other things (Cheeran et al. 2009).

Although a number of steps are being made in order to try to understand the complexities underpinning the need to tailor complex interventions, several authors (Morrison 2009, Song et al. 2010) have identified addressing 'the science of client centred replication' as a major challenge for today's health care research. As widely discussed in Chapter 1, it is of vital importance to address the issue of tailoring of the outcome evaluation intervention, if the researcher aims to investigate its fidelity in depth (Elliot and Mihalic 2004, Mihalic 2004). In line with the work in this thesis, this guidance understands fidelity as the 'quality of implementation' and recommends an in depth evaluation of the strategies in place, alongside quantitative aspects of adherence, not only to measure the tailoring but also to guide it and inform it as the trial progresses.

6.5.2 Integrating process and outcome evaluation

As the researcher explains in the proposed guidance (Table 6.4) *"complex rehabilitation interventions are those made up of a number of components which interact with each other and with patients and other factors to bring about changes in patient outcomes"*. Throughout the creation of this guidance the researcher has taken a research stance which acknowledges that the impact of complex interventions is greater than the sum of the effects of each of its components. Thus, in order to try to explain how a complex rehabilitation intervention works, for who and under what circumstances, outcome evaluation and process evaluation should be considered as being inextricably linked. The data here presented show, and as it has been discussed in the literature (Moore et al. 2015), there are arguments for both the separation and the integration of process evaluation and outcome evaluation teams. The researcher in the proposed guidance considers that data on implementation should be integrated into the analysis of outcomes and that emerging process issues identified in the process evaluation should be integrated into trial data collection. Also, the researcher understands that by considering outcome and process evaluation to be inextricably linked, the rehabilitation researcher might avoid duplication of efforts and reduce the burden on participants at data collection stages. Finally, process evaluation can identify causal processes

which can, for example, inform new decisions on outcome measures used. As raised by O'Cathain et al. (2008), effective integration and addressing the links between process and outcome evaluations will take place only when members of both teams value each other's contribution and when the principal investigator understands and agrees with the value of integration. Closely linked to this, authors such as Audrey et al. (2006) have identified that one of the main challenges of implementing process evaluation within clinical trials is the overlapping roles within the team and distinguishing between the intervention and its evaluation. The data presented in this chapter is in line with this, but, the proposed guidance supports the need for close integration of process and outcome evaluations.

6.6 Conclusion

This chapter reports on a tool for designing and carrying out process evaluations for rehabilitation intervention trials. This guidance builds on the findings from Chapter 5 in regards to the current state of process evaluation within rehabilitation research. Thus, the aim of this guidance is to update and contribute to the published evidence by tailoring its coverage to the particular challenges that define rehabilitation research, its processes and theoretical underpinnings. As mentioned above, the results presented in this chapter break new ground in terms of concepts and theory and work towards a consensus in regards to how rehabilitation researchers should go about carrying out process evaluations and how this evaluation should be linked into the proposed trials. Although this guidance is written from the perspective of researchers with experience of carrying out trials of complex rehabilitation interventions, it is also relevant and useful to stakeholders from other research domains such as funding agencies, when making decisions regarding allocation of funding.

CHAPTER 7:

Discussion and recommendations

7.1 Introduction

The present study explored the current challenges faced by neurological rehabilitation research in the context of process evaluation and clinical trial methodology. This thesis has provided a contribution to research that has uncovered new knowledge which will assist not only neurological rehabilitation researchers but also those working in the wider field of rehabilitation, at the time of undertaking a process evaluation alongside their proposed trials. The results reported here have advanced the understanding of complex interventions, have considered the merits of new methodology and have used this to revisit the design and conduct of process evaluations alongside neurological rehabilitation research. These results have also been applied to develop new conceptualisations of fidelity by highlighting the importance of learning effects within trials of rehabilitation interventions. The existing knowledge and published research on this matter has mainly focussed on identifying the challenges, but has provided limited guidance on how to address them. There is a considerable lack of unified theoretical generalisations and frameworks which can inform the investigation of fidelity when dealing with complex rehabilitation interventions. This chapter discusses the findings from this study in the context of the wider literature and it reflects on the process of undertaking this research.

The findings reported in this study have provided evidence of the appropriateness of using a realist evaluation approach to understand and identify the mechanisms triggering the processes taking place alongside an outcome evaluation. Realist evaluation has proven useful in providing a new lens through which researchers can bring light into how complex interventions might work. Thus, the potential contribution of this study to the realist

evaluation body of evidence is considered. The refined programme theory, which emerged from the findings of the OTCH process evaluation, are revisited to recommend further modifications to current frameworks for the investigation of fidelity. This modified framework is discussed in the context of its development and application in future rehabilitation research. Finally, the process evaluation methodological guidance which was informed by the work presented in Chapters 5 and 6 is reviewed in terms of its potential impact to the field of trial evaluation research.

The strengths and limitations of this study are acknowledged and discussed in order to provide a balanced view of the study as a whole and also to consider what has been learnt and what the potential future impacts for research are. This chapter then considers the recommendations from the findings of this study for research and policy. Finally a reflexive account of the process of being a PhD student is provided with the intention of showing how the researcher has evolved throughout the period of undertaking this thesis.

7.2 The research contribution

This thesis research aimed at advancing thinking and practice in process evaluation and clinical trial methodology within the field of neurological rehabilitation research. The potential contribution of this study to the process evaluation and fidelity body of evidence is now considered and discussed within the context of the wider literature.

7.2.1 Advancing process evaluation research

7.2.1.1 Proposed modification to the CFIF

The findings presented in this study contribute to advancing current frameworks for fidelity research by identifying the need to include a ‘learning over time’ component. As Slaughter et al. (2015) recently argued there is a current need for more research on how to go about understanding and reporting the fidelity of implementation strategies. The concept of fidelity is not new, but, there is no consensus on the best way to measure it (Proctor et al.

2011, Slaughter et al. 2015). In 2011, Gearing et al. carried out a comprehensive review over a 30 year span and found that there was high variability in the way aspects of fidelity were reported.

The refined programme theory generated from the OTCH process evaluation has provided evidence on how learning over time can impact on quality of implementation of rehabilitation interventions. This refined programme theory was supported by evidence of two events that potentially take place when rehabilitation interventions are being implemented in the context of a rehabilitation trial. The first event is in regards to how intervention staff become better at implementing the trialled intervention. The findings from this study show that staff learnt how to overcome challenges linked to resource limitations, institutional contexts, and patient engagement, and that this happened with time. The second event is that therapists or intervention staff's personal engagement and understanding of the purpose of the rehabilitation trial appeared to be closely linked to the observation of success of their proposed interventions. The findings from this study support the fact that: 1. Rehabilitation interventions, such as OTCH, as most complex rehabilitation interventions, are not a 'one off' and require time and repetition to reach their maximum potential and 2. Participants taking part in a research study such as OTCH have to be allowed time to develop skills and increase knowledge and comprehension, and this means that intervention staff have to continuously re-assess and modify interventions accordingly.

Further findings from the systematic review (Chapter 5), showed that neurological rehabilitation process evaluations, to date, do not monitor learning over time and do not investigate how learning curve effects may impact on outcomes. Process evaluations alongside neurological rehabilitation trials are currently not addressing the role that learning curve effects might play in influencing intervention outcomes.

The findings reported in this thesis extend the conceptualization of fidelity within complex intervention research, which, to date has neglected the learning effect. As Taekman et al. (2010, p.406) state "*to date there has been limited scrutiny of clinical trials for performance learning curves*". This learning

effect has been described as leading to higher quality of implementation over time (Ramsay et al. 2002). In other words, learning curve effects are defined as "*improvement in performance over time"* (Cook et al. 2004, p.421). However, as discussed in Chapter 4, to date most studies that have looked at learning curve effects have primarily focussed on surgical trials and the implementation of new surgical procedures (Ramsay et al. 2002, Cook et al. 2004). Recently, work by Taekman et al. (2010) reported on learning curve effects in a large pragmatic RCT pharmacological trial. Cook et al. (2004) proposed a hierarchy of influences on individual learning curves in the context of surgical performance. They reported that at the bottom level of this hierarchy is the specialist clinical community that designs and develops the techniques. The institution can then further influence learning through good facilities and funding. Next, they proposed that the characteristics of the surgical team members and their level of experience would play a major role. Finally, the characteristics of the patients undergoing the procedure and the characteristics of the surgeons (e.g. attitude, ability) would further impact the performance of the technique. In 2003, Waldman et al. explored the use of learning curve theory in medicine, which they argued was seldom methodically applied in clinical practice. In their work they reported on a conceptual model of learning taken from manufacturing systems and tailored to address the unique aspects of a healthcare setting. Their model assumed that three learning theorems form the basis of learning theory. These are: (1) outcomes improve with higher number of patients due to learning. As they explained, "*the risk for the 20th patient is less than the risk for the 2nd patient*" (p.44). (2) As more patients are seen, the incremental rate of improvement (outcomes) diminishes over time. (3) As a procedure is performed it is possible to predict patterns and rates of improvement at a provider level. Their conceptual model of learning further included the institutional context, care homes in the case of the OTCH trial, as a factor affecting learning at a group or individual level. A number of modifying factors were also part of the model. One of them was *volume of experience*; the higher this volume the faster and more advanced learning would take place. This is in line with what the OTCH process evaluation refined programme theory identified. Those OTs with previous experience learnt faster how to implement the OTCH intervention whilst

remaining in line with patients and care home requirements. Another modifying factor included in this model were *incentives,* which they described as "*powerful modifiers of behaviour*" (p.46) that therefore affect outcomes. *Loss of learning* often linked to staff turnover was described as impacting on the accumulation of experience. In this way, Waldman et al. (2003) explain that learning can atrophy, when, for example, the provider experiences a long time lapse between patients. In the case of OTCH, OTs reported that they had carried out their job better (learnt more) in those care homes where they treated several participants, since this meant spending regular amounts of time dedicated to implementing the OTCH intervention. Waldman et al. (2003) further describe a number of constraints to learning in healthcare. The first one they proposed were *ethical constraints,* which represent principles and values of the provider or the organization which may influence decision making. This is in line with the refined programme theory area describing 'OTs balancing act'. Throughout their involvement in the trial, OTs balanced the requirements of their research role (e.g. to follow the protocol) with their professional ethos of addressing individual patients' needs. According to Waldman's model, the final constraint on provider learning is *patient volume.* They explained that if the provider sees a high number of patients with similar needs, this will increase their ability to learn how to best address this type of patient. This learning would then produce better outcomes and ultimately this would reinforce the implementation of successful procedures.

In light of the above, further consideration should be given to how learning effects are currently being explored within the context of longer-term, complex rehabilitation interventions. Although training of intervention staff is widely used, and considered necessary in order to increase implementation fidelity (Santacroce et al. 2004, Horner et al. 2006), this training is often carried out mainly at the start of the trial and therefore it has the risk of neglecting how individuals engage, learn and change over time. In response to this, and supported by its findings, this thesis contributes to advancing fidelity research by proposing the inclusion of an additional component in Carroll's (2007) modified (Hasson 2010) CFIF, namely 'learning over time'. This new component is represented in a cyclical way running throughout the

implementation process (Figure 7.1). The results presented in this thesis show that learning curves are inherent in the conduct of clinical rehabilitation trials and therefore integration of this concept into current frameworks of fidelity may contribute by improving research education and strategies. The modification to the framework informed by this study identifies the vital role that 'learning over time' plays in shaping the implementation process. It further accentuates the need for intervention impacts to be regularly evaluated and the need for the development of methods to monitor learning curves and their potential impact on rehabilitation intervention outcomes. Furthermore, it highlights, as in the case of surgical trial research (Cook et al. 2004), a need for further research into identifying suitable measures of learning which are relevant and applicable to the type of complex intervention that rehabilitation researchers deal with. Rehabilitation interventions are likely to be tailored, as practitioners become more experienced, and ´learn' how to best target patients' needs whilst staying true to the protocol.

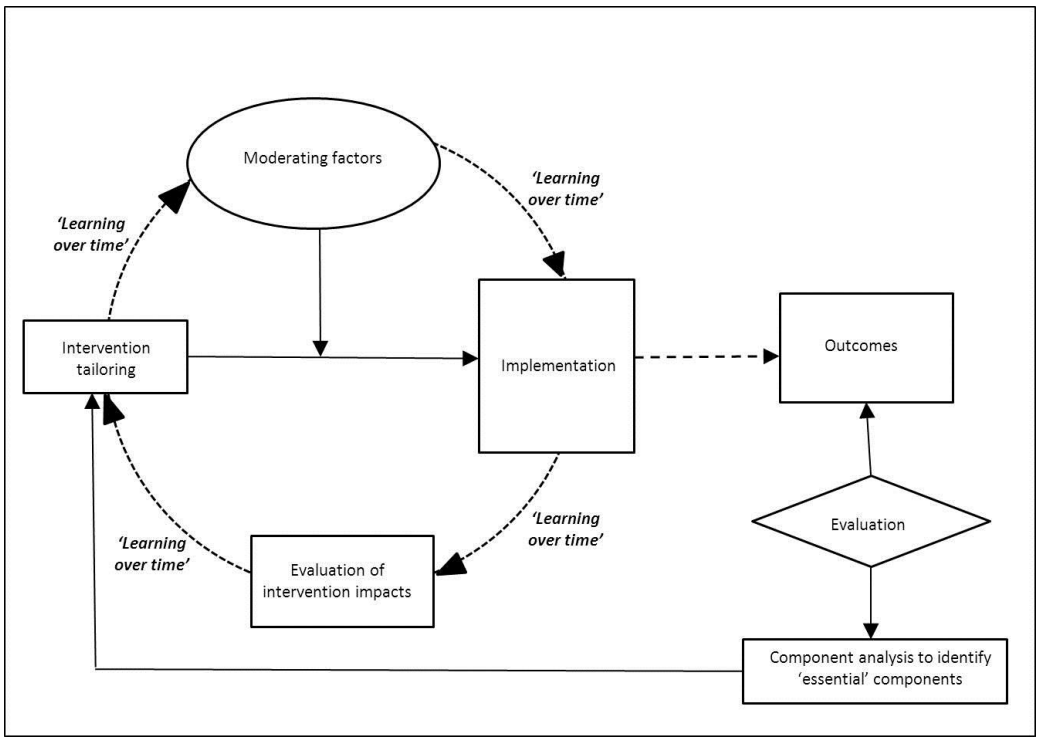

Figure 7.1 Modified conceptual framework for implementation fidelity (CFIF) (modified from Carroll et al. 2007)

The proposed modification to the CFIF framework informed by the results of the research conducted for this thesis is considered to have a direct impact on

the design and development of process evaluations alongside, not only neurological rehabilitation research, but also the wider field of rehabilitation. As previously stated this thesis takes a stance which, although not in line with authors such as Mihalic (2004, p.83), for who "*fidelity is assessed by conducting process evaluations*", is in agreement with Steckler and Linnan's (2002) approach. They consider that a process evaluation can bring clarity regarding some aspects of the 'quality of implementation' (fidelity) of a proposed complex rehabilitation intervention. It can achieve this by exploring, and when necessary measuring, a number of implementation fidelity components. By investigating relevant aspects of fidelity, a process evaluation can aim at identifying the underpinning characteristics of a complex intervention's components and how these impact on its delivery to a set standard (Rossi et al. 2004). A process evaluation will aim at firstly, identifying which fidelity components are vital in order to understand the results from a rehabilitation trial, secondly, investigating program implementation and finally, informing improvements to intervention design and choice of methods.

Although it is often reported that process evaluations are studies that ran parallel or alongside intervention trials (Byng et al. 2008, Grant et al. 2013), there is, to date, no consensus as to how the two are related and what the links between them should be. Authors such as Oakley et al. (2006) argue the importance of maintaining a distance between the process evaluation team and the main study team. Ellard et al. (2011), in their work in the OPERA (Older People's Exercise intervention in Residential and nursing Accommodation) study, reflected on the fact that in their case funding limitations meant that this was not possible and all the members of the team carrying out the process evaluation also had roles in the main trial. However, they argued that in line with recommendations by Oakley et al. (2006), they did analyse process and outcome data independently and this proved helpful in order to generate hypotheses or research questions that could then be tested by integrating both sets of data. Linked to this topic, Grant et al. (2013) argue that although guidelines such as the Consolidated Standards of Reporting Trials (CONSORT) require a series of process data measures, for example in regards to recruitment, it is important that a process evaluation provides a

more detailed examination of such processes, when considered necessary, to inform the interpretation of trial results. This study's researcher considers that outcome evaluation and process evaluation are inextricably linked. The results presented here provide further evidence to support what other authors such as Oakley et al. (2006) have stated; that many RCT designs should integrate a detailed process evaluation, this being particularly beneficial to, not only rehabilitation cluster trials where the intervention is non-standardized, but also pragmatic RCTs. However, the results of this thesis have helped identify the need to further develop methodologies and methods to embed process evaluation more securely in the design of RCTs without compromising their rigour and quality. Most importantly, the process evaluation guidance presented in this thesis tackles this issue by recommending researchers embarking on a process evaluation alongside a rehabilitation trial to address the interactions between process and outcome evaluations. It further advises that researchers should decide if they take the risk of threatening the outcome evaluation via evaluating processes or if they accept that there will be tailoring, which they can then guide through the process evaluation.

The question is then *when and how often should implementation fidelity be assessed?* As reported by Bond et al. (2000) complex interventions are not static and neither are the previously described components of fidelity. To the contrary, they are dynamic and will potentially change over time. Findings from this study contribute to the body of evidence by identifying 'learning over time' as a vital factor accentuating this dynamic nature of rehabilitation interventions. In the proposed modification to the CFIF framework 'learning over time' is represented in a cyclical way. This addresses the need for ongoing assessment of fidelity, which has been reported by several authors as being important in order to maintain consistent implementation of the intervention over time (Hill et al. 2007, Perepletchikova et al. 2007). By failing to do so, rehabilitation researchers can significantly reduce their chances of adapting and correcting the trialled interventions; this is particularly important in those cases where the drift between the planned intervention and what is actually happening is too great (Teague et al. 1995) or as the findings of this study support, the impact of 'learning over time' is significant. However, the

researcher in this study, like other authors, understands that monitoring implementation fidelity too often could lead to an unnecessary waste of resources and an unmanageable accumulation of data (Mowbray et al. 2003, Breitenstein et al. 2010) and therefore there is a further need for feasible and cost-effective strategies to evaluate fidelity (Perepletchikova et al. 2007).

The proposed modification to the CFIF framework is considered to increase its degree of tailoring to rehabilitation research interventions by addressing the particular challenges linked to this field. As previously discussed, rehabilitation interventions, more so than other healthcare interventions have a strong 'learning component'. As discussed in Chapter 1, rehabilitation trials have, until recently, largely evaluated fidelity at an intervention level, as opposed to current healthcare research which is moving towards the use of fidelity measures and conceptual models, such as the CFIF. Fidelity measures are mostly designed for use across various interventions (Hogue et al. 2008, Breitenstein et al. 2010). However, their application to rehabilitation has not, to date, been tested. As Breitenstein et al. (2010) explain, there are potential benefits of developing fidelity measures that can be used across similar interventions. Fidelity measures like the CFIF, which can be broadly applied to similar interventions, might help with the development of standardized methods for evaluating fidelity across a variety of settings and interventions. The findings here reported add to previous work by authors such as Poltawski et al. (2014) who successfully modified the NIH Behaviour Change Consortium fidelity framework (Bellg et al. 2014) to meet the characteristics of their exercise-based rehabilitation program for long term stroke survivors. The modifications to the CFIF presented in this study address the widely agreed (Whyte and Hart 2003, Poltawski et al. 2014) need for the development of rehabilitation-specific frameworks and measures for the evaluation of implementation fidelity.

7.2.1.2 A new refined programme theory for fidelity to underpin process evaluation research

As discussed at the onset of this thesis, rehabilitation interventions are often complex. This means that it is extremely challenging for the researcher to

accurately assess how they work. The findings reported in this study contribute to advancing methodological approaches to the investigation of complex rehabilitation interventions, their multi-component nature and the interactions between components. In line with the need identified by Clark et al. (2013), the new refined programme theory reported in this study addresses the OTCH intervention components, not only in terms of their individual and combined power, but also in terms of their relation with the intervention as a whole. Most importantly, the results from the OTCH process evaluation have contributed to provide evidence supporting the fact that it is not possible to separate out the programme theory of an intervention from the programme theory about its implementation. The four areas comprising the refined programme theory reported here (OTs balancing act, building rapport, OTs promoting independence via re-engineering the care home environment and OTs learning over time) meld hypotheses embedded within the therapeutic components of the intervention and from its broader implementation.

Findings from the systematic review presented in Chapter 5 showed that there is a strong need for process evaluations alongside rehabilitation research trials to investigate and monitor in detail the level of tailoring that is taking place when providers deliver the trialled intervention. The refined programme theory developed in Chapters 3 and 4 reports on tailoring as a 'balancing act' where intervention providers try to find a middle-way between patients' preferences and the requirement to follow the trial's protocol. In the OTCH process evaluation case study, the tailoring was shown to be linked to a number of balancing acts across a number of aspects of the OTs practice: intervention providers had to reconcile the intervention purpose with their personal beliefs around their proposed therapy, the participants needs and abilities and capacities to carry out intervention plans within resource constrains. This new proposed refined programme theory adds to current published research reporting the fact that there is more to delivering an intervention than just measuring how many elements were delivered (Harshbarger et al. 2006, Hawe et al. 2008). As previously discussed, in today's healthcare research, where client centeredness plays a major role, there is an increase in awareness of the need to tailor interventions to patients' needs and cultural background

(Morrison 2009). Interventions that have been designed and tested with participants that are all the same in terms of race, ethnicity, economic background or religion will have very limited generalizability (Castro et al. 2004). However, as the results of this study show, in order to be able to replicate interventions across settings or cultures it is necessary to adapt them to some extent and this generates a tension between the need for standardization and the need for tailoring. According to Morrison (2009), unavoidably initial studies will be very different from consequent replication studies; whilst in the first study facilitators will have leeway to adapt or discharge components, in the replication study staff will actively be told not to make changes. This could lead to providers feeling like they have 'less ownership' which could ultimately lead to less commitment. This study's findings contribute to further develop the current understating of the underlying mechanisms underpinning the often unavoidable tailoring of rehabilitation interventions. Prior to this study a number of authors have addressed the issue of tailoring. For example, the SPIRIT intervention (Song et al. 2010) was designed to enhance discussion with patients and their chosen surrogate decision makers regarding end-of-life care. The authors reported that for this intervention to have the potential to be effective, and be welcomed, it required to be tailored to people's needs. However, as the authors argued, that tailoring did not mean that the provider could improvise what he/she did, it meant that what was standardized would have to be contrasted and clearly defined and monitored against what was customized. As a result, Song et al. (2010) stated that the assessment of fidelity would have to be standardized and tailored to the actual level of standardization and tailoring of the trialled intervention. Song et al. (2010) reported the importance of identifying the delivery of unplanned components and proposed a rating tool with a number of elements (attempted, completed, deviated and skipped) which was used to assess if, and how well, the components were delivered. They concluded that this measure could work by helping to identify which aspects of the intervention needed to be included at the time of re-training providers to 'stick to the protocol'.

Although a number of steps in order to try to understand the complexities underpinning the need to tailor interventions are being made, several authors

(Morrison 2009, Song et al. 2010) have identified the addressing of 'the science of client centred replication' as a major challenge for today's health care research. The findings from this study have contributed to further bring light to this issue in the particular case of neurological rehabilitation interventions. However a solution to this challenge remains unclear and is in urgent need of further development.

One of the conclusions emerging from the findings from the process evaluation systematic review (Chapter 5) was the strong need for process evaluations alongside rehabilitation trials to clearly describe intervention staff skills and experience prior to joining the research and investigate how these may influence outcomes. The refined programme theory presented in Chapter 4 identifies the impact of staff's level of experience as a contextual factor which could potentially trigger the mechanism of 'balancing requirements'. Thus, rehabilitation intervention providers with prior research experience, for example, can appear to find it easier to achieve a balance between their research and therapy expectations. Similarly, those therapists with previous experience of practice in the rehabilitation intervention field can potentially be better at balancing rehabilitation treatment plans around patients' co-morbidities. Thus, they are likely to produce realistic intervention plans that address patients' needs whilst focussing on the intervention under investigation. In line with what previous authors have reported (Kerns and Prinz 2002, Bellg et al. 2004), the findings of the OTCH process evaluation show that providers that arrived to start work in a trial confident of their extensive clinical experience, may have, at times, found it harder to resist tailoring the study interventions to their clinical worldview. This had obvious consequences to fidelity. In other words, the scope of change required from the provider, in order to implement the rehabilitation intervention, might mean a shift in a therapist's holistic clinical paradigm towards a functional approach. Such a shift can strongly impact on the success of implementation and its fidelity (May and Finch 2009). The findings from this thesis strongly support what has been previously suggested by Bellg et al. (2004) when reporting that the level of expertise that intervention providers have when joining a research team will influence the way in which they deliver the trialled intervention and

therefore it is likely to have an impact on outcomes. This thesis provides further evidence to 1. Justify the need for researchers to give this issue consideration when planning and designing a research study (Horner et al. 2006). 2. Probe that those intervention providers lacking in experience will rely heavily on the protocol to inform their decisions and increase their confidence. 3. Probe that very experienced providers will be more at risk of proposing strategies which are out of the scope of the trial (Bellg et al. 2004).

Training of intervention staff is necessary in order to increase implementation fidelity (Dumas et al. 2001, Santacroce et al. 2004, Horner et al. 2006). In regard to this, the literature says that in order to maximize the chances of all participants receiving the same intervention, staff will need to be trained to a uniform standard (Dane and Schneider 1998).This will avoid researchers concluding that an intervention is ineffective based on staff having different levels of competence (Waltz et al. 1993, Perepletchikova et al. 2007). Furthermore, as findings from the systematic review (Chapter 5) show, there is rarely mention of a performance criteria, or assessments in place to measure skill acquisition post training and throughout the research program. As an exception it is worth mentioning the TRACS study (Forster et al. 2013) which looked at the impact of a structured training program for caregivers of stroke inpatients. Researchers on this trial defined a list of mandatory training components for intervention providers. Furthermore they arranged local training sessions, when necessary, to provide feedback and support. Additionally all centres involved in the trial were offered a local refresher course midway through the trial.

Training provides a chance to both discuss the philosophy underlying the intervention and practice the necessary skill set (Bellg et al. 2004). Through training and supervision, the work of the intervention providers who, in most cases, will already have experience in the trialled intervention, can be refined to fit with the trial's scope (Santacroce et al. 2004). In a similar way, intervention providers can be trained to avoid using their usual approaches when these are not within the remit of the trial (Santacroce et al. 2004). However, training and supervision of rehabilitation staff will not guarantee that

all participants will be exposed to the same program. The results reported in this thesis provide evidence to support that, as a number of authors in a number of different healthcare disciplines have agreed, there is a need for further assessments of staff performance and ability to adhere to the protocol in order to assess implementation fidelity (Sechrest et al. 1979, Kazdin 1986, Bellini and Rumril 1999, Hennessey and Rumril 2003). Findings in this study support the need to carry out these assessments at the time of training intervention staff in their role as rehabilitation intervention providers. Measuring skill acquisition post training in a variety of ways such as quizzes and questionnaires (Chung 2009) can play a major role in addressing the impact of staff's skill level in future outcomes.

7.2.2 Contribution to the realist evaluation body of evidence

This study's contribution to the realist evaluation body of evidence was provided through conducting a realist process evaluation of a complex neurological rehabilitation intervention trial, the OTCH study, and using this as a case study. Throughout the process evaluation, realist evaluation provided the methodological framework. The results from the OTCH process evaluation have shown that it is possible to use a realist evaluation lens to investigate the complex underpinnings driving a complex rehabilitation intervention and its implementation. Realist evaluation was useful at maintaining the focus and supported the development of detailed knowledge about the principal mechanisms which had the potential to contribute to, and impact on, the OTCH intervention outcomes.

The value of realist evaluation and its potential role in enhancing RCTs, such as the OTCH trial, is the source of an ongoing debate. On the one hand, authors such as Bonell et al. (2012) advocate the design and conduct of realist RCTs. According to them, these bring a new approach to evaluation science which "*addresses these gaps while preserving the strengths of RCTs*" (p.468). On the other hand, Marchal et al. (2013) strongly argue that the epistemological basis of RCTs and realist evaluation are fundamentally different (Marchal et al. 2013) and that a 'realist approach' should only be applied to studies that truly follow a realist philosophy and principles. Thus

they describe realist RCTs as an ‘oxymoron’. Bonell et al. (2013) in answer to this have reported that they reject the common belief that RCTs are necessarily positivist and that methods should not dictate the researcher’s epistemological stance. The results reported here advance the body of evidence to support a balanced solution, proposed by authors such as Byng et al. (2008) and Marchal et al. (2013), which argues for the benefits of using realist evaluation alongside trials and process evaluation research. Jamal et al (2015) state that what these authors suggest is clearly different from the realist RCTs they propose. These authors have recently published the first example of the theoretical and methodological process of undertaking a realist RCT, embedded in the evaluation of the Learning Together (LT) cluster trial, looking at the benefits of a restorative approach to reduce student bullying. Although the RCT follows a protocol, the authors report on its expansion in order for the trial ‘to be realist’. This is achieved by introducing a number of stages in the research process which involve firstly, the generation of a logic model, secondly, the identification of hypothetical CMOs that are then refined with data gathered via an embedded process evaluation, and finally the production of a mid-range theory of change. Thus, the authors consider that a realist RCT will be able to, not only evaluate the effectiveness of the LT intervention in its particular context, but also to go further by providing a mid-range theory. The authors recommend realist RCTs to be guided by a published protocol, but they embrace the ability of the researcher to allow for some iterative modifications informed by the process evaluation data. The effectiveness of the methodological approach, that Jamal et al. (2015) present, is yet to be assessed and to date no results are available.

In realist evaluation, knowledge production is considered to be a cumulative process. This means that the result from a realist evaluation will be “*the best we think we know so far”* (Westhorp et al. 2011, p.4) and that improved understanding over time will impact on the realist cycle. The realist cumulative aspect of knowledge has provided this work with a greater freedom to understand the ‘here and then’ without closing up to the future. The researcher believes that understanding fidelity of complex rehabilitation interventions is closely in tune with this concept of cumulative knowledge. The researcher

considers that the realist process evaluation reported here has generated a refined programme theory which is in line with the realist cumulative aspect of knowledge. This programme theory has the potential to inform future rehabilitation process evaluations and this process will follow a realist cycle which will contribute to the cumulative process and will further refine the proposed programme theory areas.

As Marchal et al. (2012) and Salter and Kothari (2014) explain, there is great diversity in how realist evaluation principles and terminology have been applied to health research to date. Having the 'realist evaluation cycle' underpinning the OTCH process evaluation proved useful, since it was this cycle that guided the process from an initial programme theory to a final refined one. Furthermore, the findings from this thesis prove that the identification of CMOs can help analyse the links between the intervention (in this case OTCH), the context and the mechanism in order to explain why, when and how impacts on outcomes took place. This is in line with work by Byng et al. (2005). They concluded that realist evaluation was a useful approach as long as its principles were not slavishly adhered to. As has been reported by Marchal et al. (2014), although a range of methods have been used to present CMO configurations, to date there is no hard and fast rule regarding how best to report them (Pawson et al. 2011, Salter and Kothari 2014). After trialling the use of tables and grids which did not prove useful, the researcher believes that this study's chosen method, through narratives, was successful in explaining what it was in the OTCH intervention that worked, for whom and how. The narrative structure in which the CMOs constituting the refined programme theory were described was believed to achieve the maximum integration of contexts, mechanisms and outcomes. The findings here reported are considered by the researcher to further develop approaches to the reporting of CMOs.

There are only a handful of studies reporting on process evaluations following a realist evaluation methodology (Byng et al. 2008, Harris et al. 2013 and Randell et al. 2014). The realist OTCH process evaluation is the first one carried out alongside a neurological rehabilitation trial. One example is the

work carried out by Byng et al. (2008). They carried out the process evaluation of an intervention to improve primary healthcare for patients with long term mental illness. They reported that in contrast to 'realist evaluation diagrams', where single mechanisms and context are brought together to illustrate the theoretical framework, they found that in reality there were multiple contexts and multiple involved mechanisms that brought about an outcome. They further explained that the search for CMOs was more daunting than they initially anticipated. However, Byng et al. (2008) reported that through realist evaluation the team was able to identify the interactions taking place, not only between intervention components, but also with the embedded external context. This is in line with the findings reported in this study. The researcher was aware that, through the identification of CMOs, the study achieved a better insight into how the intervention was carried out, what worked and for whom and this provided a knowledge based understanding of the trial's results. Importantly, in line with what several authors (Bate et al. 2008, Westhorp et al. 2011, Roberts and Fulop 2014), have proposed, the realist process evaluation of the OTCH trial is a clear example of how this approach has maximized the researcher's understanding of the relationship of the OTCH intervention with its context. Context investigated longitudinally (context as a process) and not in terms of cause-effects.

Realist evaluation recommends the use of a range of data collection sources whilst following a pragmatic selection appropriate to the hypotheses generated (Pawson and Tilley 1997); for practical reasons concerning time and resources the results from the OTCH process evaluation were strongly reliant on qualitative in depth interviews, critical incident report data and intervention logs (quantitative data). Realist evaluation principles allowed the researcher to take a pragmatic view and use quantitative data to inform and complement qualitative results. Thus, the findings from this study contribute to proving the compatibility of using mixed methods within a realist evaluation (Salter and Kothari 2014). These findings provide further evidence on how realist evaluation is neutral in terms of acknowledging the richness in mixed methods.

The findings reported here can help ameliorate some of the main challenges that had been linked to the implementation of realist evaluation. Firstly, the research described in this thesis provides a further example of its application which researchers applying realist evaluation can use as a guide for their work, especially at the time of following the process of identification and definition of contextual factors and linked mechanisms. The difficulty in distinguishing between what is 'context' and what is 'mechanism' has been reported by several authors (Ranmuthugala et al. 2011, Goicolea et al. 2013, and Dixon-Woods 2014) who have also argued the need for further research. In 2014, Dixon-Woods argued that context-mechanism debates are *tedious* and *unproductive* and that it is in fact impossible, close up, to distinguish mechanisms from context, this being especially true when dealing with complex interventions. Also, as previously discussed in detail (Chapter 2) there is little consensus in what constitutes a mechanism (Dixon-Woods 2014, Dalkin et al. 2015) or what should be the proposed methods for elucidating them and reaching high level conceptualisations (Øvretveit 2014, Salter and Kothari 2014). In this thesis, lengthy discussion and several iterations were necessary at most of the stages of the process, especially at the time of developing the refined programme theory. This study has attempted to identify and distinguish mechanisms from context in a number of ways that required extensive study and discussion amongst the researcher and team members. Results reported in this study attempt to help ameliorate this difficulty for those researchers thinking about embarking on a realistic evaluation.

Furthermore, this study has contributed to the body of evidence supporting the potential role that realist evaluation can play within RCT research (Byng et al. 2008, Mackenzie et al. 2009 and Marchal et al. 2013). The findings from this study provide evidence to suggest that realist evaluation can assist by informing those running and designing rehabilitation RCTs of the underlying mechanisms which could lead to impact on outcomes when triggered by particular contextual factors. The refined programme theory for fidelity reported in this thesis has the potential to be applied to future process evaluations alongside rehabilitation RCTs. It can contribute to guide the researcher towards the exploration of contextual conditions which can lead to

intervention mechanisms taking place. For example, researchers will be aware of the need to provide a context, which supports rapport building amongst trial participants and intervention staff, in order to prompt positive relationships and ultimately higher level of engagement and impact.

A recent paper by Munro and Bloor (2010) critiques current definitions of process evaluations, as leading researchers to place 'too high expectations' on what the process evaluation could help achieve. In their words they explain that current definitions are expecting "*an awful lot of bangs for their buck"* (p.701). They consider that the explanatory burden being placed on process evaluations is unrealistic. They further argue that these high expectations can lead the researcher into mis-designing the PE and end up with 'too much' for a high cost. This has been reported by other authors as well (Hong et al. 2005) who argue the need for researchers to be realistic and design process evaluations that have a clear set of aims and objectives, as any piece of research should. By applying the realist cycle to the OTCH process evaluation the researcher was able to gain an in depth understanding of the 'anticipated' factors that would impact on outcomes. This minimized the risk of collecting unnecessary data, just because 'it would be nice to have it'.

To sum up, in line with what Grant et al. (2013, p.15) have said, "*There is no single way to design and carry out a process evaluation*". The nature of rehabilitation research means that researchers will be faced with choices about what aspects of the intervention and its delivery to focus on, and what methods to select in order to address these. The refined programme theory, which has resulted from the OTCH realist process evaluation, can help neurological rehabilitation researchers at the time of designing and conducting their own process evaluations alongside complex intervention trials.

7.2.3 Contribution to guideline development

Findings from this study report on a methodological guidance to assist rehabilitation researchers at the time of designing and conducting process evaluations alongside trials of complex interventions. The proposed tool can help mitigate the current situation of researchers, discarding the idea of

carrying out a process evaluation based on perceiving it as a daunting task. This guideline contributes to advance the body of evidence reporting on process evaluation methodologies in a number of ways. Firstly, it addresses the need, reported by Grant et al. (2013), for evidence-based guidance on how to design and conduct process evaluations alongside rehabilitation trials. Although rehabilitation researchers are the main target audience for this guideline, the researcher considers that it is also relevant to other stakeholders, such as funding agencies, in order to inform their decisions regarding allocation of funding. Secondly, its recommendations are tailored to address the particular challenges that define rehabilitation research, its processes and theoretical underpinnings. In this way, and in answer to a need that has been previously identified by several authors (Grant et al. 2013, Moore et al. 2014b), this guideline's recommendations allow for sufficient flexibility and room for manoeuvre in order for them to be tailored to the type of intervention and the type of study, whilst facilitating standardisation of research practice. Furthermore this guideline includes recommendations which address the current lack of clarity in regards to the reporting of the aims of process evaluations (Grant et al. 2013). Finally, and in agreement with Ellard et al. (2011), this guideline places importance on the need for the process evaluation design to be theoretically underpinned in the same way as the design of a RCT is meant to be.

As discussed in Chapter 6, to date, one guidance has been published in this matter, the MRC guidance for carrying out process evaluations in health research (Moore et al. 2014a). The authors of this guideline argue that it is helpful if process evaluations of trials looking at similar complex interventions build on each other's findings and use methods that can be comparable. Although applicable to complex interventions this guideline presents a number of limitations. Firstly, the dynamic nature of context, created by the implementation of the trial intervention over time is neglected. Secondly, over time learning effects are ignored. The guideline proposed in this study includes a series of recommendations which address both these limitations. Thus, the results presented in this study advance the body of evidence on process evaluation guidance.

The NGT (Rycroft-Malone 2001) proved effective in offering a formal consensus approach in order to produce the guideline proposed in this study. It further provided an opportunity for collaborative working between rehabilitation researchers and the PhD student. The original formal consensus method (Rycroft-Malone 2001) had to be modified to fit the characteristics of this piece of research. However, the researcher paid particular attention to making sure the necessary modifications used to investigate expert opinions were clearly described and made explicit. As a result, the researcher believes that the modified formal consensus method described in this study contributes to advancing the development of this type of approach to consensual guideline production. This method proved to be successful at mixing strands of evidence, with some recommendations being more research-based and others more consensus-based. Regardless of this, the researcher is aware that the methods used here for consensus building will need to be refined and open to scrutiny, and, that it is by doing so, that guideline development methods will be further developed. Finally, it is important to mention that although the NGT proved useful, a limitation for the use of this method was identified during the first phase of the consensus work. Participants critiqued the fact that the rating of statements did not allow them to rank the statements in terms of their relative importance. Further work to advance this method is advisable in order to assess the potential need for ranking and its usefulness in increasing the uptake of proposed guidelines.

Grimshaw and Russell (1993) reported that guidelines will have greater scientific validity if they are developed from systematic reviews and include opinions from most key disciplines and a few potential users. The guideline produced in this study would therefore be considered scientifically valid since it was developed from results from a systematic review and also feedback from a panel of experts who belonged to key rehabilitation disciplines and were the potential guideline ‘users’. However, it has also been argued that guidelines that are not entirely developed using research evidence, such as the one presented in this study, which uses consensus opinion methods, can be less robust (Grimshaw and Hutchinson 1995). The researcher, in line with authors such as Trickey et al. (1998), considers that limiting the production of

guidelines to those areas that have sufficient research evidence could reduce the chances of further development of research that could ultimately improve quality of care.

The researcher understands firstly, that further work will be required to test the usefulness and applicability of the proposed guideline to the work that rehabilitation researchers are currently undertaking. Secondly, that it is likely that this guideline will be read and used by those researchers who share its underpinning assumptions in regards to the nature of complex interventions. Regardless of this, the researcher understands that process evaluations are complex and diverse and that the proposed guideline can contribute to a more structured approach to their design and ultimately to improving the validity and dissemination of rehabilitation trial results.

7.3 Strengths and limitations of this study

The findings reported in this study have resulted from research that draws from a variety of methods, in order to answer the research question. The overall strengths and limitations identified in the research, will now be examined and reflected upon.

The study findings need to be placed in context. The researcher is aware that whilst it is not possible to draw generalizations from one study (which was not the purpose of this study), the findings here reported provide an in depth degree of insight into the particular challenges and contextual factors underpinning rehabilitation research. However, the researcher is aware of the fact that the scope of this research is limited and that what is presented here will need to be further tested. The proposed refined programme theory for the investigation of fidelity will require further testing, and its applicability and usefulness will need to be assessed in other process evaluations, in order to identify for example the need for further modifications of adaptations. As already discussed, neurological rehabilitation research involves a wide range of interventions belonging to a wide range of disciplines. Thus, future studies will need to be carried out in order to apply the OTCH process evaluation

refined theory areas to other contexts, including an array of neurological rehabilitation interventions.

In regards to data collection methods: one of the main data collection methods used in this study, in both, the OTCH process evaluation, and the consensus work, were in depth interviews. Although the participants were considered to be open in their responses, and their answers reflected their own experiences, this cannot be completely guaranteed. For example, during the OTCH process evaluation data collection stage, the researcher was aware that prior to the interview, OTs might have felt that the interview was 'testing' how well they did their job in the trial and this could have impacted on the level of honesty. The researcher was aware of the importance of rapport building (Mason 2002) and equal balance of powers between the interviewee and the researcher (Fontana and Frey 2000) to generate rich data. Thus, during introductions, the researcher explained that the purpose of the interview was not to assess the OTs work which appeared to relax some participants. Finally, the researcher carried out two pilot interviews, after which she received feedback, which further contributed to maximising the chance of later in depth interviews to collect rich data.

In terms of quantitative data collection during the OTCH process evaluation, the researcher faced a number of limitations when trying to access the necessary data. These were out of the control of the researcher, who had to limit the amount of quantitative data to that contained in the OT intervention log (Appendix 3.4).

A key strength of the research presented in this thesis is the varied nature of chosen methodologies and data collection approaches. This study, by using both quantitative and qualitative data, has been able to broaden the scope of enquiry in order to better evaluate complex rehabilitation processes. This is supported by several rehabilitation authors (Rauscher and Greenfield 2009, Shaw et al. 2010). The researcher challenged the dualistic views (positivist versus interpretivist) and argued that the ontological and epistemological views underpinning a piece of research should not disregard data collection methods but be independent of them (Johnson et al. 2004, Denzin and Lincoln

2005, Greene 2007). In answer to Kroll et al. (2005), who argued the need for rehabilitation researchers to pay attention to the methods chosen for the integration of mixed data, the results from this study have advanced current methodologies and provide a new approach to data synthesis. Authors such as Bryman (2007) and Coleman et al. (2007) identified the lack of evidence of genuine integration of quantitative and qualitative findings. This study has addressed this issue and has payed attention and justified decisions regarding the integration of mixed data and the priority assigned to each type of method, as recommended by Kroll et al. (2005). Although, as widely reported (Lincoln and Canella 2004, Giddings 2006, Creswell 2011), healthcare research still assigns prominent role to quantitative methods, findings such as the ones reported in this study can play a role in advancing the evidence to help current research reach a more balanced stance.

Regarding the systematic review: the overall aim of this systematic review was to understand how process evaluations are being carried out alongside neurological rehabilitation research. The protocol for the systematic review was followed with no major changes taking place. However, there are still a number of limitations that are worth exploring.

Although database searches, carried out in order to identify studies to be included in stream I, were informed by reliable sources and an expert librarian reviewed the search strategies, there is a possibility that relevant studies were not identified. The main reason for this relies in the fact that the term 'process evaluation' is not as yet, considered a 'MeSH heading' in any of the databases that were searched. As a consequence, the researcher used a wide range of term combinations to the best of her knowledge.

A high proportion of evidence, found to be included in stream I, were process evaluations alongside RCTs. Although the inclusion criteria was broader, the fact that so many of them were RCTs could mean that the findings might have greater relevance to researchers thinking about this type of research design. Also, this systematic review did not carry out a formal appraisal of included studies, this was due to a lack of available tools to critically appraise process evaluations (Grant et al. 2013).

Evidence in this review cannot be universally generalizable to all types of designs in neurorehabilitation and all different conditions. However, it still offers a better understanding of the current state of process evaluation research. Finally, only studies written or translated into English were included in this review (because of limited financial resources to translate); there is a chance that, by doing this, a number of relevant studies, written in other languages, were left out.

Regarding consensus work: the number of participants who took part in both phases of the consensus work was lower than originally anticipated, due to reasons outside the control of the researcher. However, all participants were highly experienced in carrying out rehabilitation research and were all academics. In hind sight the researcher acknowledged that it would have been useful to aim at having a number of participants working in other related sectors such as funding agencies. This could have provided the researcher with a broader understanding of the possible uses and strengths of the proposed guideline. Regardless of this, the researcher considers that the participants that took part provided very rich data which was highly relevant to rehabilitation research, and therefore does not consider that this limitation had a negative impact on the final product.

The modified consensus NGT method (Rycroft-Malone 2001), used in the creation of this guideline, proved to be fairly straightforward. The nominal group meeting was demanding upon participants because there were a large number of recommendations to discuss. Also, it was hard for the researcher to judge how successfully 'group dynamics' were controlled and how much the personality and compliance of the participants impacted on the cooperation of the panel of experts. The process was designed to minimize possible impact of these factors, but, due to the limited experience of the researcher in chairing this type of meeting, this was not guaranteed. The researcher considers a number of additional strengths in this piece of work. This consensus work provided an opportunity for the researcher to be involved in collaborative working amongst a number of rehabilitation researchers from a number of different disciplines. Finally, as Rycroft-Malone (2001) points out, the use of a

collaborative approach, by listening to experts in the field, could have a positive impact on the ultimate uptake of the guideline as it is seen as being more credible.

7.4 Recommendations

The results documented in this thesis highlight a number of key areas that require further consideration in the sphere of research in rehabilitation and policy.

7.4.1 Recommendations to research

Based on the findings reported in this study, the following areas are suggested as priority areas for enacting change in the application of research practice.

For this study, the novel use of realist evaluation has highlighted the potential contribution of this methodology to advancing new knowledge in fidelity and process evaluation research, particularly when dealing with complex rehabilitation interventions. The results reported in this study highlight the importance of addressing the impact that intervention providers' learning over time can have on outcome. However, much more needs to be understood about the ways in which this learning component operates. This study's findings can illuminate the impact of learning over time, so that future research studies can benefit from addressing it throughout. This study has uncovered necessary modifications to current frameworks for the investigation of fidelity. Future research can be used to further test and refine these frameworks, in order to maximise their tailoring to other areas of rehabilitation research. Additionally, results from this study provide the evidence to suggest that there is a need for more research in order to determine the minimum frequency of fidelity monitoring that is necessary to maintain quality and identify learning curves and their potential effects. In line with this, the proposed refined programme theory for the investigation of fidelity that is reported in this study should be tested for its usefulness in understanding how other types of complex interventions, in other contexts belonging to a wide range of rehabilitation disciplines, work. Finally, the researcher recommends the

application of the refined programme theory for fidelity reported in this thesis to a variety of process evaluations alongside neurological rehabilitation research. In this way its effectiveness in guiding the researcher will be further assessed.

As previously mentioned, this study has provided evidence on the potential role that realist evaluation can play within RCT research. Realist evaluation can assist by informing those running an RCT of the underlying mechanisms which could lead to impact on outcomes when triggered by particular contextual factors. The findings in this study suggest that the quality of evidence emerging from an RCT trial informed by realist evaluation will be greater. More work needs to be done to further develop potential links between realist evaluation researchers and those involved in the design and running of RCTs.

The results reported in this study raise important issues for the conduct of research trials, especially those, such as OTCH where OTs were required to focus on a particular aspect of rehabilitation (in this case ADL activities) and follow a protocol whilst addressing individual patient's complex needs. Those recruiting therapists to deliver similar interventions may want to give this closer attention: *What should the essential requirements and optimum experience level of practitioners in charge of implementing a new intervention be?* Results from this study provide evidence to show the need to give greater attention to how intervention staff's clinical or research experience can influence fidelity. Thus, it is obvious that careful recruitment of practitioners is very important. However, their training, and on-going supervision, is equally paramount to the success of implementation (Dumas et al. 2001, Bellg et al. 2004). As the findings in this study show, there is a need for researchers to give close attention to the training of staff in charge of delivering the rehabilitation intervention. Decisions regarding its contents, the scope, and the learning outcomes expected from the training, will require close attention from those researchers aiming at identifying the effectiveness of a rehabilitation intervention.

In line with what several authors have previously identified (Grant et al. 2013,

Slaughter et al. 2015), findings from this study have shown that to date there is no consensus regarding process evaluation terminology; the results here reported provide an excellent opportunity to engage the rehabilitation research community in creating one that reflects the nuances of research in this field.

The guideline for carrying out process evaluation in rehabilitation research that is proposed in this study updates and tailors its coverage to the particular challenges inherent to rehabilitation research, its process and theoretical underpinnings. The researcher, in agreement with Grant et al. (2013), considers that it is vital for process evaluations to be tailored to the type of intervention and the type of study. Thus, further research will be needed in order to test how this guideline is used, and applied by rehabilitation researchers, working to assess the effects of a wide range of rehabilitation interventions. The degree of adaptability (flexibility) of the guideline will require close attention. Furthermore further research is necessary to assess its relevance to stakeholders from other research domains, such as funding agencies, at the time of making decisions regarding allocation of funding.

7.4.2 Recommendations to policy and guidance

The findings presented in this study provide further evidence of the need for researchers to carry out process evaluations complementary to outcome evaluations. As Moore et al. (2014a) argue, outcome evaluations conducted in isolation take the risk of leaving many important questions unanswered. They further state that "*process evaluations aim to provide the more detailed understanding needed to inform policy and practice"* (p.10). In line with this, a number of recommendations are suggested as priority areas for enacting change in the application of policy and guidance, based on the findings from this research.

Future government policies and guidelines, produced to inform the investigation of complex interventions, should address their inherent and unavoidable multi-component nature and therefore step away from focussing on standardization and terms such as 'blinding', 'control' or 'care as usual'. Thus, these policies should give contextual factors a prominent role, which will

need to be addressed when attempting to understand the underlying mechanisms of these type of interventions.

Furthermore, policies should re-inforce and incorporate the requirement for the development of process evaluations linked to research trials. These policies should: 1. Ensure provision of sufficient resources in order to do so and 2. Require funding agencies to include process evaluations as one of the eligibility criteria that researchers have to fulfil in order to be able to apply for funding. This will minimize the risk of wasting resources on testing interventions that are not guaranteed to be implemented as planned (Mowbray et al. 2003). Process evaluations should be treated as a piece of research in their own right. Thus, researchers applying for funding should produce a detailed process evaluation protocol.

The findings reported in this study have provided further evidence on the effectiveness of using a mixed method approach to answering a research question. Thus, government policies and guidelines informing the research of complex healthcare interventions should reinforce the importance of including qualitative research throughout the research process, not only during the initial stages. Also, these policies must require that the researcher justifies the use of both qualitative and quantitative methods, and provide a clear explanation of how both data sources will be synthesized.

7.5 Reflections on the research process

As Freshwater and Rolfe (2001, p.534) explain, reflexivity is the way researchers *"incorporate their social self into the research project"*. During this study it was important for the researcher to construct a reflective account of the research process; this has been described as an essential component in order to maximise rigour in a study, especially if the study includes qualitative enquiry (Woods 2003). In line with what Carpenter and Suto (2008) argue, from the start of the PhD, the researcher considered that through reflection and self-evaluation she would be able to interrogate her own beliefs and feelings in order to see how these might have impacted on the process. Thus,

the researcher made a conscious effort to consider aspects of reflexivity throughout the research process. This was done by keeping a log of notes which included ideas, plans, decisions and summaries of particular challenges and critical points. This chapter will now explore, using the first person, the researchers reflexive PhD journey.

From the very start of the PhD I was aware that I needed to explore how my own experiences could impact on the research process. My own professional background was one of the main factors that, I knew, could impact on the research process. My first degree was in ocean sciences and this was followed by a masters in research in this same field and a job as a research officer in a marine sciences research institute. After four years I decided to change careers and I trained as an OT. Soon after qualifying as an OT I started this PhD. The four years during which I carried out marine research had an impact on the way I view research, its purpose and its challenges. It was during my OT training that I was first introduced to qualitative health research, and although I was convinced of its value, I found it hard to open up to its possibilities. Starting a PhD, which required me to understand not only the value of numbers and measurements, but also the value of people's opinions and their interpretations of the world around them, was 'a shock to the system', to put it mildly. This PhD journey has followed a steep learning curve which has finally led me to an in depth understanding of what healthcare research should strive for.

Prior to starting this PhD I had no prior experience of realist evaluation. Initially, I found it hard to understand this approach and how it could be applied to my study. Through reading and discussions with researchers in the area I developed an appreciation for this approach and I was able to identify its potential benefits. Writing and submitting a paper (Masterson-Algar et al. 2014) during the second year of my PhD, which reported the findings from the realist OTCH process evaluation, further increased my confidence in my ability to apply this approach. Similarly, my qualitative research skills prior to this PhD were very limited. However, during this PhD journey I have become confident and familiar with qualitative methods. Reflecting on my clinical background and

experiences at the time of collecting and analysing qualitative data was essential in order to remain true to the data and ensure that the findings were consistent with participants' views, not mine.

During this PhD process I have had to develop a wide range of new skills, not only in terms of data collection but also data analysis and critique. Throughout the process I have always been able to reflect on my own limitations and I have considered ways to overcome them; this has greatly benefited the development of my role as an able researcher.

7.6 Concluding remarks

This thesis has detailed the outcome from a piece of research which documented the challenges linked to the investigation of fidelity and what this means to process evaluation research in complex rehabilitation interventions. The aims and objectives of this study set at the outset were addressed through a range of methodologies and approaches to data collection. In Chapters 3 and 4, drawing from the OTCH case study, the researcher conducted a realist process evaluation. Results from this work have contributed to the body of evidence by proposing the inclusion of a 'learning over time' component to current frameworks for the investigation of fidelity and by reporting on a new refined programme theory to guide fidelity research of complex rehabilitation interventions. Furthermore, this refined programme theory can assist in pointing to other mechanisms which might be melded with programme theories of other interventions prior to their evaluation. These results have advanced the body of evidence supporting the use of realist evaluation to understand what is it about a program that works, for whom and under what circumstances. In Chapter 5, the researcher carried out a systematic review looking at the current state of process evaluation design and conduct within neurological rehabilitation research. Findings showed that process evaluations rarely explore how therapists' level of experience and learning within the trial can impact on intervention outcomes. Findings from the systematic review informed the consensus work reported in Chapter 6, which reports on a new

proposed guideline on how to best design and conduct process evaluations alongside trials of complex rehabilitation interventions.

Overall this thesis offers a more comprehensive, pluralist, more developed and context-bound representation of the research of fidelity via process evaluations than the one currently portrayed in the evidence-based. This study has contributed to the body of evidence that argues that investigating implementation fidelity of rehabilitation interventions via high quality process evaluations can increase the researchers understanding on why a complex intervention works or fails. The results reported here are highly relevant to today's rehabilitation research. The researcher considers that they have advanced the thinking and practice around process evaluation methodology within this field which, to date, had not developed comprehensive plans to address its inherent challenges.

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Appendices

Appendix 3.1 OTCH Interview Schedule

PREAMBLE

Many thanks for taking the time to help with this interview.
This interview is being carried out to gather information from occupational therapists working as part of the OTCH trial. Data obtained from the interviews will inform the OTCH trial's process evaluation. The interview is carried out and recorded with consent from the OTs and transcripts will be made available. Gathered information will remain confidential but may be anonymously quoted.
Can I ask you to confirm that you are happy to proceed, and for the conversation to be recorded?

OTCH Interview Questions / Icebreaker:

Tell me about your role within the OTCH trial. Have you enjoyed it?

1. **How would you describe what happens in care homes regarding rehabilitation / occupational therapy?**
   How easy was it to establish yourself in the care home setting? Were care homes used to having OT input?
   Do you think staff at the care home see the intervention as something new? Why?
   Do you consider that the intervention is 'new' and brings a change into the way care homes think about and deliver rehabilitation?

2. **Have you had any previous experience working in care homes? And with stroke patients?**
   Do you think these previous experiences have informed your work? If so, how?
   Which decisions have you drawn upon in order to make decisions/carry out the intervention? (Maybe you have used approaches such as the neurodevelopmental before?)

3. **How helpful was the guidance you received prior and during the trial regarding how to carry out your role as an OTCH OT?**
   Was it easy to understand? Was it well explained? Did it make you feel confident about what your role entitled and what you were supposed to do? Why?

4. **How did the recording documentation methods suit your professional way of working?**
   Did you feel the way you were ask to document and record your work suited your professional working style? Why?

About the intervention

5. **To what extend have you been able to deliver the trial intervention according to plan? Which bits and why?**
   How did you deliver the intervention? What was easy or difficult about if? Challenges
   How much did you remain focussed on ADL?
   Did you find that patients were presenting with cognitive problems/co-morbidities? What did you do to deal with this?

6. **What different types of impacts did you see?**
Were there any impacts for different groups of people (e.g. care home staff/family/care homes/other health professionals)
Example of impacts: staff becoming more confident, making more decisions etc.
Do you think the outcome measures helped you identify these impacts?
Do you think these impacts are closely linked to the intervention being driven by for example the use of a compensatory approach, or neurodevelopmental approach?
Were these different in residential and nursing homes?

About OT/staff dynamics

7. **Could you describe the dynamics between you and care home staff?**
Did you work alongside staff or were you left to work independently? In your opinion did this impact on the delivery of the intervention? In what way?
Did staff know how to make the necessary referrals? Were staff a good source of information?
How did you engage with external services, did staff help? What problems did you encounter when accessing the services?
How did you go about finding out the structure and way of running of the care home (e.g. shifts, handover routine?
How did you communicate what you did with staff? Did it work ok for you?
Do you think staff considered the interventions a 'waste of time' or not? How did this affect your work?
Do you think staff were willing to change? Were there happy to make for example environmental, timetable changes to support your work?

Did you have to deal with much unmotivated patients? How did you work around it? Was it successful?
How could you have increased staff engagement in the process?
Was it necessary to tailor it? Did the trial design allow you to be flexible and tailor the intervention?
How did you decide what to do first and how? What were these decisions based on?
Other OTs have tailored the interventions around the Barthel Index, did you do as well? If no, how did you go about tailoring it? If yes, did it work for you?
How did you prioritize issues when you had a complex patient?
Did you plan the intervention differently depending on if it was a residential or a nursing home?

8. **During the process what sources of support and advice did you use? At the time, did you consider these to be sufficient?**

Did you get support from other OTs? From the trial staff? Personal reflections?

To end

Is there anything else you would like to say or you would like to discuss any further before we finish this interview?

Appendix 3.2 OTCH – Interviewee self-evaluation

OTCH Interviews – Self evaluation

Date/Time of Interview:

About how I carried out the interview

Are the conversations smooth and flowing or are they patchy?
Have I built a relationship with the OT?
Have I explained myself clearly? Did I make the point clear?
Was my style of interviewing relaxed and polite or did I ask the questions too quickly or abruptly?
Did I encourage the interviewees to express themselves and speak their mind or did I interrupt them when giving too long replies?
Did I express my own opinion in a strong way at any point during the interview?
Did I remember to use the prompts?
Did I accept general answers or did I encourage the interviewee to give examples?
Did I 'back off' when I should have encouraged further information or did I press too much when I should have 'backed off'?

About the information I have gathered

Am I hearing the themes and concepts that I was expecting to explore?
Are the interviews getting enough depth and examples?
Did I ask any questions that did not get answers or got evasive/strange responses?

About the structure and style of interview questions

Was there too many or too few questions?
Were the questions too broad or too narrow?
Were the questions too abstract or too long? Did they have too many parts?
Did I ask too many questions that had yes-or-no replies?
Did the interviewee answer a question with a different question?

Appendix 3.3 OTCH Critical Incident Report Form

OTCH THERAPIST CRITICAL INCIDENT ANALYSIS

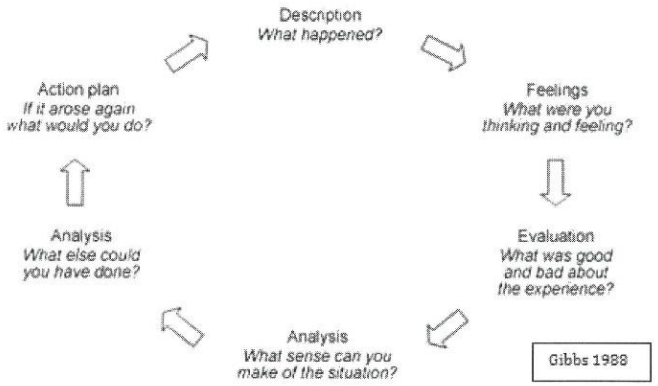
Therapist:	Participant code:	Date of completion:

Introduction

We are keen to understand the factors that are shaping your work as therapists whilst you are working with residents, staff and care homes delivering the OTCH trial intervention. This will help us explain the trial results.

Critical incident technique

We recognise that all of the trial therapists will bring different views, experiences and knowledge to their role and practice. The critical incident technique is a well-established method to systematically analyse the sense that health professionals make of situations that are important to them. Important situations are ones that stand out as being exemplary of good (or poor) clinical experience, or ones that change the way that we think about things. We use a cycle of questions to help us think systematically about a critical incident as follows:



Your role

We would like you to reflect on a number of critical incidents to help us understand your work. Overleaf is a series of questions and prompts to help you do this. There isn't a specific number of critical incidents that you should consider – it's important to focus on incidents that stand out for you. However as a general principle you should be thinking of at least one critical incident for every 10 residents you work with. You may complete more, especially as you may find it useful to bring these to clinical supervision.

Please remember confidentiality, and do not include any identifiable information other than the participant code and date of the critical incident. Please provide as much detail as you can. We may contact you be telephone to discuss the incident with you.

Please remember to ensure care home and resident confidentiality

OTCH THERAPIST CRITICAL INCIDENT ANALYSIS

1. **Choose a critical incident:**
This would be something that stands out for you, such as a successful or unsuccessful encounter with a resident, a particularly successful or unsuccessful treatment, or a specific problem that you have faced in your work with residents or care home staff.

2. **Describe the incident in the box below, including:**
- when and where it happened (time of day, location and social and organisational context)
- what OTCH interventions were you using and why
- were you doing anything any differently from what you had been doing for other residents
- what else happened (who said or did what)
- what else was going on that influenced what happened

3. **What were your feelings about the critical incident. You might consider:**
- what were you thinking and feeling at the time and just after the incident
- what were you hoping to achieve
- what led up to the incident
- how did you deal with the incident
- how the incident could have been avoided

4. Evaluation:
- What was the problem
- Why was it a problem
- What would you do if you were the person in the story
- Who would you ask for help
- Why does this incident stand out

Please remember to ensure care home and resident confidentiality

OTCH THERAPIST CRITICAL INCIDENT ANALYSIS

5. Analysis
- What is going on here – can you explain things that are going on
- Where would you have acted the same as the persons in the story, where would you have acted differently
- Did a particular mindset/bias lead to the event

6. Conclusion
- Could you have interpreted this event differently from another point of view?
- What can you learn from this episode?

7. Action plan
- How could you avoid the problem in the future?
- How could you now solve the problem which already exists?
- How can you prepare yourself to handle such problems?
- What would be your preferred (ideal) option/choice?

Once you have completed your critical incident analysis, please return it to the following address:

Patricia Masterson Algar
College of Health and Behavioural Sciences
Bangor University
Bangor, Gwynedd LL57 2EF

Please take a photocopy before you send it both for your records, and in case we ask to discuss the critical incident with you.
We may telephone you if we have any questions or points for clarification.

Many thanks for completing this critical incident analysis.

Please remember to ensure care home and resident confidentiality

Appendix 3.4 OTCH – Occupational Therapy Intervention Log

Pt ID: ☐☐☐☐☐☐☐☐

UNIVERSITY OF BIRMINGHAM

OTCH

Occupational Therapy Intervention Log

At each visit please record the approximate time in minutes spent on each of the areas below:

			Category of intervention									
			Assessment and goal setting	**Communication** *Including listening to residents' concerns or life story, information giving (to residents, staff or relatives), referrals to other agencies and ordering equipment*	**ADL training**		**Transfers and mobility** *Including aspects of wheelchair provision if directly concerned with mobility rather than seating*		**Adaptive equipment, seating, postural management and environmental adaptations** *Including preventative interventions, such as wheelchair cushions and palm protectors*	**Other** *Including treating impairments directly and the use of leisure activities*	**Total**
		Date			Cognitive	Functional	Cognitive	Functional			
Visit	1										
	2										
	3										
	4										
	5										
	6										

Appendix 3.5. OTCH Coding Framework

OTCH – Coding Framework

INTERVENTION COMPONENTS	- CARE HOME STAFF TRAINING - REFERRALS (TO EXTERNAL SERVICES) - EQUIPMENT PROVISION - ENVIRONMENTAL ADAPTATIONS - INITIAL ASSESSMENT - WASHING/DRESSING (ASSESSMENT/INTERVENTION) - TRANSFERS/MOBILITY (ASSESSMENT/INTERVENTION) - FEEDING (ASSESSMENT/INTERVENTION) - SEATING/POSITIONING (ASSESSMENT/INTERVENTION) - COGNITIVE (ASSESSMENT INTERVENTION) - HOME ASSESSMENT - EXERCISE INTERVENTION - MANUAL HANDLING - OT FEEDBACK TO CARE HOME STAFF - OT FEEDBACK TO PATIENT - OT FEEDBACK TO PATIENT'S FAMILY - NON ADL OT ASSESSMENT/INTERVENTIONS - MAINTAINANCE OF PATIENTS TREATMENT - SPLINTING		
CFIR Constructs		**Code Description**	**CODE**
Intervention Characteristics	*Evidence Strength & Quality* *Relative Advantage*	– OTCH – Innovative Intervention, is it new? – OTCH intervention – is there a need for it? – Care Homes understanding of OT – Care homes rehabilitation input prior to OTCH trial	– INNOVATION – NEED FOR OTCH INTERVENTION – CARE HOMES – OT/REHAB INPUT
	Adaptability	– OTs tailoring intervention to suit patients and care home needs – OTCH intervention – flexible or not? – Limitations of the trial intervention – Was the intervention easy to adapt?	– TAILORING OF INTERVENTION – LIMITATIONS OF INTERVENTION – SUPPORT FOR OTs
	Trialability	– OTs Previous experience in care homes – OTCH intervention – will it work?	– OTs PREVIOUS EXPERIENCE – OTs OPINION ON TRIAL INTERVENTION – OTs WORKING METHODS
	Complexity	– Patients presenting with co-morbidities – Patients at different stages and 'time after stroke' (differences in rehab potential) – Patients' cognitive impairments – OT expertise – different levels – Differences amongst care homes	– CO-MORBIDITIES – PATIENTS WITH COMMUNICATION IMPAIRMENTS – 'TIME AFTER STROKE' – COGNITIVE IMPAIRMENTS – PATIENT MOTIVATION – OTs PREVIOUS EXPERIENCE – VARIABILITY AMONGST CARE HOMES

1

		(structure, funding sources, nursing/residential, size) – OT being something very/too new for the care homes	– VARIABILITY AMONGST OTs – INNOVATION – BUDGET/FUNDING – OUTCOME MEASURES – ISSUES REGARDING EQUIPMENT PROVISION – CARE HOME STAFF KNOWLEDGE – PATIENTS CHARACTERISTICS – CHALLENGES FACED BY OTs – CARE HOMES ACCEPTING/ENGAGING WITH OT
	Design quality and packaging *Cost*	– OTCH guidelines – clarity and helpfulness, OTs knowing what is their role in the OTCH project – Recording of OT interventions – Patient allocation to OTCH – OTCH budget – impact on delivery of intervention	– OTCH GUIDELINES (opinions/organization) – RECORDING data – PATIENT ALLOCATION TO OTCH PROJECT – BUDGET/FUNDING – TIME AFTER STROKE
Outer Setting	*Patient needs and resources*	– OTCH intervention – is there a need for it? – OTCH intervention – targeting patients needs – Time available to carry out intervention, enough? – OTCH budget – impact on delivery of intervention	– NEED FOR OTCH INTERVENTION – TARGETING PATIENTS NEEDS – QUALITY OF LIFE – TIME – BUDGET/FUNDING
	Cosmopolitanism	– Care home/OTs aware and receiving input from external services available – Care homes/OTs making referrals	– EXTERNAL SERVICES (access/awareness) – REFERALS
	Peer Pressure *External policy and incentives*	– Care homes running as a business (based on profits)	– CARE HOMES AS A BUSINESS vs INTERVENTION
Inner Setting	*Structural characteristics*	– OTs finding out structures of care homes and who is in charge of the decision making - easy or not? – Turnover and shifts affecting delivery of intervention	– CARE HOME MANAGERIAL STRUCTURE vs INTERVENTION – CARE HOME DAILY ROUTINE vs INTERVENTION – CARE HOME ORGANIZATION/PAPERWORK/RESOURCES vs INTERVENTION – CARE HOME STAFF KNOWLEDGE
	Networks and Communications	– OTs verbal and written communication with care home staff – Effectiveness of communication methods/impact on delivery of trial intervention	– FEEDBACK METHODS vs INTERVENTION

	Culture	– Care homes, culture for change? – Care homes values – impact on delivery of trial intervention – Care homes' 'caring' *vs* OTs 'promoting independence'	– CARE HOME CULTURE/VALUES *vs* INTERVENTION
	Implementation climate *Readiness for implementation*	– Care homes rehabilitation input prior to OTCH trial – Care home staff aware of need for rehabilitation? – Care home in the OT training provided with intervention – Trial intervention too 'innovative'? – Staff's response to OT suggestions/changes – Training provided vs staff learning styles – staff's response – OTs and care home staff working dynamics – Staff's response to OT feedback – Staff's feedback on usefulness of the trial intervention – Managers engagement in the process – impact on delivery of trial intervention	– CARE HOMES – OT/REHAB INPUT – CARE HOME STAFF UNDERSTANDING OF OT – IMPACTS OF TRAINING (on staff) – CARE HOME STAFF TRAINING – CARE HOME STAFF OPINION ON INTERVENTION – PATIENT'S OPINION ON INTERVENTION – INNOVATIVE – CARE HOMES – WILL TO CHANGE – OT /CARE HOME STAFF INTERACTIONS – FEEDBACK METHODS vs INTERVENTION
Characteristics of Individuals	*Knowledge and belief about the intervention*	– OTCH – Innovative Intervention, is it new? – OTCH intervention – is there a need for it? – OTs preconceptions regarding care homes – OTs motivation and enthusiasm when delivering intervention – Observed impacts of the trial intervention – OTs 'client centred/holistic' approach vs trial intervention – OTs beliefs regarding impact of care home staff training – Limitations and opinions regarding outcome measures	– INNOVATIVE – NEED FOR INTERVENTION – OTS PRECONCEPTIONS – OTS ENTHUSIASM/MOTIVATION – OTs AND PATIENT'S FAMILY MEMBERS – IMPACTS (of intervention) ON PATIENTS – IMPACTS (of intervention) ON CARE HOME STAFF – IMPACTS (of intervention) ON PATIENTS FAMILY MEMBERS – OTs OPINION ON INTERVENTION – OTs DECISIONS vs TRIAL INTERVENTION – IMPACTS OF TRAINING (on staff) – CARE HOME STAFF TRAINING – OUTCOME MEASURES – CARE HOME STAFF KNOWLEDGE – QUALITY OF LIFE

	Self-efficacy *Individual stage of change* *Individual identification with organization* *Other personal attributes*	– Factors influencing OTs confidence levels when delivering trial intervention – OTs drawing upon previous experience – OTs' sources of support/tools and advice when intervention planning	– OTs PREVIOUS EXPERIENCE – OTs' PROFESSIONAL TOOLS (theory) – OTs WORKING METHODS
Process	*Planning* *Engaging*	– OTCH guidelines – clarity and helpfulness – OTs knowing what is their role in the OTCH project – OTs 'client centred/holistic' approach *vs* trial intervention	– OTCH GUIDELINES (opinions/organization) – OTs DECISIONS vs TRIAL INTERVENTION
	Executing *Reflecting and evaluating*	– Trial intervention being delivered according to plan (guidelines) – OTs 'client centred/holistic' approach vs trial intervention – Observed impacts of the trial intervention	– OTCH GUIDELINES – OTs DECISIONS vs TRIAL INTERVENTION – IMPACTS (of intervention) ON PATIENTS – IMPACTS (of intervention) ON CARE HOME STAFF – IMPACTS (of intervention) ON PROVISION OF SERVICES

Appendix 4.1 Descriptive statistics for all sites

		N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean	
						Lower Bound	Upper Bound
SITE 1							
Number of OT visits per patient	Wave 1	26	5.38	2.593	.509	4.34	6.43
	Wave 2	60	4.83	2.656	.343	4.15	5.52
	Wave 3	83	4.58	2.333	.256	4.07	5.09
	Total	169	4.79	2.493	.192	4.41	5.17
Number of min of OT per patient	Wave 1	26	178.27	122.327	23.990	128.86	227.68
	Wave 2	60	249.70	217.632	28.096	193.48	305.92
	Wave 3	83	148.86	100.448	11.026	126.92	170.79
	Total	169	189.18	160.982	12.383	164.74	213.63
% of min OTs spent carrying out assessments	Wave 1	26	19.81	10.626	2.084	15.52	24.10
	Wave 2	60	19.72	15.234	1.967	15.78	23.65
	Wave 3	83	21.05	14.589	1.601	17.86	24.23
	Total	169	20.39	14.234	1.095	18.22	22.55
% of min OTs spent communicating	Wave 1	26	58.66	22.402	4.393	49.61	67.71
	Wave 2	60	63.87	20.898	2.698	58.47	69.27
	Wave 3	83	66.91	16.676	1.830	63.27	70.55
	Total	169	64.56	19.290	1.484	61.63	67.49
% of min OTs spent carrying out ADL int.	Wave 1	26	5.52	8.958	1.757	1.90	9.14
	Wave 2	60	7.76	10.607	1.369	5.02	10.50
	Wave 3	83	2.26	5.507	.604	1.05	3.46
	Total	169	4.71	8.524	.656	3.42	6.01
% of min OTs spent working on transfers	Wave 1	26	11.84	22.268	4.367	2.85	20.84
	Wave 2	60	5.05	7.991	1.032	2.99	7.12
	Wave 3	83	3.28	8.279	.909	1.47	5.09
	Total	169	5.23	11.761	.905	3.44	7.01
% of min OTs spent in equipment prov.	Wave 1	26	2.99	6.416	1.258	.40	5.58
	Wave 2	60	2.77	5.045	.651	1.46	4.07
	Wave 3	83	5.09	7.621	.837	3.43	6.75
	Total	169	3.94	6.686	.514	2.93	4.96
% of min OTs spent in 'other' activities	Wave 1	26	2.07	4.370	.857	.31	3.84
	Wave 2	60	.83	2.647	.342	.15	1.52
	Wave 3	83	1.42	5.956	.654	.12	2.72
	Total	169	1.31	4.775	.367	.58	2.04
SITE 2							
Number of OT visits per patient	Wave 1	12	8.17	3.070	.886	6.22	10.12
	Wave 2	12	5.33	2.146	.620	3.97	6.70
	Wave 3	11	5.73	3.036	.915	3.69	7.77
	Total	35	6.43	2.983	.504	5.40	7.45
Number of min of OT per patient	Wave 1	12	405.42	225.292	65.036	262.27	548.56
	Wave 2	12	157.92	69.067	19.938	114.03	201.80
	Wave 3	11	159.55	94.616	28.528	95.98	223.11
	Total	35	243.29	186.323	31.494	179.28	307.29
% of min OTs spent carrying out assessments	Wave 1	12	21.93	12.741	3.678	13.84	30.03
	Wave 2	12	25.95	17.965	5.186	14.54	37.36
	Wave 3	11	45.39	32.224	9.716	23.74	67.04
	Total	35	30.68	23.817	4.026	22.50	38.86
% of min OTs spent communicating	Wave 1	12	24.61	12.521	3.615	16.65	32.56
	Wave 2	12	22.92	13.225	3.818	14.51	31.32
	Wave 3	11	21.62	15.514	4.678	11.20	32.04
	Total	35	23.09	13.402	2.265	18.48	27.69
% of min OTs spent carrying out ADL int.	Wave 1	12	18.47	14.740	4.255	9.11	27.84
	Wave 2	12	17.95	17.359	5.011	6.92	28.98
	Wave 3	11	10.36	16.437	4.956	-.68	21.41
	Total	35	15.75	16.154	2.731	10.20	21.29
% of min OTs spent working on transfers	Wave 1	12	7.44	14.295	4.126	-1.64	16.52
	Wave 2	12	10.25	14.305	4.129	1.16	19.34
	Wave 3	11	16.54	16.817	5.071	5.24	27.83
	Total	35	11.26	15.166	2.564	6.05	16.47
% of min OTs spent in equipment prov.	Wave 1	12	14.83	16.542	4.775	4.31	25.34
	Wave 2	12	19.50	20.026	5.781	6.78	32.22
	Wave 3	11	5.94	8.722	2.630	.08	11.80
	Total	35	13.63	16.507	2.790	7.96	19.30
% of min OTs spent in 'other' activities	Wave 1	12	12.71	13.799	3.983	3.94	21.48
	Wave 2	12	3.44	4.600	1.328	.52	6.36
	Wave 3	11	.15	.482	.145	-.18	.47
	Total	35	5.58	9.880	1.670	2.19	8.98

		N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean	
						Lower Bound	Upper Bound
SITE 3							
Number of OT visits per patient	Wave 1	5	1.40	.894	.400	.29	2.51
	Wave 2	8	3.63	1.408	.498	2.45	4.80
	Wave 3	4	4.00	2.309	1.155	.33	7.67
	Total	17	3.06	1.819	.441	2.12	3.99
Number of min of OT per patient	Wave 1	5	85.00	66.332	29.665	2.64	167.36
	Wave 2	8	70.25	32.079	11.342	43.43	97.07
	Wave 3	4	80.50	65.861	32.930	-24.30	185.30
	Total	17	77.00	49.085	11.905	51.76	102.24
% of min OTs spent carrying out assessments	Wave 1	5	42.00	27.065	12.104	8.39	75.61
	Wave 2	8	5.18	6.036	2.134	.13	10.22
	Wave 3	4	11.65	10.505	5.253	-5.07	28.37
	Total	17	17.53	22.178	5.379	6.13	28.93
% of min OTs spent communicating	Wave 1	5	28.50	12.196	5.454	13.36	43.64
	Wave 2	8	15.99	20.399	7.212	-1.07	33.04
	Wave 3	4	52.70	33.939	16.969	-1.30	106.70
	Total	17	28.31	25.688	6.230	15.10	41.51
% of min OTs spent carrying out ADL int.	Wave 1	5	9.00	12.450	5.568	-6.46	24.46
	Wave 2	8	6.19	9.022	3.190	-1.35	13.73
	Wave 3	4	5.10	10.200	5.100	-11.13	21.33
	Total	17	6.76	9.813	2.380	1.71	11.80
% of min OTs spent working on transfers	Wave 1	5	15.00	21.213	9.487	-11.34	41.34
	Wave 2	8	35.76	31.843	11.258	9.14	62.38
	Wave 3	4	26.20	22.961	11.481	-10.34	62.74
	Total	17	27.41	27.173	6.590	13.44	41.38
% of min OTs spent in equipment prov.	Wave 1	5	4.00	8.944	4.000	-7.11	15.11
	Wave 2	8	3.13	8.839	3.125	-4.26	10.51
	Wave 3	4	4.00	8.000	4.000	-8.73	16.73
	Total	17	3.59	8.148	1.976	-.60	7.78
% of min OTs spent in ‘other’ activities	Wave 1	5	1.50	3.354	1.500	-2.66	5.66
	Wave 2	8	33.80	35.867	12.681	3.81	63.79
	Wave 3	4	.35	.700	.350	-.76	1.46
	Total	17	16.43	29.170	7.075	1.43	31.43
SITE 4							
Number of OT visits per patient	Wave 1	22	5.91	2.158	.460	4.95	6.87
	Wave 2	20	6.55	2.038	.456	5.60	7.50
	Wave 3	9	3.78	1.481	.494	2.64	4.92
	Total	51	5.78	2.203	.308	5.16	6.40
Number of min of OT per patient	Wave 1	22	140.82	51.820	11.048	117.84	163.79
	Wave 2	20	150.25	57.890	12.945	123.16	177.34
	Wave 3	9	88.33	55.790	18.597	45.45	131.22
	Total	51	135.25	58.302	8.164	118.86	151.65
% of min OTs spent carrying out assessments	Wave 1	22	57.74	21.964	4.683	48.00	67.47
	Wave 2	20	44.95	19.355	4.328	35.89	54.01
	Wave 3	9	28.69	17.367	5.789	15.34	42.04
	Total	51	47.60	22.486	3.149	41.27	53.92
% of min OTs spent communicating	Wave 1	22	20.88	8.820	1.880	16.97	24.79
	Wave 2	20	42.42	12.835	2.870	36.41	48.43
	Wave 3	9	64.08	21.734	7.245	47.37	80.78
	Total	51	36.95	20.711	2.900	31.12	42.77
% of min OTs spent carrying out ADL int.	Wave 1	22	4.73	7.797	1.662	1.27	8.18
	Wave 2	20	3.03	6.746	1.508	-.13	6.19
	Wave 3	9	4.84	11.201	3.734	-3.77	13.45
	Total	51	4.08	7.977	1.117	1.84	6.33
% of min OTs spent working on transfers	Wave 1	22	2.73	6.104	1.301	.03	5.44
	Wave 2	20	5.87	6.846	1.531	2.66	9.07
	Wave 3	9	.00	.000	.000	.00	.00
	Total	51	3.48	6.177	.865	1.74	5.22
% of min OTs spent in equipment prov.	Wave 1	22	11.53	12.565	2.679	5.96	17.10
	Wave 2	20	3.72	7.192	1.608	.35	7.09
	Wave 3	9	2.38	5.363	1.788	-1.74	6.50
	Total	51	6.85	10.379	1.453	3.93	9.77
% of min OTs spent in ‘other’ activities	Wave 1	22	2.40	8.042	1.715	-1.17	5.96
	Wave 2	20	.00	.000	.000	.00	.00
	Wave 3	9	.00	.000	.000	.00	.00
	Total	51	1.03	5.348	.749	-.47	2.54

		N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean	
						Lower Bound	Upper Bound
SITE 5							
Number of OT visits per patient	Wave 1	5	9.80	.447	.200	9.24	10.36
	Wave 2	4	6.00	2.160	1.080	2.56	9.44
	Wave 3	13	3.69	2.136	.593	2.40	4.98
	Total	22	5.50	3.128	.667	4.11	6.89
Number of min of OT per patient	Wave 1	5	390.00	120.052	53.689	240.94	539.06
	Wave 2	4	295.00	121.175	60.587	102.18	487.82
	Wave 3	13	168.08	98.097	27.207	108.80	227.36
	Total	22	241.59	139.552	29.753	179.72	303.46
% of min OTs spent carrying out assessments	Wave 1	5	16.02	6.879	3.077	7.48	24.56
	Wave 2	4	20.98	3.580	1.790	15.28	26.67
	Wave 3	13	45.59	24.950	6.920	30.51	60.67
	Total	22	34.40	23.641	5.040	23.91	44.88
% of min OTs spent communicating	Wave 1	5	39.10	11.926	5.333	24.29	53.91
	Wave 2	4	35.75	26.185	13.093	-5.92	77.42
	Wave 3	13	42.97	15.785	4.378	33.43	52.51
	Total	22	40.78	16.610	3.541	33.41	48.14
% of min OTs spent carrying out ADL int.	Wave 1	5	2.10	4.696	2.100	-3.73	7.93
	Wave 2	4	4.13	8.250	4.125	-9.00	17.25
	Wave 3	13	4.12	12.020	3.334	-3.14	11.39
	Total	22	3.66	9.861	2.102	-.71	8.04
% of min OTs spent working on transfers	Wave 1	5	23.90	18.343	8.203	1.12	46.68
	Wave 2	4	15.98	10.678	5.339	-1.02	32.97
	Wave 3	13	2.57	5.052	1.401	-.48	5.62
	Total	22	9.85	13.488	2.876	3.87	15.83
% of min OTs spent in equipment prov.	Wave 1	5	12.84	10.992	4.916	-.81	26.49
	Wave 2	4	4.43	8.850	4.425	-9.66	18.51
	Wave 3	13	.00	.000	.000	.00	.00
	Total	22	3.72	7.916	1.688	.21	7.23
% of min OTs spent in ‘other’ activities	Wave 1	5	6.02	9.899	4.427	-6.27	18.31
	Wave 2	4	18.73	21.722	10.861	-15.84	53.29
	Wave 3	13	4.74	9.471	2.627	-.98	10.46
	Total	22	7.57	12.906	2.752	1.85	13.29
SITE 9							
Number of OT visits per patient	Wave 1	49	4.10	2.356	.337	3.43	4.78
	Wave 2	12	6.33	3.114	.899	4.35	8.31
	Total	61	4.54	2.649	.339	3.86	5.22
Number of min of OT per patient	Wave 1	49	178.57	141.425	20.204	137.95	219.19
	Wave 2	12	325.83	156.130	45.071	226.63	425.03
	Total	61	207.54	154.770	19.816	167.90	247.18
% of min OTs spent carrying out assessments	Wave 1	49	35.47	22.652	3.236	28.96	41.97
	Wave 2	12	28.14	22.351	6.452	13.94	42.34
	Total	61	34.02	22.599	2.893	28.24	39.81
% of min OTs spent communicating	Wave 1	49	50.63	21.239	3.034	44.53	56.73
	Wave 2	12	44.35	24.339	7.026	28.88	59.81
	Total	61	49.40	21.813	2.793	43.81	54.98
% of min OTs spent carrying out ADL int.	Wave 1	49	1.09	5.242	.749	-.42	2.59
	Wave 2	12	.00	.000	.000	.00	.00
	Total	61	.87	4.709	.603	-.33	2.08
% of min OTs spent working on transfers	Wave 1	49	3.11	4.885	.698	1.71	4.51
	Wave 2	12	3.07	4.248	1.226	.37	5.77
	Total	61	3.10	4.732	.606	1.89	4.32
% of min OTs spent in equipment prov.	Wave 1	49	7.05	9.249	1.321	4.39	9.70
	Wave 2	12	13.67	11.193	3.231	6.56	20.78
	Total	61	8.35	9.923	1.270	5.81	10.89
% of min OTs spent in ‘other’ activities	Wave 1	49	2.66	8.146	1.164	.32	5.00
	Wave 2	12	10.77	18.335	5.293	-.88	22.42
	Total	61	4.25	11.193	1.433	1.39	7.12

SITES THAT COMPLETED ONE WAVE:

	N	Min.	Max.	Mean		Std. Deviation
				Statistic	Std. Error	Statistic
SITE 6						
Number of OT visits per patient	24	1	6	2.71	.343	1.681
Number of min of OT per patient	24	30	1380	296.25	69.906	342.469
% of min OTs spent carrying out assessments	24	12	100	46.73	6.845	33.534
% of min OTs spent communicating	24	0	57	23.16	3.894	19.077
% of min OTs spent carrying out ADL int.	24	0	21	4.98	1.455	7.127
% of min OTs spent working on transfers	24	0	21	7.40	1.643	8.050
% of min OTs spent in equipment prov.	24	0	53	10.38	2.855	13.985
% of min OTs spent in 'other' activities	24	0	28	7.34	1.878	9.198
SITE 7						
Number of OT visits per patient	30	3	18	8.20	.817	4.475
Number of min of OT per patient	30	30	1325	357.50	73.279	401.368
% of min OTs spent carrying out assessments	30	0	53	22.55	2.472	13.541
% of min OTs spent communicating	30	3	100	59.42	3.945	21.608
% of min OTs spent carrying out ADL int.	30	0	10	.76	.403	2.209
% of min OTs spent working on transfers	30	0	36	5.03	1.722	9.432
% of min OTs spent in equipment prov.	30	0	32	6.20	1.679	9.196
% of min OTs spent in 'other' activities	30	0	73	6.05	2.737	14.993
SITE 8						
Number of OT visits per patient	40	1	12	4.80	.474	2.997
Number of min of OT per patient	40	15	560	171.95	20.008	126.542
% of min OTs spent carrying out assessments	40	0	100	41.04	4.081	25.811
% of min OTs spent communicating	40	0	100	44.06	4.310	27.262
% of min OTs spent carrying out ADL int.	40	0	25	1.24	.708	4.477
% of min OTs spent working on transfers	40	0	53	3.36	1.704	10.774
% of min OTs spent in equipment prov.	40	0	36	3.81	1.278	8.086
% of min OTs spent in 'other' activities	40	0	58	6.49	2.273	14.378
SITE 10						
Number of OT visits per patient	29	1	8	2.97	.338	1.822
Number of min of OT per patient	29	40	385	103.45	13.612	73.303
% of min OTs spent carrying out assessments	29	8	80	56.90	3.481	18.747
% of min OTs spent communicating	29	20	64	37.44	2.320	12.495
% of min OTs spent carrying out ADL int.	29	0	22	1.59	.939	5.055
% of min OTs spent working on transfers	29	0	22	1.77	1.009	5.433
% of min OTs spent in equipment prov.	29	0	14	.74	.543	2.923
% of min OTs spent in 'other' activities	29	0	18	1.57	.816	4.395
SITE 11						
Number of OT visits per patient	10	2	17	9.60	1.586	5.016
Number of min of OT per patient	10	120	1200	660.70	132.229	418.146
% of min OTs spent carrying out assessments	10	4	52	21.01	5.920	18.720
% of min OTs spent communicating	10	22	85	61.42	7.270	22.989
% of min OTs spent carrying out ADL int.	10	0	26	3.86	2.756	8.714
% of min OTs spent working on transfers	10	0	22	4.52	2.374	7.506
% of min OTs spent in equipment prov.	10	0	5	.83	.543	1.716
% of min OTs spent in 'other' activities	10	0	38	8.37	4.255	13.456

Appendix 4.2 Results from Levene's test for all variables in each site (note – a number of variables have been Log transformed). Variables that showed 'heterogeneous variances' are presented in red.

	Levene Stat.	df1	df2	*p*
Site 1				
Total number of OT visits per patient	.015	2	166	.985
Total number OT min. per patient (LogT)	3.811	2	166	.024
% of min. OTs spent carrying out assessments (LogT)	4.560	2	166	.012
% of min. OTs spent communicating	2.606	2	166	.077
% of min. OTs spent carrying out ADL int. (LogT)	25.858	2	166	.000
% of min. OTs spent working on transfers (LogT)	12.553	2	166	.000
% of min. OTs spent in equipment prov. (LogT)	8.898	2	166	.000
% of min. OTs spent in 'other' activities	2.145	2	166	.120
Site 2				
Total number of OT visits per patient	1.162	2	32	.326
Total number OT min. per patient (LogT)	.423	2	32	.659
% of min. OTs spent carrying out assessments (LogT)	2.285	2	32	.118
% of min. OTs spent communicating	.975	2	32	.388
% of min. OTs spent carrying out ADL int.	.043	2	32	.958
% of min. OTs spent working on transfers	.762	2	32	.475
% of min. OTs spent in equipment prov. (LogT)	.141	2	32	.869
% of min. OTs spent in 'other' activities (LogT)	10.908	2	32	.000
Site 3				
Total number of OT visits per patient (LogT)	1.701	2	14	.218
Total number OT min. per patient	2.023	2	14	.169
% of min. OTs spent carrying out assessments	2.264	2	14	.141
% of min. OTs spent communicating	2.092	2	14	.160
% of min. OTs spent carrying out ADL int.	1.148	2	14	.345
% of min. OTs spent working on transfers	1.615	2	14	.234
% of min. OTs spent in equipment prov.	.041	2	14	.960
% of min. OTs spent in 'other' activities (LogT)	1.544	2	14	.248
Site 4				
Total number of OT visits per patient	.707	2	48	.498
Total number OT min. per patient	.107	2	48	.898
% of min. OTs spent carrying out assessments	.769	2	48	.469
% of min. OTs spent communicating (LogT)	1.092	2	48	.344
% of min. OTs spent carrying out ADL int.	1.001	2	48	.375
% of min. OTs spent working on transfers (LogT)	25.120	2	48	.000
% of min. OTs spent in equipment prov. (LogT)	1.025	2	48	.366
% of min. OTs spent in 'other' activities (LogT)	11.058	2	48	.000
Site 5				
Total number of OT visits per patient (LogT)	14.275	2	19	.000
Total number OT min. per patient	.227	2	19	.799
% of min. OTs spent carrying out assessments (LogT)	4.862	2	19	.020
% of min. OTs spent communicating	1.407	2	19	.269
% of min. OTs spent carrying out ADL int.	.380	2	19	.689
% of min. OTs spent working on transfers (LogT)	1.912	2	19	.175
% of min. OTs spent in equipment prov. (LogT)	11.711	2	19	.000
% of min. OTs spent in 'other' activities (LogT)	1.703	2	19	.209

Appendix 4.3 ANOVA results for all variables that passed the Levene's test (significant results in red)

		Sum of Squares	df	Mean Square	F	*p*
Site 1						
Total number of OT visits per patient	Between Groups	13.023	2	6.512	1.049	.353
	Within Groups	1030.728	166	6.209		
	Total	1043.751	168			
% of min. OTs spent communicating	Between Groups	1393.169	2	696.584	1.892	.154
	Within Groups	61117.214	166	368.176		
	Total	62510.382	168			
% of min. OTs spent in 'other' activities	Between Groups	29.699	2	14.849	.649	.524
	Within Groups	3800.034	166	22.892		
	Total	3829.733	168			
Site 2						
Total number of OT visits per patient	Between Groups	56.056	2	28.028	3.638	.038
	Within Groups	246.515	32	7.704		
	Total	302.571	34			
Total number OT min. per patient	Between Groups	1.255	2	.628	8.571	.001
	Within Groups	2.343	32	.073		
	Total	3.599	34			
% of min. OTs spent carrying out assessments	Between Groups	.369	2	.184	2.118	.137
	Within Groups	2.787	32	.087		
	Total	3.156	34			
% of min. OTs spent communicating	Between Groups	51.853	2	25.927	.137	.872
	Within Groups	6055.322	32	189.229		
	Total	6107.175	34			
% of min. OTs spent carrying out ADL int.	Between Groups	466.329	2	233.164	.888	.422
	Within Groups	8406.378	32	262.699		
	Total	8872.707	34			
% of min. OTs spent working on transfers	Between Groups	493.437	2	246.719	1.078	.352
	Within Groups	7326.805	32	228.963		
	Total	7820.242	34			
% of min. OTs spent in equipment prov.	Between Groups	1.761	2	.880	.689	.510
	Within Groups	40.914	32	1.279		
	Total	42.675	34			
Site 3						
Total number of OT visits per patient	Between Groups	.609	2	.305	7.418	.006
	Within Groups	.575	14	.041		
	Total	1.184	16			
Total number OT min. per patient	Between Groups	733.500	2	366.750	.136	.874
	Within Groups	37816.500	14	2701.179		
	Total	38550.000	16			
% of min. OTs spent carrying out assessments	Between Groups	4353.370	2	2176.685	8.667	.004
	Within Groups	3516.145	14	251.153		
	Total	7869.515	16			
% of min. OTs spent communicating	Between Groups	3594.421	2	1797.210	3.613	.054
	Within Groups	6963.269	14	497.376		
	Total	10557.689	16			
% of min. OTs spent carrying out ADL int.	Between Groups	38.732	2	19.366	.181	.837
	Within Groups	1501.869	14	107.276		
	Total	1540.601	16			
% of min. OTs spent working on transfers	Between Groups	1334.011	2	667.005	.891	.432
	Within Groups	10479.539	14	748.538		
	Total	11813.549	16			
% of min. OTs spent in equipment prov.	Between Groups	3.243	2	1.621	.021	.979
	Within Groups	1058.875	14	75.634		
	Total	1062.118	16			
% of min. OTs spent in 'other' activities	Between Groups	10.639	2	5.320	5.313	.019
	Within Groups	14.018	14	1.001		
	Total	24.658	16			

		Sum of Squares	df	Mean Square	F	*p*
Site 4						
Total number of OT visits per patient	Between Groups	48.304	2	24.152	5.966	.005
	Within Groups	194.324	48	4.048		
	Total	242.627	50			
Total number OT min. per patient	Between Groups	24992.664	2	12496.332	4.138	.022
	Within Groups	144965.023	48	3020.105		
	Total	169957.686	50			
% of min. OTs spent carrying out assessments	Between Groups	5619.529	2	2809.765	6.859	.002
	Within Groups	19661.990	48	409.625		
	Total	25281.519	50			
% of min. OTs spent communicating	Between Groups	3.159	2	1.579	4.411	.017
	Within Groups	17.186	48	.358		
	Total	20.345	50			
% of min. OTs spent carrying out ADL int.	Between Groups	36.526	2	18.263	.279	.758
	Within Groups	3145.068	48	65.522		
	Total	3181.594	50			
% of min. OTs spent in equipment prov.	Between Groups	9.469	2	4.735	4.843	.012
	Within Groups	46.923	48	.978		
	Total	56.392	50			
Site 5						
Total number OT min. per patient	Between Groups	191792.395	2	95896.198	8.390	.002
	Within Groups	217176.923	19	11430.364		
	Total	408969.318	21			
% of min. OTs spent communicating	Between Groups	177.621	2	88.810	.300	.744
	Within Groups	5616.058	19	295.582		
	Total	5793.679	21			
% of min. OTs spent carrying out ADL int.	Between Groups	15.820	2	7.910	.074	.929
	Within Groups	2026.291	19	106.647		
	Total	2042.111	21			
% of min. OTs spent working on transfers	Between Groups	13.454	2	6.727	8.895	.002
	Within Groups	14.369	19	.756		
	Total	27.823	21			
% of min. OTs spent in ‘other’ activities	Between Groups	1.819	2	.910	.710	.504
	Within Groups	24.342	19	1.281		
	Total	26.161	21			

Appendix 4.4 Results from Tukey tests (significant results p<.05 shown in red)

Dependent Variable			Mean Difference	Std. Error	*p*	95% Confidence Interval	
						Lower Bound	Upper Bound
SITE 2							
Total number of OT visits per patient	Wave 1	Wave 2	2.833*	1.133	.045	.05	5.62
		Wave 3	2.439	1.159	.105	-.41	5.29
	Wave 2	Wave 1	-2.833*	1.133	.045	-5.62	-.05
		Wave 3	-.394	1.159	.938	-3.24	2.45
	Wave 3	Wave 1	-2.439	1.159	.105	-5.29	.41
		Wave 2	.394	1.159	.938	-2.45	3.24
Total number OT min. per patient	Wave 1	Wave 2	.385*	.110	.004	.11	.66
		Wave 3	.413*	.113	.003	.13	.69
	Wave 2	Wave 1	-.385*	.110	.004	-.66	-.11
		Wave 3	.027	.113	.968	-.25	.30
	Wave 3	Wave 1	-.413*	.113	.003	-.69	-.13
		Wave 2	-.027	.113	.968	-.30	.25
SITE 3							
% of min. OTs spent carrying out assessments	Wave 1	Wave 2	36.825*	9.035	.003	13.18	60.47
		Wave 3	30.350*	10.631	.032	2.53	58.17
	Wave 2	Wave 1	-36.825*	9.035	.003	-60.47	-13.18
		Wave 3	-6.475	9.705	.786	-31.88	18.93
	Wave 3	Wave 1	-30.350*	10.631	.032	-58.17	-2.53
		Wave 2	6.475	9.705	.786	-18.93	31.88
Total number of OT visits per patient	Wave 1	Wave 2	-.412*	.116	.008	-.71	-.11
		Wave 3	-.422*	.136	.020	-.78	-.07
	Wave 2	Wave 1	.412*	.116	.008	.11	.71
		Wave 3	-.011	.124	.996	-.34	.31
	Wave 3	Wave 1	.422*	.136	.020	.07	.78
		Wave 2	.011	.124	.996	-.31	.34
% of min. OTs spent in 'other' activities	Wave 1	Wave 2	-1.529*	.570	.045	-3.02	-.04
		Wave 3	.121	.671	.982	-1.64	1.88
	Wave 2	Wave 1	1.529*	.570	.045	.04	3.02
		Wave 3	1.650*	.613	.043	.05	3.25
	Wave 3	Wave 1	-.121	.671	.982	-1.88	1.64
		Wave 2	-1.650*	.613	.043	-3.25	-.05
SITE 4							
Total number of OT visits per patient	Wave 1	Wave 2	-.641	.622	.561	-2.14	.86
		Wave 3	2.131*	.796	.027	.21	4.06
	Wave 2	Wave 1	.641	.622	.561	-.86	2.14
		Wave 3	2.772*	.808	.003	.82	4.73
	Wave 3	Wave 1	-2.131*	.796	.027	-4.06	-.21
		Wave 2	-2.772*	.808	.003	-4.73	-.82
Total number OT min. per patient	Wave 1	Wave 2	-9.432	16.979	.844	-50.50	31.63
		Wave 3	52.485	21.745	.051	-.11	105.07
	Wave 2	Wave 1	9.432	16.979	.844	-31.63	50.50
		Wave 3	61.917*	22.058	.019	8.57	115.26
	Wave 3	Wave 1	-52.485	21.745	.051	-105.07	.11
		Wave 2	-61.917*	22.058	.019	-115.26	-8.57
% of min. OTs spent carrying out assessments	Wave 1	Wave 2	12.786	6.253	.113	-2.34	27.91
		Wave 3	29.047*	8.008	.002	9.68	48.42
	Wave 2	Wave 1	-12.786	6.253	.113	-27.91	2.34
		Wave 3	16.261	8.124	.123	-3.39	35.91
	Wave 3	Wave 1	-29.047*	8.008	.002	-48.42	-9.68
		Wave 2	-16.261	8.124	.123	-35.91	3.39

Dependent Variable			Mean Difference	Std. Error	*p*	95% Confidence Interval	
						Lower Bound	Upper Bound
% of min. OTs spent communicating	Wave 1	Wave 2	-.378	.185	.113	-.82	.07
		Wave 3	-.654*	.237	.022	-1.23	-.08
	Wave 2	Wave 1	.378	.185	.113	-.07	.82
		Wave 3	-.276	.240	.489	-.86	.30
	Wave 3	Wave 1	.654*	.237	.022	.08	1.23
		Wave 2	.276	.240	.489	-.30	.86
% of min. OTs spent in equipment prov.	Wave 1	Wave 2	.784*	.305	.035	.05	1.52
		Wave 3	1.013*	.391	.033	.07	1.96
	Wave 2	Wave 1	-.784*	.305	.035	-1.52	-.05
		Wave 3	.229	.397	.833	-.73	1.19
	Wave 3	Wave 1	-1.013*	.391	.033	-1.96	-.07
		Wave 2	-.229	.397	.833	-1.19	.73
SITE 5							
Total number OT min. per patient	Wave 1	Wave 2	95.000	71.719	.399	-87.20	277.20
		Wave 3	221.923*	56.261	.002	78.99	364.85
	Wave 2	Wave 1	-95.000	71.719	.399	-277.20	87.20
		Wave 3	126.923	61.130	.122	-28.37	282.22
	Wave 3	Wave 1	-221.923*	56.261	.002	-364.85	-78.99
		Wave 2	-126.923	61.130	.122	-282.22	28.37
% of min. OTs spent working on transfers	Wave 1	Wave 2	.513	.583	.659	-.97	2.00
		Wave 3	1.784*	.458	.003	.62	2.95
	Wave 2	Wave 1	-.513	.583	.659	-2.00	.97
		Wave 3	1.270*	.497	.049	.01	2.53
	Wave 3	Wave 1	-1.784*	.458	.003	-2.95	-.62
		Wave 2	-1.270*	.497	.049	-2.53	-.01

Appendix 4.5 Results from non-parametric Kruskal Wallis tests (significant results p<.05 shown in red)

Null Hypothesis: the distribution of following variables is the same across waves	*p*	Pairwise Comparisons				
			Test Statistic	Std. Error	Std. Test Statistic	*p*
SITE 1						
Total number OT min. per patient	.005	Wave 3-Wave 1 Wave 3-Wave 2 Wave 1-Wave 2	16.406 26.860 -10.454	10.991 8.287 11.483	1.493 3.241 -.910	.407 .004 1.000
% of min. OTs spent carrying out assessments	.659					
% of min. OTs spent communicating	.271					
% of min. OTs spent carrying out ADL int.	.001	Wave 3-Wave 1 Wave 3-Wave 2 Wave 1-Wave 2	15.117 26.062 -10.945	9.045 6.820 9.450	1.671 3.821 -1.158	.095 .000 .247
% of min. OTs spent working on transfers	.016	Wave 3-Wave 2 Wave 3-Wave 1 Wave 2-Wave 1	12.189 23.910 11.721	6.689 8.872 9.269	1.822 2.695 1.265	.068 .007 .206
% of min. OTs spent in equipment prov.	.109					
% of min. OTs spent in 'other' activities	.107					
SITE 2						
% of min. OTs spent in 'other' activities	.001	Wave 3-Wave 2 Wave 3-Wave 1 Wave 2-Wave 1	5.337 13.754 8.417	3.858 3.858 3.774	1.383 3.565 2.230	.167 .000 .026
SITE 4						
% of min. OTs spent working on transfers	.011	Wave 3-Wave 1 Wave 3-Wave 2 Wave 1-Wave 2	5.955 13.850 -7.895	4.839 4.909 3.779	1.230 2.821 -2.089	.219 .005 .037
% of min. OTs spent in 'other' activities	.128					
SITE 5						
% of min. OTs spent carrying out assessments	.078					
% of min. OTs spent in equipment prov.	.003	Wave 3-Wave 2 Wave 3-Wave 1 Wave 2-Wave 1	3.000 8.600 5.600	2.726 2.509 3.199	1.100 3.427 1.751	.271 .001 .080

Appendix 4.6 Identified iCMO for each 'area of interest' in the form of contingent narratives, including supporting units of meaning (quotes).

Trial Factors – OTs working in a research study

iCMO1: OTs with previous experience in research are taking a more practical view on how to be a research OT. They feel that even if the protocol is not necessarily in accordance with their normal way of working they are have to be aware of their role as research OTs and follow the protocol. They accept that it is part of the research role and they are motivated to works towards increasing the score in outcome measures. Interventions as a result have targeted ADL and this is likely to increase participants' independence and positively influence outcome scores.

'I think as well my experience of having worked in research before influenced that because I knew that I needed to ... the only way we were going to show something was with ... with the changing in outcome score. So I knew it was important to target an intervention like that, and that was a research bit rather than an OT bit ... that was, you know, previous experience. So ... so I think maybe actually sort of saying, you know, yes we want you to be an OT, but bear in mind that these are the outcome scores and these are the things that we'd like you to influence. And work on something ... you know, you've only got limited time; maybe choose the thing ... that you're most likely to get a change in outcome score for'.

iCMO2: Even OTs with previous experience in stroke rehabilitation have found aspects of this trial challenging. Patients in the OTCH trial have frequently had co morbidity. OTs have had to deal with complex patients and have in cases found themselves 'lost' due to their lack of experience in particular areas such as dementia treatment or other physical impairments. OTs have dealt with this in different ways. A number of OTs have made use of outside advice such as other OTs, colleagues or internet searches. Other OTs decided that some of the patients with severe cognitive impairments were not appropriate for intervention and therefore stopped their OT input. Promotion of independence for patients with co morbidity has therefore been influenced by OTs previous experience.

'And there were times when I went in and thought 'I don't know what I'm going to do here'. I think there was ... in particular there was one care home where I went in, and that was the one where I had all of the patients, and they all had dementia as well as their ... as well as the stroke ... diagnosis, and ... and I just looked and I just thought 'I don't even know where to start here'.

iCMO3: OTs have felt worried about having to 'stick' to the protocol, however with time, many OTs became less aware of the protocol and carried out interventions outside the scope of the trial. This decision was based on OT principles of 'purposeful activities' and client centred approach. By doing this OTs have expressed their awareness of the fact that their interventions might not therefore increase outcome scores in any way. OTs have felt less worried about this and more worried about making patients' lives more pleasant and potentially increasing their quality of life. As a result OT interventions have often been outside of the scope of the trial and therefore there is less chance of possible impacts of OT being quantified in terms of OTCH outcome measures.

'I've just had to accept that for some people, even though I've done interventions that might be meaningful to them and might have changed their lives in some way that it won't actually be measured as ... as anything that has ... has happened within the trial. So ... so a lot of my managing tone might not show as a good outcome in the trial ... but it may have made their lives more comfortable'.

iCMO4: A number of OT interventions have not been carried through due to funding and resources limitations. OTs have worked in a system where care homes are in many cases not eligible for a number of external services. Furthermore care homes are ran as a business and try to limit costs in order to be profitable. OTs have struggled to 'work around' this problem reaching a point where they couldn't implement their proposed intervention plans simply because they were not able to provide the right equipment or the right service to the patient. OTs have expressed than in some cases they didn't know how far to go in their recommendations since they were aware that if the recommendation was in relation to purchasing a piece of equipment then it wouldn't be implemented due to its expense. OTs also felt that by recommending expensive (but necessary) equipment they could damage their relationship with managers and staff. This has a clear impact on the success of OT intervention and decreases any chance for rehabilitation and promotion of independence.

'I think a lot of it ... comes out ... you know, the ... like commissioning of services, the ... that commissioners completely obviously forget that there's people in care homes. So that's ... I guess that's the thing with the wheelchairs, I mean that people aren't ... when they're designing services and deciding how they're going to spend the money ... they're not considering this massive population of people'.

iCMO5: OTs with previous experience working in the geographical area of their assigned care homes have been able to implement interventions plans more successfully than those new to the area. Those OTs that had previously worked in the care home postcode have made use of their knowledge regarding available services, equipment provision, referral procedures, etc. available to that area. This has made their job less time consuming. On the other hand those OTs working in care homes in areas new to them have felt like they have wasted valuable time 'finding their way around'. As a result there has been decreased chance of interventions being carried through as OTs would have liked and patients might not have received the best possible OT treatment.

'The main one has been around Portsmouth is ... well we've got two different equipment stores that cover the patch that we ... we've got. If a client comes under Portsmouth we can get lots of help from the equipment stores, they've got a specialist moving and handling adviser there, a specialist seating adviser ... and they've got me to borrow equipment to trial with residents; in some cases they've even funded it. If they come under Basingstoke stores ... nothing, they won't even let me borrow anything. It's a ... postcode lottery I think really, it depends where you live'.

iCMO6: Some OTs have been lone workers and haven't had regular peer support in order to 'bounce ideas' or ask for advice. Some OTs have found the lone working challenging and they consider this has affected their decision making especially with complex patients, maybe they have 'given up' earlier than they would have if they had had peer support. Most OTs haven't made use of the trials online discussion forum and therefore those using it haven't found it very useful. OTs have found trial OT meetings helpful but identified limitations such as PIs being present which could inhibit open discussion. Lone working might have led to OTs decrease motivation when they had to deal with complex patients. This means a decrease in the chances of rehabilitation taking place to its full extent.

'And then ... and I think, because we were all spread out so much, I mean we didn't really have ... well we didn't meet with each other until months and months and months down the line ... when the trial was well under way, and then everyone was quite shy and we didn't know each other. And we also had ... you know, kind of the ... Chief Investigator there, and maybe some of the PIs, so you might not be ... you might not feel like you can just open up and be as honest as if it was just the therapists in that situation'.

iCMO7: OTs have been carrying out their research role 'out of hours'. A number of OTs have been 'popping in an out' when possible for them due to their other job commitments. OTs have found this a limitation especially when having to deal with regimented environments such as care homes. Working 'out of hours' has had, at times, a negative impact on OTs relationships with care home staff. Other OTs have benefited from it since they have been able to have contact with patient's family members who normally visit at the end of the day. Since OTs couldn't be at care homes full time they struggled to make sure their interventions were being implemented. As a result OTCH interventions might not have been carried out as OT would have recommended and therefore this might have decreased the chances of a shift from caring to rehabilitative approach.

'I think initially it was difficult for myself and my other colleague because we were doing it as overtime ... so we were doing it after normal work hours. So we were tending to get to the care home and the care staff were trying to toilet everybody, or get everybody ready for teatime, so it was more difficult to coordinate the intervention from that perspective, which I could appreciate from working in a care home because I know you've got your daily routine that you've got to follow to make sure that you get everything done for all the clients'.

iCMO8: OTs have at times doubted whether the OTCH trial outcome measures would be able to 'show' subtle differences or improvement in areas not included in the Barthel Index. OTs have realized that some of their work won't show any increase in outcome measures scores. OTs explain that within the trial's time frame and considering the complex nature of patients' needs their interventions would not show a big enough impact that would increase scores. OTs have expressed their worry regarding the fact that their work is not 'going to show'. This could have led to a decrease in OT motivation because 'what is the point?'

I think so yeah, especially the feeding because it's not ... unable to feed, I think 1) is minimum assistance and 2) is independent. And we have made people be able to eat more independently but it hasn't changed their score because they still can't cut up feed. If you can't cut up food you only score 1). So they started off with a 1) because they couldn't cut up ... but also they couldn't, you know, get say, peas in their mouth, of couldn't pick up the peas on a spoon or fork ... we've got them being able to pick up peas on a fork or spoon but we still haven't solved the cutting issue. So that's the whole bit, they look they haven't improved, they still scored 1), but it ... yeah.

iCMO9: Some OTs have enjoyed the freedom of their research roles. Those OTs that feel confident enough (at times due to their previous experience as OTs) have enjoyed being their own boss and being able to work on a 'blank canvas'. Motivation levels in this OTs would have been high and this could have led to higher productivity and consequently a higher chance of impact on outcome measures.

'I've worked in various different departments from hand clinics to stroke patients, to the elderly, physical and mental health. You know I've practically been there and done it. I have felt confident and I have been happy. Yes I thoroughly enjoyed being like my own boss in a way. I have really enjoyed it'.

iCMO10: OTCH guidelines have provided a good enough tool for OTs, however OTs have felt that at times they 'felt a bit lost'. Many OTs have felt, at times, unsure of what their research job entitled and what was expected from them. It has been hard for OTs to know how far to go with their interventions especially when it came down to funding. OTs were doubtful as to whether searching for funding sources was considered part of their role. These doubts have at times caused disparity amongst how different OTs have worked and it might have affected the consistency and intensity of OT intervention plans.

'Yeah well fine, I had a bit of a rocky start because ... and Katie helped me a lot with various e-mails, because obviously I didn't have any ... you know, I just knew nothing, I was just given a file and said ... you know, 'Here's your new job and get on with it' type of thing'.

iCMO11: The quality/type of input of the OTs hasn't been consistent throughout the time of the trial. In some cases, OTs have changed their working methods and their reasoning paths during the running of the trial. With time OTs became more relaxed regarding their research role and became more confident and more realistic regarding what could be achieved under the circumstances. OTs got used to the new environment (care homes) and started to understand in detail what their role in the trial was. This could have led to patients receiving different quality treatment depending, for example, on the wave they were part of.

'Maybe it takes a year or so to get it set up properly. Because ... I feel like only now, only in the last sort of ... maybe three months or so do I feel like now ... oh yeah, now I know what I'm doing, now I'm up and running, now I know how things work. How to do ... and now it's nearly over'.

Therapists factors – Expectations of OTs

iCMO12: Patient allocation to the OTCH project has impacted on the work of OTs. OTs work has been limited at times to 'reviewing' patient's situation and current management. OTs believe that they haven't been able to show care home staff what is the purpose of OT as much as they wanted to because patients allocated to the project have often been severely ill not only as a consequence of stroke but also co-morbidity. At times, staff have not been able to witness a positive impact of OT and this has decreased the chance of staff shifting from a caring to a rehab approach and has impacted on staff's perception of what OT is. This has impacted on OTs motivation as they have felt at times their involvement was not appropriate and they felt there was nothing for them to do.

'Well with some of them it, it really wasn't appropriate for me to be involved I don't think, not from a rehab point of view if their management was such that physically they were being managed as well as they could be. And I can think of one resident who had end stage dementia and, you know, physically she was managed, she'd got suitable seating, bed positioning stuff, those sorts of things so I think from an OT point of view I didn't really feel there was much I could do to intervene with her. And that always leaves me with a sense of, 'oh gosh, I should be doing something' but I don't think there was necessarily anything more I could do'.

iCMO13: OTs feelings regarding their involvement in the trial have changed over time. OTs have struggled at times emotionally and they have felt negative about the work they were doing to the point of thinking of stopping. In most cases OTs have had a realistic attitude and this has helped them tackle challenges and feelings of failure or frustration. OTs have felt that maybe they haven't done enough or that there wasn't much for them to do. This way of thinking hasn't been constant, OTs have felt very differently during their time working for OTCH: there has been a fluctuation between 'good times' and 'bad times'.

'I would say I have enjoyed it, but it has been challenging as well. And it's ... it has its peaks and troughs; sometimes you can have a real success and you feel really good and ... you think I'll really make difference for that person. Other times I've felt that I haven't made a difference at all and ... you know, you just have to keep going really'.

iCMO14: OTs have been motivated throughout their involvement in the trial and have had a critical mind which has made them think about the trial and 'ask questions'. In some cases OTs are motivated because of personal reasons, they really believed in the need for this intervention and they understand why this research can help improve quality care of patients in care homes. OTs were aware before they joined the trial or have become aware of the lack of OT intervention in care homes whilst working in the trial. This realization has increased their motivation and their drive to implement OT and achieve the best possible results.

'Well I think ... because I had three months in the home, coming in quite regularly and just getting to know people, I think they liked having somebody coming in who was just ... even if it was just to have a chat with; like sometimes I'd just come in and I'd just sit and have a ten minute chat with them, and there wasn't really any intervention that I was doing, but I was just ... showing them some interest, you know. Maybe e talking about the ... what they used to do when they were younger, or their family or whatever, but some ... some people don't have any visitors. But then people would get more motivated I suppose as they got to know me a bit more and realised that I was taking an interest in them, and that I was there to try and ... improve things for them if I could'.

iCMO15: During the time of the trial OTs have worked hard at communicating with the right staff and providing regular feedback regarding the work they were doing with patients. OTs used verbal and written feedback methods according to care home recording rules and also what OTs thought was more appropriate depending on the situation. Those OTs that have shown a proactive and perseverant way of working have been able to get staff to listen to them and engage, however, many OTs have still faced communication difficulties that have resulted in OT recommendations not being followed through by staff.

'No they were very keen for me to write in the patients' notes. And I was asked to document in notes every time I visited, even if it was only the fact I'd visited. If there was anything that I needed to share, obviously to put that in there as well. I tended to ... I tended to report back to care staff because I'm not confident that they read the notes ... where you document them. I suspect, but I don't know, that it's a paper exercise. I was going to say, so I verbally reported back and then generally documented as well'.

iCMO16: OTs have made referrals as part of their role in OTCH. At times OTs have felt that the procedures in order to make the referrals have been longwinded and difficult and this has limited their chance of success and in cases it has stopped the intervention from being implemented. In some cases, this meant that ultimately patients haven't been able to access the adequate services and therefore OT interventions have been unsuccessful.

'It just seems like a massive sort of paperwork exercise for the sake of it. So you could put something in writing, or explain it in great detail over the phone to the person, and then they'll ... they'll want you to still fill in their referral form. Then I'll send it, and then it's not always even ... possible to complete it, but if you ... say, for example, say someone does need specialist seating and you want them to be assessed for it ...and ... so you want the team to come out and do the assessment, and then ... but the person at the moment is ... maybe nursed in bed or they're ... the way that they're ... because their Stroke's so severe and they've been ... kind of left along for such a long time they're in a position where you can't stand them up or sit them ... you know, nicely balanced on the edge of the bed to do the measurements. So they want all these loads of different bits of information, and it's really hard to get, you know, height and stuff like that, and you can't ... if its someone that's immobile and they're always [unclear - 1:33:12] but you can't ... or they're in a chair or whatever'.

iCMO17: OTs have worked with patients with different levels of motivation. OTs have used their professional reasoning to try to influence motivation levels: <u>firstly</u> they have been aware that patient's trust can lead to increase motivation and engagement in the intervention. OTs have taken their time to build rapport and a positive professional relationship. <u>Secondly</u> OTs have used a client centred approach when identifying goals, patients have been able to voice what their goals. Getting patients to do 'what they want to do' has increased their motivation and engagement. Ultimately OTs have been able to work successfully with motivated patients and have been able to implement intervention plans that have led to promotion of independence.

'Yes a lot of ... very unmotivated ... de-motivated, unmotivated. The ... it took ... a bit of cajoling and ... nicely, I mean I don't ... don't get me wrong, not for a minute bullying, and the care staff were nearly always there. You know, but it was a bit ... yeah it did take some cajoling. And if they did it for you once they tended ... if they were de-motivated they wouldn't do it for you again. You know, you had this one window of opportunity; and often it's catching them at the right moment ... at a time when they wanted to do that activity anyway'.

iCMO18: Throughout the time in the trial OTs have proposed 'small and easy' interventions such as issuing small pieces of equipment. They have found that this sort of intervention has generated good and fast positive outcomes. OTs have been realistic about how 'keeping it simple' has made their work more encouraging and has brought higher chance of promotion of independence. Seeing success in this way has had a direct impact on OTs motivation and might have helped OTs overcome other challenges more successfully.

'There was another lady in the residential home, again I was working on her with her feeding and she'd been struggling with her rheumatoid arthritis, she'd been struggling to cut up food and to get food onto her fork so and I had a plate surround and an adapted fork for her to try and she seemed a lot happier, you know, she wasn't making a mess which was bothering her before. So that had a positive impact as well'.

iCMO19: OTs have been overall happy with the level and quality of care given in the care homes. On some occasions this has meant that OTs found that there wasn't much for them to do since what they would have done was already in place. OTs have been able to recognize this situation and understand that this is a good outcome in itself. OTs also felt that they didn't want to disrupt or make big changes to patient's care unless they saw it absolutely necessary.

'Sometimes, you know, we were able to do ... what we thought we would be able to do with them, and then other times it wasn't as successful as we would have hoped. But, again, I think that could be the fact that they actually are being well maintained in the care home, which ... you know, which is a positive, it means you don't have to go in and ... you know, really completely disrupt everything, which ... which was good'.

iCMO20: OTs have worked hard at finding solutions for patients limitations. Although at times it was hard to find these solutions OTs haven't 'taken a no for an answer' and haven't given up after the first attempt. OTs have worked around problems and made use of professional and creative skills to achieve the patient's goals. This had had direct impact on the rate of success of OT interventions and therefore could have potentially helped the promotion of independence.

'So he had no means of proper communication for years basically, so obviously my first priority was to try and sort that out. But you know how I said ... you know, a lot of it you learn as you go along ...and I had absolute ... I mean I hadn't even seen a light writer in real life before ...obviously I'd seen it on the ... on the TV with what's it, Steven Hawkins and ... so I had no idea whether this thing was something that was commonly available or not, or ... you know ... but I did know there was a sticker on the back ... so I rang that phone number, which ... didn't ... it was an old number so it didn't exist anymore, but they gave me the number for the new place, and I rang around, spoke to a few people, and then I spoke to the speech and language ... therapy department in the local hospital ... and told them about the guy, and because it was all ... because it was so long ago, his Stroke, they said 'Oh well all his records won't be on the computer but we might have a paper record for his somewhere'. Anyway, I ... I think I laid it on a bit thick on the telephone ... but this woman at the other end was obviously sympathetic and she said 'Oh yeah, don't worry, we've got some spare in our cupboard I think. So yeah, if you pop up this afternoon ...', so within a couple of hours I think I'd ... well I'd got ... managed to get a brand new one, a replacement one, it didn't cost anything ...she just gave me it out of their cupboard. Whether that's normal or not, or she just felt sorry for me and the guy, I don't know ...but I got one ... you know, within an afternoon of ... within a day of meeting him, I came back, within a couple of hours I'd gone and physically picked it up and was able to take it out to him'.

iCMO21: OTs have carried out 'informal training' throughout their time in the trial. In their everyday contact with staff they have 'educated' staff on how to promote rehabilitation and independence. OTs have explained to staff, through every day examples, the reasons behind proposed interventions. Education has mainly been regarding equipment, self-care routines and posture. Furthermore, OTs have educated staff on how promoting patients' independence will also benefit them by reducing the amount of help patients' need which will 'free up' their time and will allow them to dedicate more time to more disabled patients.

'It was a lot of repetition and a lot of education of the staff, it was things like making sure everyone was sitting upright before they gave them drinks. And, you know, that just had to be repetition, and I had to be there in the room and ... and sort of do it and say 'Oh we'll just sit her up because otherwise she might choke'.

iCMO22: OTs have struggled to carry out their job because they have found resistance from patients for a number of reasons. Some patients that have been in care for a long time are happy and content with the way things are and are resistant to change. Also, during their time at the care home they have had time to establish strong relationships with their carers and they feel vulnerable and dependant on them. These patients don't want to risk doing anything that could negatively affect that relationship. OTs have had to respect patient's choices and therefore when patient's preferred to 'be helped' and continue with their usual care OTs have had to accept it. All these factors have at times

limited OTs chances of promotion of independence and therefore chances of increase in outcome measure's scores.

'If he thought I was upsetting the carers I don't think he would have been happy either because… they're obviously very reliant on their carers and they really don't like it if you upset them or say anything that might affect the care they're receiving. You know, obviously they're very dependent on them, aren't they, so… There is still a big culture around that. Don't rock the boat, don't upset people, don't… you know, say anything, do anything that might make them fall out with me or affect the care I might receive'.

iCMO23: Care homes are environments with strict rules and timetables; as a consequence they are environments lead by routines. Staff work according to that routine and patients are familiar with it and resistant to change. OTs have found it hard to find a balance between implementing their proposed intervention plans and not 'upsetting' the care homes daily routine. OTs have tried to 'work around the routine' and tailoring their intervention plans to this routine as much as possible. OTs have been flexible in their work and have accepted this reality and this could have potentially increase the success rate of their interventions and their ability 'fit in' the care home and built rapport with staff.

'Because certainly in the homes you know, things can be, not can be, they are quite rigid mostly and, you know, this is when we get people up and washed and dressed and this is when we give them their afternoon tea and this is when we give them their dinner or. You know, and you've got to kind of play a game, you've, you've got to work around that a little bit. But I think as long as you do, you know, there's not too much of a problem. Yeah you've sort of got to incorporate that into what you're doing really'.

iCMO24: OTs not only have had to adapt to a new environment (care homes) but have had to adapt to the high variability amongst care homes. Every care home has been a different challenge. OTs have had to tailor their work to suit the differences amongst nursing and residential homes. OTs have had to spend time and effort adapting to each setting and have found different ways to achieve this. Many OTs have decided to 'muck in' as a way to build rapport and understand staff pressures and every day work. OTs time spent in the adaptation process would have reduced the time spent on patients' assessments and intervention planning and execution.

'I think the nature ... and I think it's very different between residential and nursing homes ... I think the nature of client groups in residential homes, people tend to be a little more mobile, more energy, and they are ... I guess there's less ... heavy intervention required from care staff, whereas I think in nursing homes there is ... such a high level of care required, and there is a high turnover of staff, that ... so I think ... my impression was that the homes were coping with meeting basic needs. And therefore rehabilitation is not really a priority in that environment ... for the care staff'.

Making changes (to the care home environment)

iCMO25: Small changes to patient's environments proposed by OTs have been well received by staff, especially small equipment such as handrails. OTs have been able to carry out their 'environmental' interventions with engagement from staff. With OT input patients' environment has become safer and more appropriate to their needs. OTs have worked with available resources (e.g. when changing or adapting patients' rooms). This has been possible mostly because this sort of intervention was free of charge for the care home and not time consuming for care home staff. Furthermore managerial staff were aware that these changes would benefit the results from future quality inspections. These interventions were likely to have a positive impact on promoting patients functional independence and therefore increase outcome scores.

'They were very happy for that (laughs). If I was going in and saying 'Oh we need some handrails here' and ... 'If we turned the bed round then that would be easier' and ... but certainly handrails, they were very, very grateful for handrails because I was paying for them. They were 'Oh yes, fine' that will look good when the inspection people come round (laughs). I'd be like 'You have got someone to put them up haven't you, because I'm not doing it'. So yeah, they were more than happy for environmental things'.

iCMO26: OTs have had to work with care homes with a strong 'risk aware' culture. This, at times, has affected their ability to carry out environmental changes that involved for example changes in the way furniture was arranged in communal areas. When OTs haven't been able to make the suggested changes they have felt frustrated and this could have led to a loss of motivation and engagement with the trial which could have negatively impacted on outcome measures' scores.

'It was the position of the seating that I objected to, and we've still got this rule where everybody sits around the outside. You know one big circle and ... that ... that's what I didn't like. But, you know ... there's no room to move it round, you know, it becomes a ... a moving and handling risk and a trip hazard and everything when you start ... rearranging furniture slightly differently'.

iCMO27: OTs have had to realise that resource availability is limited and the referral procedure is lengthy and winded, therefore environmental changes involving costly seating and postural equipment available from external services will be difficult to carry through. Funding limitations have played a big role since care homes are often not eligible for this funding. Care homes are businesses and are profit driven; therefore money is not easily spent. OTs have found this frustrating and unfair, making their work regarding postural and seating improvements more challenging and at times impossible. This could have a negative impact on promotion of patients' independence.

'I think a lot of it ... comes out ... you know, the ... like commissioning of services, the ... that commissioners completely obviously forget that there's people in care homes. So that's ... I guess that's the thing with the wheelchairs, I mean that people aren't ... when they're designing services and deciding how they're going to spend the money ... they're not considering this massive population of people'.

iCMO28: Care home staff 'sticking' to what they know. OTs have found that staff systematically use specific equipment because they are familiar with it and they are not very keen on trying new things. Even with the equipment they know they will use it in a standard manner and won't use the equipment to its full potential. In view of this some OTs, at time of proposing intervention plans have decided to make use of the resources staff already know and this had led to realistic intervention plans that have had more chance to be implemented successfully since staff were 'on board'.

'And the care home staff tends to favour things like curtain armchairs. I'm not entirely sure why that is. Whether there's an issue of familiarity of use with the curtain chairs. And, you know, they're not very familiar with the tilt in space type of chairs and how to use them and those sorts of things. And I think unless residents are going out which they do rarely they tend then to not use the wheelchairs, they'll only use them if the person is actually going out of the building'.

iCMO29: OTs have been able to suggest environmental changes that although targeted at one OTCH patient in particular they also have a positive effect on the care home as a whole. By helping one patient via implementing changes in his environment then care home staff realised the usefulness of some equipment and decided to use it for other patients.

'And I took something in for one person, and they said to me 'Oh that ...' and it didn't work for that one person, but they said 'Oh that would be really good to try with somebody else', who actually wasn't on the trial. So at least they were then thinking at little bit ... outside the box of me and the trial ... and what would be beneficial to their residents. So I may not have helped a resident on the trial but I may have helped somebody'.

Organizational factors – changing staff attitudes

iCMO30: OTs have had to deal with communication problems, how is it best to feedback to staff? OTs have taken different approaches (written and verbal) to that with more or less success depending on the cases. The method chosen for feedback would depend not only on the way the home run but also on the patient, his/her condition. When staff are aware of what is happening and what OT is and what it does then there is a higher chance of engagement and therefore more chance of shift towards a more rehabilitation approach.

'I doubt anyone's read anything that I've written to be fair. Well I think out of sort of duty that I always document what I've done but yeah, I would be very surprised if anyone's read it. So I always, I always speak to the nurse in charge when I'm visiting before and when I finish to kind of let them know what I'm doing, what my plans are and I'll talk to whichever care staff are around as well but I always make sure I speak to the nurse in charge. But I think again that varies. Some of them I'll leave information with and ask them to do things or so on and so forth and I think there's a classic, I say right I'm going to come tomorrow and do a personal care assessment with Mr X. And you turn up tomorrow and Mr X has already been sorted. That kind of thing happens'.

iCMO31: OTs have been very aware of how care home staff work under a very tight schedule and time is precious for them. Keeping this in mind OTs have tried to change staff attitudes by making them understand that an increase in patient's independence not only benefits the patients but also frees up staff time and allows them to spend more time with patients who really need their assistance.

'They were okay. I had to change the care plan and talk to the other members of staff. And as far as I was aware they were quite happy, because actually they were sending two in to assist him, because they were rolling him on the bed and things ... and so it meant that they literally didn't need any staff going in so it freed them up ... they just went in for a very small amount of time when he did his transfers ... and ... to observe, and then left him to it. So it actually freed up their time. So I think from being initially suspicious and a little bit hostile, actually they were quite pleased with that'.

iCMO32: OTs found that the process of making referrals is not easy or straightforward, staff feel like it's a lengthy process and also they are not entitled to make the referrals in some cases so they rely on other professionals. This can have a negative impact on their motivation to pursue referrals and external services. OTs have worked alongside staff and have experienced this and therefore have understood the difficult situation that staff face. Potential for rehabilitation is minimized because even if staff know they should promote independence they struggle to access the right services for it.

iCMO33: The 'caring culture' of care homes has had a direct impact on OTs work. OTs have felt that care home staff see their role as a 'caring role' and therefore this limits potential for rehabilitation and independence. OTs have had to deal with this and at times this has meant that they haven't been able to put in place interventions that they considered appropriate (e.g. transfers vs hoisting). OTs agree that shifting this thinking towards a more 'rehab approach' is very hard in this type of environment because it's embedded in all aspects of daily routine. OTs have identified that although staff understand OTs suggestions they still do not implement them.

'They'd got into, the staff in this particular home, were sort of into the mode of working like you know the full caring role. And it was difficult to break, you know I went in there about three times and each time I felt as if I was saying the same thing to get it through to them but they were still hoisting'.

iCMO34: OTs have found that another factor limiting their interventions being implemented or followed through is the fact that care home staff are not willing to take responsibility. OTs have worked on trying to encourage a more 'rehab approach' by explaining to carers that they can help patients achieve higher levels of independence. OTs have had the feeling that carers didn't want the responsibility linked to this change of approach and that this was due to a lack of confidence that staff have and that due to a lack of confidence staff were always seeking 'permission'. This could have potentially impacted on the positive implementation of proposed OTCH interventions.

'I don't think they like to take responsibility, and I think that was sometimes a bit difficult. So you'd go through and review and it would be 'Oh, resident ... washed completely by carers', and it's like 'Well why have you done that when you know ... it's above the bed, it's in the care plan that actually they can do some of it themselves', and somebody ... 'Oh I didn't see, I didn't see'. But, you know ... sometimes I think it's just a lack of onus on them wanting to take responsibility for ... for a little bit of rehab with somebody'.

iCMO35: The 'risk aware' culture of care homes has had an impact on the success of OT interventions. OTs have carried out interventions with patients that have challenged this 'risk aware culture'. OTs have been happy to challenge it and have seen positive effects on patients' independence and wellbeing. At times, OTs have had to work hard at creating a shift towards a more flexible 'risk aware' culture. OTs have realized that them going in the care home has changed patient's lives and this has encouraged OTs and motivated them.

'So that was kind of quite encouraging because I think, had I not gone in, she would have been a little, very frail little old lady that would have sat in the corner of her room and probably not done anything, because the staff would have said, 'well she's very frail, we don't want her to fall, better to keep her safe' and actually, you know, her function would deteriorate so'.

iCMO36: Care homes have a high number of staff, shifts and staff turnover which leads to low continuity. OTs have been aware of this so have tried to tackle the problem by working alongside staff and trying to become one of them, that way they got to know the staff better and they might have been able to change the perception that staff had of OTs. This might have impacted on the time OTs have had to actually spend with patients.

'Well I'd just try and ... join in with the staff a bit, so instead of coming in and just doing therapy and leaving again I'd actually try and sort of say, 'Okay, well I'll stay around at dinnertime and I'll ... whilst I may be observing one person, perhaps I'll help with somebody else who needs feeding'. And it may be somebody that I was working with or maybe not, but it gave me a role ... whilst I was observing somebody else, rather than just me sitting opposite and watching it. But it also sort of helped build a rapport with the staff. And pause) and just an awful lot of sort of ... chatting and explaining and ... and also trying to not just focus on work, you know, trying to have normal conversations as well and ...spending time in the tea room with them and things, you know'.

iCMO37: OTs have realized that due to the nature of care homes, which often follow a 'business model' it is very difficult to change staff attitudes in isolation. This means that for the patient to benefit from it the change needs to impact on staff as a 'whole'. For clear and important benefits to be seen

impact has to reach staff as a 'whole', changing the thinking of one particular member of staff will be beneficial but won't lead to major shifts from a caring to a rehab culture. OTs have understood this and have worked hard at feeding back their work to managers and decision-makers at each of the care homes. OTs have tried to work 'globally' and not have a narrow view on their involvement in the trial since they have understood that ultimately their impact should be as wide as possible. Success of the OTCH intervention has heavily relied on getting managers and the leadership to engage and act on changes proposed by OTs.

'Because I think even if people are ... willing as individuals, you have to approach these things as a team so that means everyone's got to be behind it, everybody's got to be engaged in it, and I ... I just think that the business model of many of these homes isn't ... is ... is possibly not going to support some of these different ways of working'.

iCMO38: Overall OTs have found a lot of variability regarding how staff have welcomed their work. OTs have often felt that staff are suspicious and believe that they are being tested. In answer to this OTs have often worked hard at shifting this belief by working on building rapport with care home staff. OTs have been aware that the level of success of their interventions has been directly and strongly linked to the level of engagement and positive rapport they were able to build with care home staff.

'I actually find them ... in many instances the carers were quite defensive, because I think they thought you were examining their work ... rather than trying to do the residents and it didn't matter how much you tried to explain it ... you know ... you know, one carer commented 'Well we've already tried all this', you know, and ... you know, 'It's not like we don't do anything for them' type attitude it was, you know 'We have tried' and ... and what have you, and I think they felt a bit ... yeah, I do think some of them felt defensive ... that I was checking up on them and that obviously wasn't the case at all'.

Appendix 5.1 Summary of data extracted from studies included in stream I (PP: participants perceptions investigated; FA: fidelity/adherence measures; C: context considered - more than just mentioned (briefly (1), in detail (2)); IS: intervention staff characteristics described in detail; ST: staff training; PC: performance criteria included as part of training and preparation of intervention staff; LO: learning over time considered; TB: theoretical base and underpinnings considered; PO: linking of process evaluation and outcome results explained (briefly explained (1); in detail (2))

ID, Author(s). Year. Study type. Study design	Study intervention. Health condition. Intervention provider	PP	FA	C	IS	ST	PC	LO	TB	PO
1. A'campo et al., 2010. Exploratory study; Questionnaires and rating - formative first evaluation, no RCT and no control group	Psychosocial education program. Parkinson's disease (caregivers and patients). Group leaders (mostly psychologists)	Evaluation questionnaire (3pt scale)	X	X	X	X	X	X	X	X
2. Alwin et al., 2007. Study protocol; Main study: Before/after design. 3. Alwin et al. 2013. PE of study [2] – results.	Assistive Technology and OT. Provision of AT and also teaching of support strategies to use in everyday life. Dementia	Standardized instrument (POCR)	X	X	X	X	X	X	X	X
4. Ang et al. 2011. Study/trial results; Randomized attention-controlled trial	Motivational interviewing - efficacy of telephone delivered motivational interviewing (MI) that targets exercise adherence to improve FM-relevant clinical outcomes – Fibromyalgia. Health practitioner	X	√	X	X	X	X	X	X	X
5. Ayan et al. 2009. Feasibility/Pilot study; Questionnaires and rating	Multimodal programme combining techniques of relaxation with physical exercises, concentrating on the development of flexibility and muscular resistance – Fibromyalgia. Physiotherapists.	X	√	X	X	X	X	X	X	1
6. Bowen et al. 2010. Study/trial results; Assignment to individual groups, no randomization	New rehabilitation service - Leeds Head Injury Team (HINT) – TBI. MDT	X	X	√	X	?	?	X	X	1
7. Braun et al. 2007. Study protocol; Multi centre RCT. 8. Braun et al. 2010. PE results	Mental practice embedded in daily therapy – Stroke. Paramedical staff	Questionnaire for int. staff. Interview, mood logs and questionnaires for participants	√	√	X	√	X	X	X	1
9. Brittle et al. 2009. Exploratory study; cluster RCT	Group exercise - Care homes residents with cognitive impairments. Physiotherapists	X	√ - Attendance	√	X	X	X	X	X	1

ID, Author(s). Year. Study type. Study design	Study intervention. Health condition. Intervention provider	PP	FA	C	IS	ST	PC	LO	TB	PO
10. Brumfitt & Sheeran, 1997. Exploratory study; Within subject design	Group therapy - Aphasia	Satisfaction scale (7-items)	X	X	X	X	X	X	X	X
11. Canning et al. 2012. PE results; Assessor-blinded, prospective, Pilot RCT	Six weeks of home-based treadmill training – Parkinson's disease. Physiotherapists	X	√ - Screening log books	X	X	X	X	X	X	1
12. Chan et al. 2012. Feasibility/Pilot study; RCT (single blinded)	Yoga and exercise - Post stroke disability (hemiparesis). Yoga instructor	X (informal discussions)	√ - Attendance. Screening of recording sheets	X	X	X	X	X	X	1
13. Chaplin et al. 2012. Study/trial results; Feedback from users and professionals	Self-management programme. Long term neurological conditions (Stroke, Parkinson's, MS). Health professionals	Evaluation questionnaires	√ - Attendance	X	X	X	X	X	X	1
14. Christy et al. 2010. Study/trial results; It looks at a number of different studies	Intense model of physical therapy. Cerebral palsy. Physical therapists	Semi structured interviews	X	2	X	X	X	X	X	X
15. Chung 2009. Study/trial results; pre- and post- one group design	Intergenerational reminiscence programme. Dementia. OTs and young volunteers	Questionnaire	X	2	X	√	√	X	X	X
16. Clarke et al. 2013. PE results; Pragmatic multicentre, cluster RCT 17. Forster et al. 2013. HTA report 18. Forster et al. 2013. Trial results	Structured training program for caregivers of stroke inpatients. TRACS trial. Stroke. MDT	Semi structured interviews/researcher observations	√ - Compliance. Field notes, reflective accounts, steering committee	√	X	√	√	√	√	2
19. Cup et al. 2011. Study/trial results; Consultations and questionnaires - prospective cohort study	Multidisciplinary advice to allied health care professionals - Neuromuscular diseases.	Questionnaire	X	X	X	X	X	X	X	X
20. Dodd et al. 2006. Study/trial results; Qualitative - interviews	Progressive resistance exercise (PRE) programme. Multiple Sclerosis. Physiotherapists	Semi structured interviews to participants	X	1	X	X	X	X	X	2
21. Döpp et al. 2013. PE results; Cluster single-blinded RCT. 22. Döpp et al. 2011. Trial protocol 23. Van't Leven et al. 2012. Trial results: Qualitative (grounded theory)	Multifaceted Implementation Strategy (MFI) to carry out the Community OT in Dementia (COTiD) programme. Dementia. OTs	Questionnaire/focus groups	√ - Research log, questionnaires, frequency	1	X	√	X	√	√	1

ID, Author(s). Year. Study type. Study design	Study intervention. Health condition. Intervention provider	PP	FA	C	IS	ST	PC	LO	TB	PO
24. Drummond et al. 2013. Feasibility/Pilot study; RCT and cohort study	OT pre discharge home visits for people after stroke (HOVIS).Stroke. OTs	X	√	X	X	X	X	X	X	1
25. Drury et al. 2013. PE results; Cluster RCT	Intervention to improve management of fear, hyperglycaemia and swallowing dysfunction after acute stoke. Quality in Acute Stroke Care (QASC) trial. MDT	X	√ - Audit of records	X	X	√	X	X	X	2
26. Ellis et al. 2013. Study/trial results; Single group, nonrandomized clinical trial	Virtual exercise coach to promote walking. Parkinson's Disease. Patient (self-administered)	Evaluate acceptance: single item scale	√ - Completion	X	NA	√	X	X	X	X
27. Elsworth et al. 2011. Feasibility/pilot study; Phase II RCT	Physical activity support system (PASS): supported community exercise. Long-term neurological condition. Physiotherapists	X	√ - Attendance	X	X	√	X	X	X	1
28. Eyssen et al. 2013. Study/trial results; Multicentre cluster RCT	OT according to a client-centred process framework compared to usual OT care. Multiple Sclerosis. OTs	ECGP questionnaire (patients and OTs)	√ - Compliance	X	X	√	X	X	X	1
29. Garcia-Jalon et al. 2013. Feasibility/Pilot study; RCT	Energy conservation programme. Multiple Sclerosis.	Group discussion with patients	√ - Attendance	X	?	?	X	X	X	1
30. Gitlin et al. 2009. Feasibility/Pilot: 2 group controlled pilot randomized trial 31. Gitlin et al. 2008.	Tailored Activity Program for at-home dementia patients (TAP). Dementia. Care givers. Teachers	Questionnaires, ranking scales, individual interviews and observations	√ - Dose	X	X	X	X	X	X	2
32. Grossman et al. 2010. Study/trial results; RCT	Mindfulness-based, group intervention (MBI) for enhancing HRQOL. Multiple Sclerosis	Post intervention interviews (to patients)	√ - Post intervention questionnaire	X	√	X	X	X	X	X
33. Gu 2012. Thesis; One group pre-post-test.	Home based exercise program with Wii. Parkinson's D. Patients (self-administered)	Informal discussions/obs.	√ - Dose received	X	X	√	X	X	X	X
34. Hafsteinsdottir et al. 2007. Study/trial results; Non randomised study	Neurodevelopmental treatment (NDT). Neurological conditions. Nurses	X	√	X	X	X	X	X	X	X

ID, Author(s). Year. Study type. Study design	Study intervention. Health condition. Intervention provider	PP	FA	C	IS	ST	PC	LO	TB	PO
35. Heijnen et al. 2010. Study protocol; Non randomised comparative study for two groups	Re designed care pathway for stroke patients. Stroke. MDT. Stroke	In depth semi structured interviews (patients and int.staff)	X	X	X	X	X	X	X	N/A
36. Hohmann et al. 2009. Study/trial results; Non randomized two group design	Intensified pharmaceutical care (PC). Stroke (TIA, IA). Pharmacists	Questionnaire	X	X	X	X	X	X	X	1
37. Hollands et al. 2013. Study protocol; 3-arm, parallel group, multi-centre, single blind, randomised control feasibility trial	Over ground visual cue training (O-VCT), treadmill visual cue training (T-VCT) and usual care (UC). Stroke. Research therapists	Telephone interviews to patients; Focus group with therapists	√ - Compliance. Research logs, video obs. and review.	X	X	√	X	X	X	N/A
38. Huijbregts et al. 2008. Study/trial results; Prospective, longitudinal cohort design	Moving on after stroke (MOST) and Living with stroke (LWS). Stroke. MDT	Written and verbal feedback from int. staff. Focus groups with patients	√ - Attendance records. Observations of sessions	1	X	√	X	X	X	1
39. Hutchison et al. 2006. Feasibility/pilot study; Evaluation study prior to the RCT	Hypothermia therapy. TBI. Health professionals	X	√ - Pre-trial adherence criteria	X	X	√	√	X	X	X
40. Khalil et al. 2012. PE results; Exploratory mixed method design 41. Khalil et al. 2013. Feasibility/Pilot study; RCT	Home-based exercise DVD. Huntington's disease. Physiotherapists and patients (self-administered)	Telephone semi structured interviews	√ - Telephone calls and exercise diaries	X	X	√	X	X	√	2
42. King et al. 1998. Feasibility/Pilot study; One group test (no control group)	Goal attainment scaling (GAS) and several standardized measures in evaluating the effects of paediatric therapy services in the school setting. Children with articulation difficulties, developmental coordination disorder, or cerebral palsy. OTs and Physiotherapists.	Client satisfaction questionnaire. Telephone interviews (parents and patients). Self-administered questionnaire and brain storm (int. staff)	√ - Individual reviews and checklists	X	√	√	√	X	X	X
43. Klein & Rivers. 2006. Study/trial results; Pre-post-test assessments. Qualitative - questionnaires, focus groups.	Taiji exercise program. Parkinson's disease. Taiji instructor	Self-report questionnaire, focus groups, reflexions	√ - Attendance	X	X	X	X	X	X	1

ID, Author(s). Year. Study type. Study design	Study intervention. Health condition. Intervention provider	PP	FA	C	IS	ST	PC	LO	TB	PO
44. Knapp et al. 2013. Feasibility/Pilot study; One group analysis	Virtual dialogue method, virtual conversations. Acquired BI. Patients (self-administered)	Attitude survey	X	X	X	X	X	X	X	1
45. Kolanowski et al. 2006. Protocol for fidelity monitoring. Randomized Clinical Trial	Prescribed recreational activities for optimal engagement and reduction of behavioural Dementia (residents in care homes). Recreational therapists and nursing students	X	√ - Fidelity. Treatment fidelity checklist, random checks, diaries and field notes	2	X	√	X	X	√	N/A
46. Kurz et al. 2012. Study/trial results; Multicentre RCT	Cognitive rehabilitation (CR). Alzheimer's disease. Behavioural therapists	Satisfaction questionnaire (patients)	√ - Acceptance. Therapist manual on-site monitoring visits, data monitoring and safety committee	X	X	√	X	√	X	1
47. Lavoie et al. 2005. PE results; RCT	Psycho-educational group for caregivers of persons with dementia. Dementia.	Semi structured interviews (to patients)	X	X	?	X	X	X	X	1
48. Letts & Dunal. 1995. Study/trial results; Repeated measures design (of one group, no comparison group)	Community rehabilitation programme. Adults with brain injury. Rehabilitation worker and OTs	X	√ - Implementation	X	X	X	X	X	√	X
49. Leuty et al. 2013. Study/trial results; Pragmatic, Mixed methods, concurrent nested design	ePAD - Engaging Platform for Art Development (touch screen). Dementia. Therapists	Quantitative questionnaire (perceptions) (to patients and int. staff)	√ - Recording of sessions, ePAD, research log	X	X	√	X	X	X	1
50. Li et al. 2007. Feasibility/Pilot study; One group (single arm, unmasked) pre/post-test design	Newly developed TaiChi based exercise program. Parkinson's disease (early stage). TaiChi Instructor	Exit interviews and rating opinion survey	√	X	√	X	X	X	X	X
51. Macht et al. 2007. Study/trial results; Single group, pre and post-test design	Education program for PD. Parkinson's disease. Group leaders	12 Item questionnaire	X	X	X	X	X	X	X	X

ID, Author(s). Year. Study type. Study design	Study intervention. Health condition. Intervention provider	PP	FA	C	IS	ST	PC	LO	TB	PO
52. Sackley et al. 2006; Feasibility/Pilot study; Cluster multicentre RCT 53. Masterson et al. 2013. PE results/Abstract. RE 54. Masterson-Algar et al. 2014. PE results. RE 55. Sackley et al. 2012. Study protocol.	OT intervention focused on promoting independence in self-care activities of patients with stroke living in care homes. OTCH study. Stroke. OTs	Semi structured interviews (prof)	√ - Fidelity. Intervention logs.	X	√	√	X	√	√	2
56. Mayo et al. 2013. Study/trial results; RCT (observed blinded, pragmatic with repeated measures)	Two home based exercise programmes (cycling and mobility exercise/brisk walking) to improve functional walking. Stroke. Physical therapists	Weekly phone calls	√	1	X	X	X	X	X	1
57. McCluskey & Middleton. 2010. Study/trial results; RCT	Intervention to increase outdoor mobility after stroke and other neurological conditions. OTs	Interviews	√	X	X	√	X	X	√	2
58. McCurry et al. 2011. Study/trial results; RCT with blinded assessors	Walking, light exposure and a combination intervention (walking, light and sleep education) on the sleep of persons Alzheimer's D. MDT	Rating exercise (patients)	√ - Daily logs, recorded sessions and reviewed with checklist.	X	√	√	X	X	X	1
59. McDougall et al. 2006. Study/trial results; Pre-post-test design, comparison group and follow up.	Family/community-focused programme (PABICOP) for improving outcomes for children with ABI. MDT	Interviews an questionnaires (to patients)	√	X	X	X	X	X	X	2
60. McGinley et al. 2012. Feasibility/Pilot study; RCT	Physical therapy, three groups: Progressive strength training (PST), movement strategy training (MST) and control ('life skills'). Parkinson's disease. OT and social workers	X	√ - Attendance and compliance. Therapy forms, booklets with exercise photos	X	√	√	X	X	X	1
61. Mead et al. 2007. Exploratory study; Randomized trial	Exercise training versus relaxation for people after stroke. Stroke. Exercise instructor	X	√ - Attendance	X	X	X	X	X	X	X
62. Miller et al. 2007. Feasibility/Pilot study; one group pre-test.	Sensory integration approach (OT-SI) to treat sensory processing disorders (SPD). OTs	X	√ - Video sessions which are reviewed	X	X	X	X	X	√	X
63. Morris et al. 2009. PE results; Multisite RCT	Extremity constraint induced therapy. Stroke. Physical therapists	X	√ - Fidelity. Video sessions which are reviewed	X	X	√	√	√	X	2

ID, Author(s). Year. Study type. Study design	Study intervention. Health condition. Intervention provider	PP	FA	C	IS	ST	PC	LO	TB	PO
64. Mumby & Whitworth. 2012. Study/trial results; Qualitative and quantitative, over one year.	Communication Hub for Aphasia in North Tyneside (CHANT). Structured programme for goal setting. Stroke (long term aphasia). Speech and language therapist.	Interview and rating exercise (with patients)	√ - Completion numbers	1	X	X	X	X	X	2
65. Netz et al. 2007. Study/trial results; Randomized Controlled design	Group physical activity in day-care centre. Dementia. Physiotherapists and exercise instructors	X	√ - Attendance. Video recordings and observer (reviewed with testing scales).	X	X	X	X	X	X	2
66. Nomura et al. 2009. PE results; Community health action research model	Cognitive rehabilitation (CR) - group activity programme. Dementia. MDT	Focus groups and counselling (patients)	√ - Attendance	2	√	X	X	X	√	2
67. O'Brien et al. 2013. Study/trial results; RCT 68. Das Nair & Lincoln 2013. Trial results; RCT	Comparing compensation, restitution and self-help treatments. ReMIND study. Neurological disabilities (memory problems) due to TBI, stroke or MS. Psychologists	X	√ - Fidelity. Manual review and observation of recorded sessions	X	X	X	X	X	X	2
69. Oh et al. 2012. Study/trial results; Prospective cohort study	Brief interdisciplinary treatment program (FTP). Fibromyalgia. MDT	FIQ questionnaire	X	X	X	X	X	X	X	2
70. Østensjø et al. 2008. Study/trial results; Multi-case study	9-month rehabilitation programme consisting of two blocks of setting and implementing goals. Mild to moderate Cerebral Palsy. MDT	Questionnaire (to patients and int. staff)	√	X	X	X	X	√	X	X
71. Page et al. 2002. Study/trial results; Questionnaires	Constraint-induced movement therapy (CIT). Stroke. MDT	Questionnaire (to patients and int. staff)	X	X	√	√	X	X	X	2
72. Powell et al. 2006. PE results; Different trials using the TSP, controlled and qualitative	Training and support programme (TSP) - massage for children with CP. Administered by patients' parents (who are trained by massage therapists)	Record sheet (patients and int. staff)	√ - Only completion	X	X	√	X	X	X	1
73. Redfern et al. 2008. Abstract; Cluster RCT	Stop Stroke intervention (management of multiple risk factors post stroke). Stroke	Semi structured interviews (intervention arm)	?	?	?	?	?	X	X	1

ID, Author(s). Year. Study type. Study design	Study intervention. Health condition. Intervention provider	PP	FA	C	IS	ST	PC	LO	TB	PO
74. Resnick et al. 2011. Report; RCT	Exercise training - hemi paretic stroke intervention development study (Treadmill Study). Stroke. Exercise physiologists	Informal chat	√ Fidelity components and attendance. 20 observations and checklist to review them. Supervised intervention sessions	1	X	√	X	X	√	3
75. Roehrs & Karst. 2004. Feasibility/Pilot study - one group pre/post-test design.	Aquatic exercise program. Progressive MS. Physical therapy student	Sign-in sheet with comments section	√ - Attendance. A physiotherapist participated in the session every other week	X	X	√	X	X	X	2
76. Rolland et al. 2007. Study/trial results; RCT	Exercise program. Alzheimer's disease. OTs	X	√	X	X	X	X	X	X	2
77. Romberg et al. 2004. Study/trial results; RCT	Progressive exercise program. Multiple Sclerosis. Physiotherapists and patients' self-administered	X	√ - Participant diaries, phone calls.	X	X	√	X	X	X	1
78. Sale et al. 2013. Feasibility/Pilot study; RCT	Robot-assisted walking training. Parkinson's disease. Physiotherapists	X	√ - Compliance	X	X	X	X	X	X	X
79. Schachter et al. 2003. Study/trial results; RCT	Home based, videotape based low impact aerobic exercise. Fibromyalgia. Physiotherapists and patients (self-administered)	X	√ - Encouragement from leaders. Video of exercise, booklet and logbook, telephone calls	X	X	X	X	X	X	2
80. Scianni et al. 2012. Study/trial results; RCT	Strengthening exercises for stroke rehabilitation. Stroke. Physical therapists	X	√ - Attendance and adherence. Individual encouragement, attendance logs and record for non-attendance	X	X	X	X	X	X	1
81. Scobbie et al. 2013. PE results; Qualitative in depth interviews	Goal setting and action planning framework (G-AP). Stroke. MDT health professionals	Qualitative interviews (to patients and int. staff)	√ - Fidelity. Review of case notes	√	X	√	X	X	√	2

ID, Author(s). Year. Study type. Study design	Study intervention. Health condition. Intervention provider	PP	FA	C	IS	ST	PC	LO	TB	PO
82. Shatil et al. 2010. Study/trial results; 2 group design: control and intervention	Home based, computerized cognitive program. Multiple Sclerosis. Patients (self-administered)	X	√ - Completion. Phone calls, technical support	X	X	X	X	X	X	1
83. Shevil & Finlayson. 2009. PE results; Mixed methods	Group based, self-management cognitive program. Multiple Sclerosis. OTs	Evaluation questionnaires (rating and open questions) to patients	√ - Attendance. Phone call reminders	X	X	X	X	X	X	2
84. Simpson & Long. 2004. PE results; Surveys and questionnaires.	Sex education and information resources. Traumatic Brain Injury. Health professionals	Rating questionnaire. purpose-designed evaluation protocols for staff and consumers	NA	X	√	X	X	X	√	1
85. Sims et al. 2009. Study/trial results; RCT	Community based progressive resistance training (PRT). Stroke. Fitness trainer	Informal comments, problems reported in the attendance log	√ - Attendance and completion.	X	X	X	X	X	X	1
86. Sjo et al. 2010. Study/trial results; Intervention group and pre-post-test assessment	Memory and attention training for children (AMATC). Acquired brain injury (ABI). Health professionals and teachers	4 evaluation questions (rating 1-3) (to patients and int. staff)	√ - Weekly observation of sessions by supervisor	1	X	X	X	X	X	2
87. Hale et al. 2012. Exploratory phase II study - single-group, pre-post-test clinical design 88. Smith et al. 2013. Qualitative study	Blue Prescription, a physiotherapy approach aimed at optimising long-term adherence with physical activity. Multiple Sclerosis. Physiotherapists	Interviews with patients	√ - Log book. Activity diaries checks	X	X	X	X	X	√	2
89. Smith et al. 2012. Study/trial results; Small Randomized Trial	Motivational Interviewing (MI). Multiple Sclerosis. Social workers.	Self-report scales	√ - Attendance, treatment integrity as fidelity. Supervision, audio recordings analysed and reviewed.	X	X	√	X	X	X	2
90. Steinberg et al. 2009. Study/trial results; Controlled pilot trial	Home-based exercise programme. Alzheimer's disease. Patients (self-administered)	X	√ - Compliance and completion. Weekly diaries of subject activities checked	X	X	X	X	X	X	X

ID, Author(s). Year. Study type. Study design	Study intervention. Health condition. Intervention provider	PP	FA	C	IS	ST	PC	LO	TB	PO
91. Stephens et al. 2008. Feasibility/Pilot study; RCT	Exercise intervention. Children with fibromyalgia. Trained exercise instructors.	X (only records of adverse events)	√ - Diaries, attendance. Phone contact to motivate, study diary and rewards	X	X	X	X	X	X	1
92. Struchen et al. 2011. Feasibility/Pilot study; RCT	Social peer-mentoring program. Traumatic Brain Injury. Peer mentors (trained by neuropsychologists)	Intervention and surveys (ranking and open questions)	√ - Monthly mentor, log sheet, ongoing supervision	X	X	√	√	X	X	2
93. Sturkenboom et al. 2013. PE results; Exploratory multicentre assessor blinded, two-armed RCT 94. Sturkenboom et al. 2013. Study protocol	Home based OT programme. Parkinson's disease. OTs	Interviews (to patients and int. staff), focus groups (int. staff), self-report questionnaires (patients)	√	√	√	√	X	√	√	3
95. Suttanon et al. 2012. Study/trial results; Qualitative retrospective study	Home-based balance exercise program. Alzheimer's disease. Patients (self-administered)	Semi structured interviews	√ - Exercise recording sheet. Verbal reminder, booklet, help from physiotherapists	X	X	X	X	X	X	2
96. Tak et al. 2012. Study/trial results; RCT	Folate Physical Activity Cognition Trial (FACT) - moderate-intensity aerobic walking program. Mild cognitive impairment. Trained instructor	Rating satisfaction survey Questionnaire	√ - Attendance	X	X	√	X	X	X	1
97. Tappen et al. 2000. Study/trial results; a repeated measures three-group randomized design	Exercise, conversation - walking only and conversation only. Alzheimer's disease. MDT	X	√ - Fidelity (amount of treatment received)	X	X	X	X	X	X	X
98. Taylor et al. 2009. Feasibility study; Programme delivered and outcome measures taken at three different times	Videoconference delivery of the Moving On after Stroke (MOST) multimodal psycho-educational and exercise self-management program. Stroke. Health professionals	Survey, focus groups (to patients and int. staff). Individual interviews. Reflexions, field notes	√ - Attendance	2	X	√	X	X	X	1
99. Taylor et al. 2004. Study/trial results; RCT - the PE is based on qualitative interviews	Home based strength training programme. Cerebral Palsy. Physiotherapists	Interviews	√ - Visits by the physiotherapists, logbooks	X	X	X	X	X	X	2

ID, Author(s). Year. Study type. Study design	Study intervention. Health condition. Intervention provider	PP	FA	C	IS	ST	PC	LO	TB	PO
100. Taylor-Piliae & Coull 2012. Feasibility/Pilot study; Two-group prospective pilot study with random allocation	Tai Chi intervention. Chronic stroke. Nurses and Tai Chi instructors.	Single item satisfaction questionnaire	√ - Attendance. Session observations	1	X	1	X	X	X	X
101. Teri et al. 1998. Study/trial results; Measures taken at baseline and 12 weeks after the programme.	Community based program to increase balance, flexibility, strength and endurance. Training of caregivers to facilitate and supervise exercise activity. Alzheimer's disease. Health professional	Informal conversation	√ - Exercise log, treatment adherence log. Observation and progress notes)	X	X	X	X	X	X	X
102. Thomas et al. 2011. Feasibility/Pilot study; A cluster RCT pilot.	Systematic voiding programme for the management of continence after stroke. Stroke. Nurses	Semi-structured interviews (to patients and int. staff)	√ - Fidelity. Management group, steering group.	1	X	√	X	X	X	NA
103. Togher et al. 2012. Study/trial results; Clinical Trial	Communication training program. Traumatic Brain Injury. Speech pathologist.	Semi structured interviews with patients	√	X	X	?	?	?	√	X
104. Topolovec-Vranic et al. 2010. Study/trial results; A one group study (no control)	Internet delivered CBT (MoodGYM). Mild and moderate TBI and depression	Survey	√ - Telephone calls	X	X	X	X	X	X	1
105. Verbeek et al. 2012. Process evaluation results; Cross-sectional descriptive design	Two types of institutional dementia care in the Netherlands: small-scale living and regular wards in nursing homes. Dementia. Nurses	Questionnaire and semi structured interviews (to patients and int. staff)	NA	2	X	X	X	X	X	X
106. Vluggen et al. 2012. Study protocol; Two group multicentre RCT	Multidisciplinary rehabilitation programme (three care modules) vs usual care. Stroke. MDT	Process questionnaire and semi-structured interviews (patients and prof)	√ - Focus group. Questionnaire asking about protocol	X	X	X	X	X	√	NA
107. Voigt-Radloff et al. 2009. Study protocol; Multi-centre single blind RCT 108. Voigt-Radloff et al. 2011. PE results	Evidence based community OT programme, WHEDA study. Dementia. OTs	5 pt scale question. (Patients). Self-report/reflexions. Semi structured questionnaires to OTs	√ - Cooperation. Video tape and checking of recording. Quality reports. Focus group discussion	2	X	√	√	X	X	2

ID, Author(s). Year. Study type. Study design	Study intervention. Health condition. Intervention provider	PP	FA	C	IS	ST	PC	LO	TB	PO
109. Vroomen et al. 2012. Study protocol; Prospective, observational, controlled, cohort study	Case management care model (combination of intensive (linkage) case management and joint agency care models). Dementia. MDT	Interview (to int. staff)	√ - Case records	X	X	X	X	X	√	NA
110. Whiting et al. 2012. Study protocol; Single-centre, two armed, Phase II RCT	Acceptance and commitment therapy (ACT). TBI. Behavioural therapists (trained by an ACT therapist)	Questionnaire (engagement and wiliness)	√ - Fidelity. Homework book. Manuals, independent assessors (treatment sessions recorded). Fidelity assessments, rating scales.	X	X	√	X	X	√	NA
111. Yardley & Kirby 2006. Study/trial results; RCT	Booklet-based education: symptom control (SC) and vestibular rehab (VR). Meniere disease	PETS scale	√	X	X	X	X	X	X	1
112. Yuen et al. 2012. Study/trial results; randomized controlled design.	Home orofacial exercise program. Systemic Sclerosis. Self-administered (orofacial therapists and dental hygienists carried out training)	X	√ - Record calendar, telephone reminders. Photos of exercises	X	NA	√	X	X	X	1
113. Zanker et al. 2007. Feasibility study; Single group, pre and post-test design	Interdisciplinary circuit class therapy. Stroke. OTs and physiotherapists	Questionnaire about satisfaction (patients)	√ - Attendance	X	X	X	X	X	X	X
114. Logan et al. 2006. Study/trial results; RCT	Outdoor mobility promotion. Stroke. OTs	X	√ - Intervention record form. Steering group	X	X	X	X	X	√	1
115. Van Uffelen et al. 2007. Study/trial results; Randomized, placebo controlled intervention trial, based on a two-by-two factorial design.	Walking and vitamin B supplementation. Cognitive impairment. Exercise instructors	X	√ - Attendance	1	X	X	X	X	X	X
116. Speelman et al. 2014. RCT	ParkFit program: A multifaceted intervention aimed to promote physical activity. Parkinson's Disease. Physiotherapy	Telephone interview with therapists. Self-administered questionnaires (patients and int. staff).	√ - Compliance. Logbook and 'contract' workbook	X	√	√	√	X	√	1

ID, Author(s). Year. Study type. Study design	Study intervention. Health condition. Intervention provider	PP	FA	C	IS	ST	PC	LO	TB	PO
117. Skidmore et al. 2014. Non-randomized two-group intervention pilot study.	Strategy training. Stroke. OTs	Daily journals (patients), Client satisfaction questionnaire (int. staff)	√ - Fidelity checklist. Recorded sessions checked for fidelity	X	X	X	X	X	√	1
118. Biasin et al. 2014. Prospective cohort study	Aerobic training intervention. Stroke. Physiotherapy	Exit interview and structured questionnaire	√ - Attendance. Supervision of day to day running by the supervising physical therapist	X	X	√	X	X	X	1

Appendix 5.2 Details of studies included in stream II (methodological guidance evidence)

Study ID	Author(s) and Title	Year	Area
G1	Medical Research Council. **A framework for development and evaluation of RCTs for complex interventions to improve health.** Guideline. London: Medical Research Council	2000	Guideline
G2	Medical Research Council UK. **Developing and evaluating complex interventions: New guidance.** Guideline. London: Medical Research Council.	2008	Guideline
G3	Campbell M, Fitzpatrick R, Haines A, Kinmonth AL, Sandercock P, Spiegelhalter D & Tyrer P. **Framework for design and evaluation of complex interventions to improve health.** *British Medical Journal*, 321(7262), 694-696.	2000	Reporting on guideline
G4	Campbell N C, Murray E, Darbyshir, J, Emery J, Farmer A, Griffiths F, Guthrie B, Lester H, Wilson P & Kinmouth AL. **Designing and evaluating complex interventions to improve health care.** *BMJ: British Medical Journal* (International Edition), 334(7591), 455-459.	2007	Reporting on guideline
G5	Craig P, Dieppe P, Macintyre S, Mitchie S, Nazareth I & Petticrew M. **Developing and evaluating complex interventions: The new medical research council guidance**. BMJ: *British Medical Journal*, 337(7676), 979-983.	2008	Reporting on guideline
G6	Craig P. & Petticrew M. **Developing and evaluating complex interventions: reflections on the 2008 MRC guidance**. *International Journal of Nursing Studies*, 50(5), 585-592.	2013	Reporting on guideline
G7	Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, & Petticrew M. **Developing and evaluating complex interventions: The new medical research council guidance**. *International Journal of Nursing Studies*, 50(5), 587-592.	2013	Reporting on guideline
G8	Schulz KF, Altman DG & Moher D. **CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials.** *British Medical Journal*, 340, 698-702.	2010	Reporting on guideline
G9	Chan A, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin JA, Dickersin K, Hróbjartsson A, Schulz KF, Parulekar WR, Krleža-Jeric K, Laupacis A & Moher D. **SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials.** *British Medical Journal*, 346, 1-42.	2013	Reporting on guideline

G10	Hoffmann TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D, Altman DG, Barbour V, MacDonald H, Johnston M, Lamb SE, Dixon-Woods M, McCulloch P, Wyatt JC, Chan A & Michie S. **Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide.** *British Medical Journal*, 348, 1-13.	2014	Reporting on guideline
F1	Mowbray C, Holter M, Teague G & Bybee D. **Fidelity criteria: Development, measurement, and validation**. *American Journal of Evaluation*, 24(3), 315-340.	2003	Fidelity research
F2	Bellg AJ, Borrelli B, Resnick B, Hecht J, Minicucci DS, Ory M, Ogedegbe G, Orwig D, Ernst D & Czajkowkski S. Enhancing treatment fidelity in health behaviour change studies: best practices and recommendations from the behaviour change consortium. *Health Psychology,* 23(5), 452-456.	2004	Fidelity research
F3	Borrelli B, Sepinwall D, Ernst D, Bellg AJ, Czajkowski S, Breger R, DeFrancesco C, Levesque C, Sharp DL, Ogedegbe G, Resnick B & Orwig D. **A new tool to assess treatment fidelity and evaluation of treatment fidelity across 10 years of health behavior research**. *Journal of Consulting and Clinical Psychology*, 73(5), 852-860.	2005	Fidelity research
F4	Horner S, Rew L, & Torres R. **Enhancing intervention fidelity: A means of strengthening study impact**. *Journal for Specialists in Pediatric Nursing*, 11(2), 80-89.	2006	Fidelity research
F5	Carroll C, Patterson M, Wood S, Booth A, Rick J & Balain S. **A conceptual framework for implementation fidelity**. *Implementation Science*, 2, 40-49.	2007	Fidelity research
F6	Hasson H. **Systematic evaluation of implementation fidelity of complex interventions in health and social care**. *Implementation Science*, 5, 67-76.	2010	Fidelity research
F7	Borrelli B. **The assessment, monitoring, and enhancement of treatment fidelity In public health clinical trials.** *Journal of Public Health Dentistry*, 71, S52-S63.	2011	Fidelity research
F8	Gearing RE, El-Bassel N, Ghesquiere A, Baldwin S, Gillies J, & Ngeow E. **Major ingredients of fidelity: A review and scientific guide to improving quality of intervention research implementation**. *Clinical Psychology Review*, 31(1), 79-88.	2011	Fidelity research
F9	Masterson-Algar P, Burton CR, Rycroft-Malone J, Sackley CM and Walker MF. **Towards a programme theory for fidelity in the evaluation of complex interventions.** *Journal of Evaluation in Clinical Practice*, 20(4), 445-452.	2014	Fidelity/Process evaluation research

F10	Hart T & Bagiella E. **Design and Implementation of Clinical Trials in Rehabilitation Research**. *Archives of Physical Medicine and Rehabilitation,* 93(2), S117-S126.	2012	Fidelity research
F11	Hart, T. **Treatment definition in complex rehabilitation interventions**. *Neuropsychological Rehabilitation*, 19(6), 824–840.	2009	Fidelity research
P1	Linnan L & Steckler A. **Process evaluation for public health interventions and research: an overview.** In: Steckler A & Linnan L (2002). *Process evaluation for public health interventions and research*. (pp. 1-25). San Francisco: Wiley.	2002	Process evaluation research
P2	Hulscher M, Laurant MGH & Grol R. **Process evaluation on quality improvement interventions**. *Quality and Safety in Health Care*, 12, 40-46.	2003	Process evaluation research
P3	Saunders RP, Evans MH, Joshi P. **Developing a process-evaluation plan for assessing health promotion program implementation: a how-to guide**. *Health Promotion Practice*, 6(2), 134-147.	2005	Process evaluation research
P4	Oakley A, Strange V, Bonell C, Allen E & Stephenson J. **Process evaluations in randomized controlled trials of complex interventions**. *British Medical Journal*, 332, 413-416.	2006	Process evaluation research
P5	Clarke D, Hawkins R, Sadler E, Harding G, Forster A, McKevitt C, Godfrey B, Monaghan J & Farrin A. **Interdisciplinary health research: Perspectives from a process evaluation research team.** *Quality in Primary Care*, 20(3), 179-189.	2012	Process evaluation research
P6	Moore G, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, Moore L, O'Cathain A, Tinati T, Wight D & Baird J. **Process evaluation of complex interventions: Medical Research Council guidance.** London: MRC Population Health Science Research Network.	2014	Guideline
L1	Ramsay CR, Grant AM, Wallace SA, Garthwaite PH, Monk AF & Russell IT. **Assessment of the learning curve in health technologies**. *International Journal of Technology Assessment in Health Care*, 16(4), 1095-1108.	2000	Learning curve research
L2	Ramsay CR, Wallace SA, Garthwaite PH, Monk AF, Russell IT & Grant IT. **Statistical assessment of the learning curves of health technologies.** *Health Technologies Assessment* 5(12): 1-4.	2001	Learning curve research
L3	Ramsay CR, Wallace SA, Garthwaite PH, Monk A F, Russell IT & Grant AM. **Assessing the learning curve effect in health technologies. Lessons from the nonclinical literature.** *International Journal of Technology Assessment in Health Care*, 18 (1), 1-10.	2002	Learning curve research

Appendix 5.3 Complete list of initial codes identified in studies included in stream II.

INITIAL CODES			
1	Trial setting	41	Measuring tailoring
2	Pragmatic trials	42	Tailoring as a challenge to implementation
3	Policy	43	Guide for tailoring
4	Effectiveness	44	Motives of staff to join the trial
5	Cost-effectiveness	45	Quality of delivery
6	Post-evaluation implementation	46	Intervention staff competence
7	Recruiting participants - challenges	47	Trial protocol benefits
8	Enhancing recruitment	48	Trial protocol aim
9	How to measure context	49	Competence of staff - changes over time
10	Definitions of context	50	Learning curve effects
11	Critique on context	51	Staff's learning process
12	Recruiting staff for delivering the intervention	52	Measuring staff's learning
13	Environmental contextual factors	53	Adherence to protocol
14	Training for staff delivering intervention	54	Barriers to implementation
15	Monitoring delivering the intervention	55	Facilitators to implementation
16	Reporting recruitment	56	Active ingredients
17	Reporting results	57	Use of theory
18	Strategies to 'check the delivery'	58	Participants experience
19	Recruitment over time	59	Complex interventions - underpinning theories
20	Change of context with time	60	Framework to explain what is taking place
21	Approaching participants	61	The use of guidance
22	Participants engagement	62	Aims of a PE
23	Intervention staff's opinions on the trial	63	Quantitative data
24	Criteria for selecting participants	64	Qualitative data
25	Criteria for selecting staff delivering	65	Data collection
26	What is the right level of experience?	66	Defining PE terminology
27	Context prior to trial	67	What do the results of a PE mean?
28	Context during trial	68	How to explain trial results?
29	Organizational contextual factors	69	Using PE results to explain trial results
30	Dose delivered	70	PE and methodology
31	Dose received	71	PE as a piece of research
32	Attendance	72	Benefits of doing a PE
33	Defining fidelity		
34	Measuring fidelity		
35	What is adherence		
36	Impact of adherence		
37	Defining complex interventions		
38	Incentives for intervention staff		
39	Standardization of intervention		
40	Tailoring to patients needs		

Appendix 5.4 Recommendations for process evaluation research – Synthesis of stream II evidence.

1. Complex interventions should be clearly defined as such.

1.1 Complex interventions should be described in terms of their 'active ingredients' - By defining these 'active ingredients' the research can identify how the intervention works and how are these 'active ingredients' exerting their effect.

Recommended strategies: create a steering group of experts (e.g. researchers, practitioners, stake holders) which will clearly define the intervention and its characteristics.

2. Process evaluations should be theory based.

2.1 Is the process evaluation guided by any theory or guidance? Researchers must draw on existing evidence and frameworks in order to understand and theoretically explain what the processes they expect to take place are.

3. Context should be acknowledged and accounted for throughout the research process:

The context in which the intervention was developed, implemented and finally evaluated should be clearly identified

3.1 Has a clear description of context been provided? It is necessary to describe and monitor changes in the social, physical, economic, political and organizational context in which the intervention is embedded.

3.1.1 There should be strategies in place to measure contextual factors (e.g. what provision of the intervention already exists?)

3.2 What are the possible effects of context on implementation and outcomes?

3.2.1 Contextual changes over time will need to be accounted for throughout the research process

Recommended strategies: can be studied via interviews with project leaders, participants and other relevant stakeholders, project leaders' logbooks and questionnaire items to participants included in the follow-up measurements.

4. Research trials' and process evaluations recruitment strategies and over time development should be clearly explained.

4.1 Researchers need to identify and assess the strategies in place to approach and recruit participants for both, the research trial and the process evaluation. A number of items should be described and analysed:

4.1.1 Were the recruitment strategies as successful and efficient as it had been anticipated in the original plan?

4.1.2 What were the barriers and facilitators to recruitment?

4.1.3 What strategies were in place to assure that participants remained involved and engaged?
4.1.4 What were the barriers and facilitators to maintaining participants' engagement?

Recommended strategies: can be studied via interviews with participants and staff involved in the recruitment process, participants' and provider's logbooks and questionnaire items to participants included in the follow-up measurements or at the time of withdrawal.

5. Information regarding intervention staff should be analysed in detail, important factors to identify are:

5.1 A detailed description of intervention staff should be provided, including:

5.1.1 Description of the number of intervention staff involved, their background and level of experience related to the trialled intervention.
5.1.2 Researched should explain if intervention staff's involvement in the trial was part of their normal role or if they have been recruited especially for it.
5.1.3 Description of any incentives that intervention staff were provided with as part of their role in the trial.

5.2 It is necessary to acknowledge and account for differences amongst intervention staff: researcher should assess intervention staff's motivations for joining the trial and their perceptions in regards to the study intervention's impacts and outcomes.

Recommended strategies: self-report questionnaires and qualitative interviews with participants in order to explore their perceptions regarding providers' credibility. Other methods can be provider's reflexive diaries and intervention logs. Researchers can also conduct a survey amongst providers in order to quantitatively rate their opinions according to a particular itemized scale.

6. A process evaluation should monitor the delivery of the complex intervention throughout the research period.

6.1 How well is the intervention being delivered?

6.1.1 The delivery of a complex intervention should be described in a study protocol/manual – this will need to provide a detailed explanation of the intervention. Important factors to consider are:

6.1.1.1 There needs to be a clear consensus regarding standardization of the intervention. A key early task for researchers is to agree on how much flexibility (tailoring) should be allowed at the time of implementation. Assessment of the quality of delivery will be directly related to the degree of standardization required by the study protocol. Researchers should produce a brief guide for

tailoring in order to assist intervention staff's work with participants.

6.1.2 Training for staff in charge of delivering the intervention should be available. Factors to consider are:

6.1.2.1 Training should be standardized and delivered similarly to all intervention staff.

6.1.2.2 Training should be designed to reach well-defined performance criteria. Skill acquisition will need to be assessed once the training concludes. Intervention staff not reaching the desired level should be excluded or re-trained.

6.1.2.3 Has competence in the delivery of the intervention been monitored over time and learning curve effects been acknowledged and accounted for? Are there strategies in place to demonstrate that intervention staff's skills at the beginning are not significantly different that at the end?

6.1.3. Process evaluations should have strategies in place to investigate if the intervention is being delivered as planned in terms of dose and content:

6.1.3.1. Strategies should be in place in order to measure how well are protocols being adhered to.

6.1.3.2. Are there methods in place to monitor how well were the groups separated (minimize contamination between conditions)?

Recommended strategies: train intervention staff on the use of the protocol via role playing and clearly explain the rationale for keeping treatment conditions separate. Use treatment hand-outs, presentation materials, manuals, etc. Carry out regular booster training sessions, schedule weekly supervision or with intervention staff were adherence to protocol is discussed. This can be done using a variety of methods such as audio or video tape sessions that can be evaluated by supervisors who are blind to the treatment condition. Also, randomly monitor audiotapes throughout the trial for both protocol adherence and non-specific treatment effects. Intervention staff can also be asked to complete checklists of intervention components delivered. Carry out patient exit interviews/focus groups to ensure that patients in the control group did not receive treatment.

6.2 <u>How much of the intervention has been delivered (dose)?</u>

6.2.1 Each participant within a particular treatment condition should receive the same treatment dose in terms of number, frequency, length of contact and content.

6.2.1.1 Are data collection tools in order to register 'dose delivered' adequate?

6.3 How much of the intervention is being received (enacted, intervention reach, attendance)?

6.3.1 To what extent did participants engage in the intervention? Were the attendance rates in lines with what was expected? What proportion of the included population participated?
6.3.2 There should be documentation in place in order to investigate barriers and facilitators to implementation
6.3.3 There should be available information regarding how participants receive the treatment:

6.3.3.1 Were there strategies in place to ensure that participants comprehended what the intervention is about? Do participants understand the information provided?
6.3.3.2 Are participants being assessed in terms of how much they are using the skills provided with during the intervention, do they use them appropriately?
6.3.3.3 Reactions, experiences, motivations and opinions of those exposed to the intervention should be investigated

Recommended strategies: ask participants and intervention staff to complete intervention logs, reflective logs and diaries as well as to record attendance when applicable. Carry out interviews with participants, self-report questionnaires that include items regarding comprehension of the intervention. Organize a focus group at the end of the intervention period in order to explore perceptions and understanding of the intervention.

7. Results from process evaluations should be analysed in detail in order to identify possible links with main trials' outcomes/results

7.1 Process evaluation data will be of vital importance in order to avoid Type III errors when analysing neurological rehabilitation trials' outcomes.

8. Regarding methodologies and methods to carry out process evaluations

8.1 Process evaluation data should be collected from all intervention and control sites.
8.2 Chosen terminology and reasoning behind it should be clearly stated at the start of the process evaluation: definitions of terms and what is going to be measured should be available.
8.3 Research trials should include a detail description and rationale behind process evaluation's chosen strategies and data collection methods.
8.4 Collected data should be both qualitative and quantitative
8.5 Process data should be analysed before outcome data to avoid bias in interpretation

Appendix 6.1 Consensus work – Information sheet

PRIFYSGOL BANGOR UNIVERSITY

INFORMATION SHEET

Title: Consensus work to generate a best practice guidance for carrying out process evaluations within neurological rehabilitation research

Name of researcher: Patricia Masterson-Algar (PhD student)
Supervisors: Prof Christopher Burton and Prof Jo Rycroft-Malone.

Aim of the research:

This consensus work focuses on the challenges of conducting process evaluations alongside clinical trials within neurological rehabilitation. The ambition of this work is to produce best practice guidance for process evaluations within this context. A number of provisional recommendations (statements) for carrying out process evaluations in neurological rehabilitation research have been identified via a systematic review of process evaluation research in neurological rehabilitation. To build on this review, we are undertaking a formal consensus process based on a **nominal group technique** with a small group of rehabilitation researchers in the North West of England/North Wales. This will be done in the following ways:

1. **Nominal group meeting** where participants will have the chance to discuss face to face, critique and rate each of the proposed statements. Using this nominal group technique participants can voice their opinions on the relevance of each of the suggested recommendations.
2. Results from the initial nominal group meeting will be analysed and a summary of results will be emailed to all participants. Participants will be then invited to provide further feedback (via email or telephone), focusing primarily on those statements that were the source of the most disagreement during the nominal group meeting.
3. All participants' feedback will lead to the final write-up of selected recommendations, and their rationales, in the form of a guidance for carrying out process evaluations in neurological rehabilitation research.

Participants' contributions will be acknowledged at the time of collating and publishing the results from this research study. If you have any questions or would like more detailed information please contact:

Patricia Masterson-Algar
Tel: 01248 38 3129
Email: p.m.algar@bangor.ac.uk

School of Healthcare Sciences, Bangor University, Fron Heulog, Ffriddoedd Road, Bangor LL57 2EF. Tel: 01248 383129

Version 1 15th of June 2015

Appendix 6.2 Consensus work – Participant consent form

PRIFYSGOL BANGOR UNIVERSITY

PARTICIPANT CONSENT FORM

Title: **CONSENSUS WORK** to generate a best practice guidance for carrying out process evaluations within neurological rehabilitation research

Name of Researcher: Patricia Masterson Algar (PhD student)

1. I confirm that I have read and understood the information sheet dated 15th of June 2015 for the above study. I have had the opportunity to ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason and with no detrimental effect. Where possible, any contribution I make to the consensus work will be removed if requested. ☐

2. I agree to take part in a face to face nominal group meeting. I agree for the meeting to be audio recorded. ☐

3. I agree to the use of **anonymous** quotes in written reports (including a PhD thesis), conference presentations and/or publications in professionals or academic journals. ☐

4. I understand and agree that data will be anonymised and that anonymous data may be used again in the future for education or research purposes. ☐

Name of Participant	**Date**	**Signature**
Name of Researcher	**Date**	**Signature**

School of Healthcare Sciences, Bangor University, Fron Heulog, Ffriddoedd Road, Bangor LL57 2EF. Tel: 01248 383129

Version 1 15th of June 2015

Appendix 6.3 Statements for consensus work – Nominal Group Technique

Statements for consensus work – June 2015

Complex interventions and theoretical approaches

1. There should be a clear description of the theoretical base behind the structure and delivery of the neurological rehabilitation intervention (e.g. a way to do this could be by process evaluations testing the validity and usefulness of proposed theoretical rehabilitation frameworks)

Disagree 1 2 3 4 5 6 7 8 9 **Agree**

2. The structure of the neurological rehabilitation intervention should be clearly described in terms of its components

Disagree 1 2 3 4 5 6 7 8 9 **Agree**

3. Process evaluations should draw on methodological guidance

Disagree 1 2 3 4 5 6 7 8 9 **Agree**

SUPPORTING INFORMATION:

Rehabilitation interventions are often complex:

Complex interventions are defined as those made up of a number of components or active ingredients that interact with each other and with outside factors to bring about changes to outcomes. It is important to be clear regarding what is 'complicated' and what is 'complex': complicated problems are formed of a number of parts that can be solved and their functioning can be predicted by using identified formulae and instructions; complex problems however rarely benefit from these tools, since they are uncertain. Complex problems are solved allowing time for learning about each component and for making sense of events taking place. Thus, the evaluation of complex interventions represents a great challenge since their path to success is variable and cannot be accurately predicted. Crucially, the difficulty in defining in detail rehabilitation treatments in terms of what are their 'active ingredients' and what is their impact is very challenging. Most of rehabilitation interventions will have several active ingredients.

Complex rehabilitation interventions can often be:

- Offered multiple times to multiple participants that can belong to a number of different groups.
- Complex behavioural treatments to the contrary of passive or surgical treatments.
- Delivered in a personal way where interactions therapist/patient play a significant role.
- Tailored to patient's needs at the time of defining goals or treatment plans.
- Designed in a number of sessions to allow time for individuals to learn and comprehend its content.
- Delivered in different locations and sites which can change.
- Delivered to individuals, families, combinations, etc.
- Delivered to individuals who are not 'passive recipients' of the intervention, individuals who will perceive and take on board the intervention in their own unique manner (for example individuals will decide how intensively they want to get involved in the intervention)

2

4. There should be a clear explanation of how the methodological guidance is applied to the process evaluation (e.g. if a guidance is chosen it is necessary to clearly explain how was the guidance followed and how did the process evaluation remain in line with the guidance's proposed frameworks/steps)

Disagree 1 2 3 4 5 6 7 8 9 **Agree**

- Furthermore rehabilitation research is often **context specific** and defined as the interaction between the individual and the environment. In other words, identifying contextual processes (physical, psychological, social, etc.) and acknowledging that researchers bring their values into situations is of great importance when thinking about the science of rehabilitation. Therefore, researchers working in this field need to design strategies and ways to explore and measure context.

It is feasible to describe an intervention in terms of its 'active ingredients'. However, throughout the research process the intervention should be seen *as a whole which is greater than the sum of its parts.* Reducing the complex intervention to a number of components and understanding how these work individually might make the intervention loose its essence. Understanding how parts of the intervention work should always be considered in close relation to how the intervention works as a whole.

Theories and rehabilitation

Rehabilitation professionals share assumption regarding firstly, the nature of their work: they need to be apolitical, relevant and useful. Secondly, the nature of their goals: to increase function, independence and quality of life and finally, the nature of the relationship with the client, which has to be holistic and client-centred. The problem is that these theoretical assumptions so far lack in evidence base support. Many areas of rehabilitation are underdeveloped from a theoretical perspective and energy should be invested, as it is spend in empirical research, in developing well-articulated theories and consequent theoretical models. The theory behind the structure and delivery of a proposed rehabilitation intervention will need to reflect its complexity and address it.

What is the 'theory of change' behind the proposed rehabilitation intervention? How many theories are needed to guide rehabilitation research, or should there be an overarching one? Many theories appear relevant to rehabilitation, for example learning theories, theories of goal setting, theories related to self-management and also theories looking at changes at the person-environment interface such as theories of diffusion of innovation.

3

Context

5. The organizational context prior to the intervention being implemented should be clearly described through the use of both qualitative and quantitative methods.

Disagree **Agree**

1 2 3 4 5 6 7 8 9

6. Contextual changes over time should be investigated – the dynamic nature of context which is created by the implementation of the trial intervention over time

Disagree **Agree**

1 2 3 4 5 6 7 8 9

7. Researchers should aim to clarify possible impacts that organizational contextual factors could have had throughout the research process.

Disagree **Agree**

1 2 3 4 5 6 7 8 9

SUPPORTING INFORMATION:

Regarding context

It is of vital importance for researchers to acknowledge the vital role that context plays in explaining how interventions work. Context can be described as all surrounding systems in which the intervention is embedded. In other words, context is involved not only with the surrounding environment (e.g. institutions, organizations) but also their culture in terms of social behaviours, interactions amongst members and individual perceptions and preconceptions.

Complex rehabilitation interventions will be determined and embedded in a context which will not remain passive but will change with time. For example:

- It can be said that often rehabilitation interventions will be politically determined (e.g. a government accepting or rejecting national service frameworks).
- In rehabilitation interventions the quality and characteristics of the interactions between the patient and the health professionals can play a major role in shaping their success or failure (e.g. If an OT is not able to build rapport with a patient the level of engagement and motivation of both, patient and OT, most likely will be affected).

4

Recruitment

8. Process evaluations of neurological rehabilitation research studies should clearly describe the trial's recruitment procedures.

Disagree **Agree**

1 2 3 4 5 6 7 8 9

9. Reasoning behind participants being recruited for the trial should be provided (e.g. excluding patients with cognitive impairment is often the case. The rationale behind this decision should be clearly explained considering the considerable prevalence of stroke survivors having a cognitive impairment)

Disagree **Agree**

1 2 3 4 5 6 7 8 9

10. Barriers and facilitators to recruitment for the trial should be clearly investigated.

Disagree **Agree**

1 2 3 4 5 6 7 8 9

11. Strategies to recruit participants to the process evaluation should be clearly described.

Disagree **Agree**

1 2 3 4 5 6 7 8 9

SUPPORTING INFORMATION:

Recruitment in rehabilitation research can present a number of difficulties and challenges, both at an individual and at an organizational level.

For example:

- At present rehabilitation practice lacks of a nationally standardized and accepted set of outcome measures, therefore researchers often have to use and individual and trial/specific screening tools in order to identify and assess the suitability of the participants. Having a recruitment criteria that is therapeutically based is a more complicated procedure and therefore is more expensive and time consuming that the recruitment process in medical trials who often utilise a simple chart review.
- Rehabilitation researchers often have to give special attention to retention due to the nature of the patients, for example, their recruitment budget will often need to include cost of participants transportation to and from the research base or 'reminding methods' such as postcards or phone calls.
- It is often hard to reach patients who are not registered as being part of rehabilitation services. The recruiting effort will be considerable and often needs to use other alternative sources and venues which can be time consuming and costly.
- Recruiting effort will need to account for the characteristics of this group of service user who will often have mobility and/or cognitive difficulties which might have led to limited social involvement and very little time spent out of his/her home.

5

12. Criteria for selecting participants for the process evaluation should be clearly identified.

Disagree								Agree
1	2	3	4	5	6	7	8	9

13. Barriers and facilitators to recruitment of participants into the process evaluation should be investigated.

Disagree								Agree
1	2	3	4	5	6	7	8	9

14. Process evaluations should investigate measures in place to attract participants and encourage them to remain involved in the trial.

Disagree								Agree
1	2	3	4	5	6	7	8	9

15. The involvement of participants recruited for the process evaluation should be monitored.

Disagree								Agree
1	2	3	4	5	6	7	8	9

6

16. Process evaluations of clustered trials should clearly describe the site recruitment procedure in place (e.g. minimum quality standards, funding, incentives).

Disagree								Agree
1	2	3	4	5	6	7	8	9

17. How withdrawal from sites was carried out should be clearly explained.

Disagree								Agree
1	2	3	4	5	6	7	8	9

7

Description of intervention staff

18. A detail description of who (and how many) delivered the neurological rehabilitation intervention should be given.

Disagree 1 2 3 4 5 6 7 8 9 **Agree**

19. Intervention staff previous relevant experience and skills should be recorded.

Disagree 1 2 3 4 5 6 7 8 9 **Agree**

20. Motives for the participation of intervention staff in the study should be explored.

Disagree 1 2 3 4 5 6 7 8 9 **Agree**

21. Intervention staff perceptions regarding the research study and possible impacts of the intervention should be investigated.

Disagree 1 2 3 4 5 6 7 8 9 **Agree**

SUPPORTING INFORMATION:

Neurological rehabilitation interventions often require a level of skill and understanding of different techniques and methods. They often involve treating complex patients with complex needs. Thus, it is vital to have a good understanding of the characteristics of all staff responsible for delivering the neurological rehabilitation intervention. Staff's previous experience and level of skill will potentially have an impact on the way the intervention is being delivered and also on the way this intervention will bring about changes to outcomes.

8

Description of intervention

22. The study intervention should be detailed in a protocol/manual.

Disagree 1 2 3 4 5 6 7 8 9 **Agree**

23. All structures and processes involved in the intervention should be fully described.

Disagree 1 2 3 4 5 6 7 8 9 **Agree**

24. The protocol should state how much tailoring and flexibility of the intervention is allowed.

Disagree 1 2 3 4 5 6 7 8 9 **Agree**

25. A guide for tailoring should be provided to all professionals implementing the intervention.

Disagree 1 2 3 4 5 6 7 8 9 **Agree**

26. The degree of tailoring should be investigated within the evaluation.

Disagree 1 2 3 4 5 6 7 8 9 **Agree**

SUPPORTING INFORMATION:

Tailoring rehabilitation interventions

The **'science of replication'** in rehabilitation research requires further development. There is more to delivering a rehabilitation intervention than just measuring how many elements were delivered. Rehabilitation research should avoid a 'cookbook' approach if it intends to understand the vital role played by contextual factors. As a result there is an increased awareness of the need to tailor rehabilitation interventions to patients' needs and cultural background in order to increase their potential to be effective. To be able to replicate a rehabilitation intervention across different settings it will be necessary to adapt it (tailor it) to some extent and this is likely to create tension between the need to tailor and the need to maximise treatment integrity.

Tailoring should not mean intervention staff 'improvising as they go along', it should mean that what is standardized will be contrasted and clearly defined and monitored against what is customized. As a result, the assessment of how the rehabilitation intervention was administered according to the plan will have to be standardized and tailored to the actual level of standardization and tailoring of the trialled intervention. Succeeding at this can be extremely challenging for rehabilitation researchers. A first vital step could involve identifying and recording the delivery of unplanned components (for example using specific recording sheets). This information can help for example, to identify which aspects need to be included in the re-training of intervention staff on the requirements to follow the protocol. It can also help identify aspects of the intervention which need modifying.

9

Preparing and assessing intervention staff

27. The training provided to intervention staff involved in the research should be clearly described (e.g. details on when and where will the training take place, who needs to attend, who will deliver it, etc.)

Disagree 1 2 3 4 5 6 7 8 9 **Agree**

28. Training provided should have a defined set of goals to achieve.

Disagree 1 2 3 4 5 6 7 8 9 **Agree**

29. There should be well-defined performance criteria associated with the intervention.

Disagree 1 2 3 4 5 6 7 8 9 **Agree**

30. Skill acquisition/competence of intervention staff should be measured post training as the basis for participating in the study.

Disagree 1 2 3 4 5 6 7 8 9 **Agree**

SUPPORTING INFORMATION:

Training staff to provide a rehabilitation intervention

It is widely accepted that training the staff responsible for the implementation of the trialled rehabilitation intervention is beneficial:

- Through training and supervision you can refine the work of the providers who in most cases will already have experience in this trialled intervention.
- The training can help teach the provider to not use their usual approaches if they are not part of the intervention - staff should familiarize themselves with the trial's manual/protocol during the training.
- Training provides a chance to discuss the philosophy underlying the intervention.
- Training will give a chance to intervention providers to practice the necessary skill set.

In rehabilitation trials it should be feasible to assess professionals' skills prior to the start of the trial. However, training staff involved in rehabilitation trials is often ongoing in order to assure that skills are maintained over time. In such cases an initial skill assessment could not be used as a basis for participation but regular/periodical assessments could be the solution.

Staff involved in delivering a rehabilitation intervention will learn overtime and they will become more familiarized with the techniques, patient characteristics, organizational contexts etc. Therefore, investigating staff learning curves throughout the trial and how these might explain trends in outcomes would be highly beneficial. It is equally important to have measures in place to assess how intervention staff have maintained skills over time.

10

31. Competence of intervention staff should be monitored over time in order to identify learning curve effects.

Disagree 1 2 3 4 5 6 7 8 9 **Agree**

32. Methods should be in place in order to maintain skills over time (e.g. re-training, supervision, peer support, online notice boards, etc.)

Disagree 1 2 3 4 5 6 7 8 9 **Agree**

33. Any additional implementation strategies to improve/support the fidelity of the intervention should be evaluated (e.g. performance evaluation).

Disagree 1 2 3 4 5 6 7 8 9 **Agree**

11

Delivery of the trial intervention

34. Process evaluations should investigate barriers and enablers to the implementation of the intervention.

Disagree								Agree
1	2	3	4	5	6	7	8	9

35. Process evaluations should clearly define quantitative indicators that reflect acceptable adherence to the intervention dosage across constituent components.

Disagree								Agree
1	2	3	4	5	6	7	8	9

36. Process evaluations should clearly define what strategies were in place in order to measure 'dose delivered'.

Disagree								Agree
1	2	3	4	5	6	7	8	9

37. There should be well defined strategies in place to be able to measure 'dose received'.

Disagree								Agree
1	2	3	4	5	6	7	8	9

SUPPORTING INFORMATION:

Whilst for example in drug trials the delivery of the intervention is relatively simplistic in the case of rehabilitation interventions it often is not. For example, in the case of rehabilitation the accurate delivery of the intervention can be highly dependent on for example:

- The level of skill, previous experience and knowledge of the intervention staff - possible biases and previous experience can influence or clash with intervention
- Individual characteristics of patients beyond the intervention (e.g. depression, cognitive impairment, acceptance or attitude towards the intervention, personal factors, geographical factors, etc.). Heterogeneity of trial participants will be likely even after detailed screening according to inclusion and exclusion criteria.
- The difficulty with blinding, participants will know, in most cases, the intervention they are receiving.
- Difficulty with assessing participants understanding of the purpose of the intervention (for example when participants have some level of cognitive impairment which is often the case in rehabilitation research).

Understanding if the intervention has been carried out as initially planned can therefore prove both, very challenging and highly dependent on the quality and level of detailed information included in the plan to execute procedures and assessment. Strategies in order to address this need to be clearly described and in place throughout the research trial.

12

38. Process evaluations should clearly define quantitative and qualitative indicators that reflect acceptable quality in the delivery of the study intervention.

Disagree								Agree
1	2	3	4	5	6	7	8	9

39. Process evaluations should clearly explain the strategies in place in order to assess quality of intervention implementation.

Disagree								Agree
1	2	3	4	5	6	7	8	9

40. Process evaluations should assess the quality of the strategies in place to monitor adherence to protocol (e.g. via a variety of both qualitative and quantitative data recording methods).

Disagree								Agree
1	2	3	4	5	6	7	8	9

41. Participants' understanding of the intervention should be assessed.

Disagree								Agree
1	2	3	4	5	6	7	8	9

13

42. There should be strategies in place to monitor participants' utilisation of the intervention provided.

Disagree 1 2 3 4 5 6 7 8 9 Agree

43. The process evaluation should collect data regarding participants' experiences of the intervention, and the level of acceptability that was achieved.

Disagree 1 2 3 4 5 6 7 8 9 Agree

14

Understanding and interpreting process evaluation results

44. There should be a detailed description of the synthesis of process evaluation findings with trial results.

Disagree 1 2 3 4 5 6 7 8 9 Agree

45. Theoretical frameworks should be used in order to build explanations that link process and outcome evaluations.

Disagree 1 2 3 4 5 6 7 8 9 Agree

46. Process evaluations should provide evidence surrounding the chances of Type III errors (implementation failure) at the time of analysing trial's results.

Disagree 1 2 3 4 5 6 7 8 9 Agree

47. Plans to develop a theory as part of the process evaluation research results should be clearly described

Disagree 1 2 3 4 5 6 7 8 9 Agree

SUPPORTING INFORMATION:

In regards to the contributions that process evaluations should bring to rehabilitation theory development: process evaluation should provide a clear description of what did or did not work, why it did or did not work and in what way. As a results, it can help to understand and improve theory-informed interventions.

Process evaluation in rehabilitation research can help rehabilitation theory development in two ways:

1. Process evaluation can help understand and critique the theoretical frameworks that were considered at the time of developing the intervention. Process evaluations can therefore contribute to further development and modifications of published frameworks in order to tailor them and make them applicable to rehabilitation research.
2. Process evaluation data and research can also be used to develop new frameworks on how rehabilitation interventions work.

15

Methodology

48. The design of the process evaluation should be reported in detail.

Disagree **Agree**

1 2 3 4 5 6 7 8 9

49. Ethics and other approvals for process evaluations data collection should be included in the trial approval process.

Disagree **Agree**

1 2 3 4 5 6 7 8 9

50. A process evaluation should use a clear set of measures and evaluation criteria that will need to be described and reasoning behind them provided.

Disagree **Agree**

1 2 3 4 5 6 7 8 9

51. Methods used to investigate the different components of the process evaluation should be reported.

Disagree **Agree**

1 2 3 4 5 6 7 8 9

SUPPORTING INFORMATION:

When rehabilitation researchers decide to carry out a process evaluation they should provide clear details describing how the process evaluation data collection and design are going to be 'linked' to the research trial in order to explain its results.

For example: when embedding process evaluation at the start and throughout a rehabilitation research trial is not possible or feasible (in cases due to budget or staff limitations) the research team might decide that the process evaluation will be carried out as a retrospective analysis or that it will remain at 'arm's length'. This needs to be clearly stated and the rationale behind this decision should be described.

16

52. Reasoning behind timing for data collection should be clearly stated.

Disagree **Agree**

1 2 3 4 5 6 7 8 9

53. Process evaluation data should be collected from all intervention and control sites.

Disagree **Agree**

1 2 3 4 5 6 7 8 9

54. Process evaluations should use a variety of methods and strategies to gather data, including both qualitative and quantitative approaches.

Disagree **Agree**

1 2 3 4 5 6 7 8 9

55. Details regarding the triangulation of the data within the process evaluation should be clearly reported.

Disagree **Agree**

1 2 3 4 5 6 7 8 9

17

Appendix 6.4 Results from the ratings of each of the statements discussed in the Nominal Group Meeting (Phase I) (the number of participants who chose each value is presented in red)

	Consensus statement	Median	Lowest score	Highest score
1	There should be a clear description of the theoretical base behind the structure and delivery of the neurological rehabilitation intervention. **3 0 0 0 0 0 0 0 2** **1 2 3 4 5 6 7 8 9** **Disagree** **Agree**	1	1	9
2	The structure of the neurological rehabilitation intervention should be clearly described in terms of its components. **1 0 0 0 0 1 0 0 3** **1 2 3 4 5 6 7 8 9** **Disagree** **Agree**	9	1	9
3	Process evaluations should draw on methodological guidance **0 2 0 0 0 0 1 1 1** **1 2 3 4 5 6 7 8 9** **Disagree** **Agree**	7	2	9
4	There should be a clear explanation of how the methodological guidance is applied to the process evaluation. **0 2 0 0 0 0 1 1 1** **1 2 3 4 5 6 7 8 9** **Disagree** **Agree**	7	2	9
5	The organizational context prior to the intervention being implemented should be clearly described through the use of both qualitative and quantitative methods. **0 0 0 0 0 0 1 2 2** **1 2 3 4 5 6 7 8 9** **Disagree** **Agree**	8	7	9
6	Contextual changes over time should be investigated – the dynamic nature of context which is created by the implementation of the trial intervention over time. **0 0 0 0 0 0 0 2 3** **1 2 3 4 5 6 7 8 9** **Disagree** **Agree**	9	8	9
7	Researchers should aim to clarify possible impacts that organizational contextual factors could have had throughout the research process. **0 0 0 0 0 0 0 3 2** **1 2 3 4 5 6 7 8 9** **Disagree** **Agree**	8	8	9

	Consensus statement	Median	Lowest score	Highest score
8	Process evaluations of neurological rehabilitation research studies should clearly describe the trial's recruitment procedures. 2 0 0 0 0 0 1 0 2 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	7	1	9
9	Reasoning behind participants being recruited for the trial should be provided. 3 0 0 0 0 1 0 0 1 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	1	1	9
10	Barriers and facilitators to recruitment for the trial should be clearly investigated. 2 0 0 0 0 0 0 0 3 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	9	1	9
11	Strategies to recruit participants to the process evaluation should be clearly described. 0 0 0 0 0 0 0 0 5 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	9	9	9
12	Criteria for selecting participants for the process evaluation should be clearly identified. 0 0 0 0 0 0 0 0 5 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	9	9	9
13	Barriers and facilitators to recruitment of participants into the process evaluation should be investigated. 0 0 0 0 0 1 1 0 3 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	9	6	9
14	Process evaluations should investigate measures in place to attract participants and encourage them to remain involved in the trial. 3 0 0 0 0 0 1 0 1 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	1	1	9
15	The involvement of participants recruited for the process evaluation should be monitored. 0 0 1 0 0 1 0 1 2 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	8	3	9

	Consensus statement	Median	Lowest score	Highest score
16	Process evaluations of clustered trials should clearly describe the site recruitment procedure in place (e.g. minimum quality standards, funding, incentives). 2 0 0 1 0 0 0 0 1 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	2.5	1	9
17	How withdrawal from sites was carried out should be clearly explained. 3 0 0 1 0 0 0 0 1 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	1	1	9
18	A detail description of who (and how many) delivered the neurological rehabilitation intervention should be given. 1 0 0 0 0 0 0 1 2 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	8.5	1	9
19	Intervention staff previous relevant experience and skills should be recorded. 1 0 0 0 0 0 0 1 2 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	9	1	9
20	Motives for the participation of intervention staff in the study should be explored. 0 0 0 0 0 1 2 0 1 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	7	6	9
21	Intervention staff perceptions regarding the research study and possible impacts of the intervention should be investigated. 0 0 0 0 0 1 1 1 1 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	7.5	6	9
22	The study intervention should be detailed in a protocol/manual. 1 0 0 0 0 0 0 1 2 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	8.5	1	9
23	All structures and processes involved in the intervention should be fully described. 1 0 0 0 0 0 0 0 2 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	9	1	9

	Consensus statement	Median	Lowest score	Highest score
24	The protocol should state how much tailoring and flexibility of the intervention is allowed. 1 0 0 0 0 0 0 0 2 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	9	1	9
25	A guide for tailoring should be provided to all professionals implementing the intervention. 1 0 0 0 1 0 0 0 2 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	7	1	9
26	The degree of tailoring should be investigated within the evaluation. 0 0 0 0 0 1 1 1 1 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	7.5	6	9
27	The training provided to intervention staff involved in the research should be clearly described. 1 0 0 0 0 0 0 0 3 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	9	1	9
28	Training provided should have a defined set of goals to achieve. 1 0 0 0 0 0 0 0 3 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	9	1	9
29	There should be well-defined performance criteria associated with the intervention. 0 0 0 0 0 0 1 0 3 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	9	7	9
30	Skill acquisition/competence of intervention staff should be measured post training as the basis for participating in the study. 1 0 0 0 1 0 0 0 2 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	7	1	9
31	Competence of intervention staff should be monitored over time in order to identify learning curve effects. 0 0 1 0 0 1 0 1 1 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	7	3	9

	Consensus statement	Median	Lowest score	Highest score
32	Methods should be in place in order to maintain skills over time. 1 0 0 0 0 0 1 1 1 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	7.5	1	9
33	Any additional implementation strategies to improve/support the fidelity of the intervention should be evaluated. 0 0 0 0 1 0 1 1 1 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	7.5	5	9
34	Process evaluations should investigate barriers and enablers to the implementation of the intervention. 0 0 0 0 0 0 0 2 2 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	8.5	8	9
35	Process evaluations should clearly define quantitative indicators that reflect acceptable adherence to the intervention dosage across constituent components. 1 0 0 0 0 1 0 0 2 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	7.5	1	9
36	Process evaluations should clearly define what strategies were in place in order to measure 'dose delivered'. 0 0 0 0 0 0 2 0 2 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	8	7	9
37	There should be well defined strategies in place to be able to measure 'dose received'. 1 0 0 0 0 0 1 0 2 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	8	1	9
38	Process evaluations should clearly define quantitative and qualitative indicators that reflect acceptable quality in the delivery of the study intervention. 1 0 0 0 0 0 0 1 2 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	8.5	1	9
39	Process evaluations should clearly explain the strategies in place in order to assess quality of intervention implementation. 0 0 0 0 0 0 1 1 2 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	8.5	7	9

	Consensus statement	Median	Lowest score	Highest score
40	Process evaluations should assess the quality of the strategies in place to monitor adherence to protocol. 0 0 0 0 0 0 1 1 2 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	8.5	7	9
41	Participants' understanding of the intervention should be assessed. 0 0 0 0 0 1 2 1 0 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	7	6	8
42	There should be strategies in place to monitor participants' utilisation of the intervention provided. 1 0 0 0 0 0 0 0 3 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	9	1	9
43	The process evaluation should collect data regarding participants' experiences of the intervention, and the level of acceptability that was achieved. 0 0 0 0 1 0 1 0 2 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	8	5	9
44	There should be a detailed description of the synthesis of process evaluation findings with trial results. 0 0 0 0 0 0 0 1 3 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	9	8	9
45	Theoretical frameworks should be used in order to build explanations that link process and outcome evaluations. 1 0 0 0 0 0 2 0 1 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	7	1	9
46	Process evaluations should provide evidence surrounding the chances of Type III errors (implementation failure) at the time of analysing trial's results. 0 0 0 0 0 1 1 1 0 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	7	6	8
47	Plans to develop a theory as part of the process evaluation research results should be clearly described. 1 0 0 0 0 0 3 0 0 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	7	1	7

	Consensus statement	Median	Lowest score	Highest score
48	The design of the process evaluation should be reported in detail. 0 0 0 0 0 0 0 1 3 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	9	8	9
49	Ethics and other approvals for process evaluations data collection should be included in the trial approval process. 0 0 0 0 0 0 2 0 2 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	8	7	9
50	A process evaluation should use a clear set of measures and evaluation criteria that will need to be described and reasoning behind them provided. 0 0 0 0 0 0 0 0 4 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	9	9	9
51	Methods used to investigate the different components of the process evaluation should be reported. 0 0 0 0 0 0 0 0 4 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	9	9	9
52	Reasoning behind timing for data collection should be clearly stated. 0 0 0 0 0 0 1 0 3 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	9	7	9
53	Process evaluation data should be collected from all intervention and control sites. 0 0 0 0 0 1 2 0 1 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	7	6	9
54	Process evaluations should use a variety of methods and strategies to gather data, including both qualitative and quantitative approaches. 0 0 0 0 0 0 1 0 3 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	9	7	9
55	Details regarding the triangulation of the data within the process evaluation should be clearly reported. 0 0 0 0 0 0 0 1 3 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	9	8	9

	Consensus statement	Median	Lowest score	Highest score
56	Process evaluation protocols should be clearly described and made available. 0 0 0 0 0 0 0 2 1 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	8	8	9
57	Process evaluation results should be published alongside trial results. 0 0 0 0 0 0 0 1 2 1 2 3 4 5 6 7 8 9 **Disagree** **Agree**	9	8	9

Appendix 6.5 Recommendations for consensus work – Phase II

Consensus work to generate a best practice guidance for carrying out process evaluations within complex interventions rehabilitation research

Note: these recommendations should be considered alongside recommendations on reporting outcome evaluations (e.g. CONSORT guidelines)

STARTING POINT: These guideline recommendations build on the following assumptions about the nature of complexity in complex intervention research:

- Complex rehabilitation interventions are those made up of a number of components which interact with each other, and with patient and other factors to bring about changes in patient outcomes.
- The impact of complex interventions is greater than the sum of the effects of their component parts, and is a product of both the changes embedded in both the intervention hypotheses and the implementation approaches used. In other words, and in order to provide explanations of how a complex intervention works, for who and under what circumstances, this guideline considers that outcome evaluation and process evaluation are inextricably linked.

Please read the following recommendations which will from part of the final guidance and assess their weigh following the criteria described in Table 1. Please include any thoughts or reasoning informing your choices in the 'comment' box.

Table 1 Criteria for 'weighing' proposed guideline recommendations

Essential **(E)**	▪ Critical requirement of a process evaluation ▪ Must be done ▪ Apply to all types of interventions ▪ Resources should be allocated to these
Important **(I)**	▪ They should be done ▪ (Ideally) there should be a set amount of resources allocated to these
Additional **(A)**	▪ Low priority in terms of providing evidence ▪ These objectives will be intervention-dependent, they will only be addressed in the case of a particular type of intervention ▪ Only if there are enough resources to address all the above the researcher will allocate funding to these

N	Recommendation	Weighing			Comments
	Complex interventions and theoretical approaches – *The process evaluation should...*				
1	Review in depth the theoretical underpinnings behind the rehabilitation intervention under investigation	E	I	A	
2	Review in depth the theoretical underpinnings behind the implementation approach of the rehabilitation intervention under investigation	E	I	A	
3	Describe in depth the structure of the rehabilitation intervention in terms of its components and their potential interactions	E	I	A	
	Regarding context – *The process evaluation should...*				
4	Clearly describe and investigate contextual factors and their potential impact on the process and outcome evaluation. *The role of context in shaping both implementation (e.g. how it's done) and impact (whether it works) should be clearly investigated*	E	I	A	
5	Account for the dynamic nature of context - investigate contextual changes and their potential impact on the process and outcome evaluation over time	E	I	A	
	Regarding recruitment – *The process evaluation should...*				
6	Review the outcome evaluation's recruitment procedures in order to identify potential recruitment barriers and facilitators	E	I	A	
7	Review the strategies that the outcome evaluation has in place to maximize participant retention levels	E	I	A	
8	Clearly describe the strategies and criteria informing the recruitment of participants into the process evaluation	E	I	A	

N	Recommendation	Weighing			Comments
9	Investigate the barriers and facilitators to the recruitment of participants into the process evaluation	E	I	A	
	Intervention staff: describing, preparing and assessing them – *The process evaluation should...*				
10	Review the characteristics of the outcome evaluation intervention staff (e.g. level of skill, experience, number, demographics, motivations and perceptions regarding the outcome evaluation) and identify those potentially impacting on intervention delivery and impact	E	I	A	
11	Review the training provided to intervention staff in order to identify possible impacts on outcomes. Explore issues such as: *does the training define a performance criteria and set of goals to achieve? Is skill acquisition/competence of intervention staff assessed post training? Does the training include systems in place in order to maintain and support staff's skills over time?*	E	I	A	
12	Review the outcome evaluation's strategies in place to assess competence of intervention staff over time in order to identify possible learning curve effects	E	I	A	
	Delivery of the intervention – *The process evaluation should...*				
13	Review the outcome evaluation intervention protocol in order to identify areas of uncertainty (major risks to fidelity) and their possible impacts on outcomes.	E	I	A	
14	Investigate any strategies in place in order to guide and inform the tailoring of the outcome evaluation intervention	E	I	A	
15	Investigate the focus and degree of any tailoring of the outcome evaluation intervention in order to identify possible impacts on outcomes - *identify what was tailored and how much*	E	I	A	
16	Review and assess the quality of any implementation strategies to improve/support the fidelity of the proposed intervention.	E	I	A	

N	Recommendation	Weighing			Comments
17	Investigate, in detail, barriers and enablers to the implementation and delivery of the intervention and evidence surrounding the chances of Type III errors (implementation failure)	E	I	A	
18	Review the strategies in place in order to measure the 'dose delivered'	E	I	A	
19	Review the strategies in place in order to measure the 'dose received'	E	I	A	
20	Review and assess the quality of the strategies in place to monitor adherence to protocol	E	I	A	
21	Investigate in detail participants' experiences and acceptability of the intervention	E	I	A	
	Understanding and interpreting results – *The process evaluation should...*				
22	Describe in detail the synthesis of process evaluation and outcome evaluation results	E	I	A	
23	The theoretical underpinnings behind both, the outcome evaluation intervention and its implementation should inform the explanations and the synthesis of process and outcome evaluation results	E	I	A	
	Regarding design and chosen methods – *The process evaluation should...*				
24	Provide a clear definition of chosen terminology (e.g. adherence, fidelity, integrity etc.)	E	I	A	
25	Have a defined scope and clear aims and objectives - a process evaluation protocol should be produced	E	I	A	
26	Clearly describe and justify the use of a set of measures and evaluation criteria for the process evaluation	E	I	A	

N	Recommendation	Weighing			Comments
27	Provide a detail description and justification of selected process evaluation data collection methods	E	I	A	
28	Clearly explain and justify chosen timings for process evaluation data collection	E	I	A	
29	Collect relevant /appropriate data from all intervention and control sites	E	I	A	
30	Use a variety of methods and strategies to gather data, including both qualitative and quantitative approaches	E	I	A	
31	Should aim at publishing its results alongside outcome evaluation results (in order to reduce the chance of biases)	E	I	A	
32	Address the interactions between process and outcome evaluations *(e.g. researchers should decide if they take the risk of threatening the outcome evaluation via evaluating processes or if they accept that there will be tailoring and change which can be guided through the process evaluation)*	E	I	A	

Additional comments

Appendix 6.6 Results from the ranking of recommendations included in the revised guidance (Phase II). (E (essential), I (important), A (additional), B (blank). The number of participants who selected each choice is displayed in red.

N	Recommendation	Weighting			
1	Review in depth the theoretical underpinnings behind the rehabilitation intervention under investigation	E (2)	I	A (2)	B
2	Review in depth the theoretical underpinnings behind the implementation approach of the rehabilitation intervention under investigation	E (2)	I	A (2)	B
3	Describe in depth the structure of the rehabilitation intervention in terms of its components and their potential interactions	E (3)	I (1)	A	B
4	Clearly describe and investigate contextual factors and their potential impact on the process and outcome evaluation. *The role of context in shaping both implementation (e.g. how it's done) and impact (whether it works) should be clearly investigated*	E (4)	I	A	B
5	Account for the dynamic nature of context - investigate contextual changes and their potential impact on the process and outcome evaluation over time	E (2)	I (1)	A (1)	B
6	Review the outcome evaluation's recruitment procedures in order to identify potential recruitment barriers and facilitators	E (2)	I (1)	A	B (1)
7	Review the strategies that the outcome evaluation has in place to maximize participant retention levels	E (2)	I (2)	A	B
8	Clearly describe the strategies and criteria informing the recruitment of participants into the process evaluation	E (2)	I (1)	A (1)	B
9	Investigate the barriers and facilitators to the recruitment of participants into the process evaluation	E (2)	I (2)	A	B
10	Review the characteristics of the outcome evaluation intervention staff (e.g. level of skill, experience, number, demographics, motivations and perceptions regarding the outcome evaluation) and identify those potentially impacting on intervention delivery and impact	E (4)	I	A	B
11	Review the training provided to intervention staff in order to identify possible impacts on outcomes.	E (2)	I (2)	A	B
12	Review the outcome evaluation's strategies in place to assess competence of intervention staff over time in order to identify possible learning curve effects	E (1)	I	A (2)	B (1)
13	Review the outcome evaluation intervention protocol in order to identify areas of uncertainty (major risks to fidelity) and their possible impacts on outcomes.	E (1)	I	A (2)	B
14	Investigate any strategies in place in order to guide and inform the tailoring of the outcome evaluation intervention	E (3)	I	A (1)	B

N	Recommendation	Weighting			
15	Investigate the focus and degree of any tailoring of the outcome evaluation intervention in order to identify possible impacts on outcomes - *identify what was tailored and how much*	E (1)	I (1)	A	B (2)
16	Review and assess the quality of any implementation strategies to improve/support the fidelity of the proposed intervention.	E (3)	I	A (1)	B
17	Investigate, in detail, barriers and enablers to the implementation and delivery of the intervention and evidence surrounding the chances of Type III errors (implementation failure)	E (3)	I (1)	A	B
18	Review the strategies in place in order to measure the 'dose delivered'	E (4)	I	A	B
19	Review the strategies in place in order to measure the 'dose received'	E (4)	I	A	B
20	Review and assess the quality of the strategies in place to monitor adherence to protocol	E (2)	I	A (1)	B (1)
21	Investigate in detail participants' experiences and acceptability of the intervention	E (4)	I	A	B
22	Describe in detail the synthesis of process evaluation and outcome evaluation results	E (1)	I (2)	A	B (1)
23	The theoretical underpinnings behind both, the outcome evaluation intervention and its implementation should inform the explanations and the synthesis of process and outcome evaluation results	E (2)	I	A (1)	B (1)
24	Provide a clear definition of chosen terminology (e.g. adherence, fidelity, integrity etc.)	E (2)	I (2)	A	B
25	Have a defined scope and clear aims and objectives - a process evaluation protocol should be produced	E (3)	I	A (1)	B
26	Clearly describe and justify the use of a set of measures and evaluation criteria for the process evaluation	E (3)	I	A (1)	B
27	Provide a detail description and justification of selected process evaluation data collection methods	E (4)	I	A	B
28	Clearly explain and justify chosen timings for process evaluation data collection	E (4)	I	A	B
29	Collect relevant /appropriate data from all intervention and control sites	E (3)	I	A (1)	B
30	Use a variety of methods and strategies to gather data, including both qualitative and quantitative approaches	E (2)	I (2)	A	B
31	Should aim at publishing its results alongside outcome evaluation results (in order to reduce the chance of biases)	E (3)	I	A (1)	B
32	Address the interactions between process and outcome evaluations	E (2)	I (1)	A (1)	B