

The generation of consensus guidelines for carrying out process evaluations in rehabilitation research

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BMC Medical Research Methodology

DOI:
[10.1186/s12874-018-0647-y](https://doi.org/10.1186/s12874-018-0647-y)

Published: 29/12/2018

Peer reviewed version

[Cyswllt i'r cyhoeddiad / Link to publication](#)

Dyfyniad o'r fersiwn a gyhoeddwyd / Citation for published version (APA):
Masterson Algar, P., Rycroft-Malone, J., & Burton, C. (2018). The generation of consensus guidelines for carrying out process evaluations in rehabilitation research. *BMC Medical Research Methodology*, 18, [180]. <https://doi.org/10.1186/s12874-018-0647-y>

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1 **TITLE**

2 The generation of consensus guidelines for carrying out process evaluations in rehabilitation
3 research

4

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15

16

17 **ABSTRACT**

18 **Background**

19 Although in recent years there has been a strong increase in published research on theories
20 (e.g. realist evaluation, normalization process theory) driving and guiding process evaluations
21 of complex interventions, there is limited guidance to help rehabilitation researchers design
22 and carry out process evaluations. This can lead to the risk of process evaluations being
23 unsystematic. This paper reports on the development of new consensus guidelines that
24 address the specific challenges of conducting process evaluations alongside clinical trials of
25 rehabilitation interventions.

26 **Methods**

27 A formal consensus process was carried out based on a modified nominal group technique,
28 which comprised two phases. Phase I was informed by the findings of a systematic review,
29 and included a nominal group meeting with an expert panel of participants to rate and discuss
30 the proposed statements. Phase II was an in depth semi-structured telephone interviews with
31 expert panel participants in order to further discuss the structure and contents of the revised
32 guidelines. Frequency of rating responses to each statement was calculated and thematic
33 analysis was carried out on all qualitative data.

34 **Results**

35 The guidelines for carrying out process evaluations within complex intervention rehabilitation
36 research were produced by combining findings from Phase I and Phase II. The consensus
37 guidelines include recommendations that are grouped in seven sections. These sections are

38 theoretical work, design and methods, context, recruitment and retention, intervention staff,
39 delivery of the intervention and results. These sections represent different aspects or stages
40 of the evaluation process.

41 **Conclusion**

42 The consensus guidelines here presented can play a role at assisting rehabilitation researchers
43 at the time of designing and conducting process evaluations alongside trials of complex
44 interventions. The guidelines break new ground in terms of concepts and theory and works
45 towards a consensus in regards to how rehabilitation researchers should go about carrying
46 out process evaluations and how this evaluation should be linked into the proposed trials.
47 These guidelines may be used, adapted and tested by rehabilitation researchers depending
48 on the research stage or study design (e.g. feasibility trial, pilot trial, etc.).

49 **KEYWORDS**

50 Consensus guidelines, process evaluation, nominal group technique, rehabilitation research,
51 complex interventions

52 **BACKGROUND**

53 - Rehabilitation interventions are often complex, hence, their investigation can be
54 particularly demanding [1,2]. Complex interventions can be defined as those made up
55 of a number of components or *active ingredients* that interact with each other and with
56 outside factors to bring about changes to outcomes [3]. Complex interventions are
57 regarded as having inherent heterogeneity [4]. They will often be offered multiple times
58 to multiple participants, the location and site of delivery can change as well and they

59 can be delivered to individuals, families, combinations, etc. [5]. Similarly, they are
60 designed in a number of sessions to allow time for individuals to learn and comprehend
61 their content [6]. Rehabilitation interventions are complex and present a number of
62 specific challenges: They often involve complex behavioural treatments in contrast to
63 passive or surgical treatments [7].

64 - They are often delivered face to face, where personal interactions and relationships play
65 an important role in influencing patient engagement.

66 - They are linked treatment plans which will need to be tailored to patients' needs, and
67 wider social circumstances.

68 - They are context specific and defined as the interaction between the individual and the
69 environment [8]. In other words, rehabilitation interventions can be shaped by the
70 wider environmental and therapeutic milieu in which it is practiced.

71 Because of these particular characteristics, it can be extremely difficult to know why
72 rehabilitation interventions work (or not). Hence, rehabilitation research is highly challenging
73 for a number of reasons. Firstly, rehabilitation outcome measures are varied and complex,
74 there is no agreed taxonomy [9]. Hence, rehabilitation research will often use several
75 measures. Secondly, this research will involve a multidisciplinary team. Finally, samples sizes
76 are often small [10] since the range of disabilities is very extensive and diversity of conditions
77 is high. Thus, rehabilitation research is often highly individualized to a small homogeneous
78 group of people.

79 **Evidence in process evaluation research**

80 The aim of a process evaluation is to understand the underpinning mechanisms that explain
81 why an intervention works (or fails) [11,12]. They are focussed on understanding how the
82 characteristics of intervention components impact on its delivery and implementation to a
83 set standard (MRC). Although in recent years process evaluations are becoming a common
84 part of trial research proposals with an increased use in theories and frameworks driving and
85 informing them (e.g. realist evaluation, normalization process theory), there is to date, limited
86 guidance to help researchers design process evaluations [13, 14]. This is particularly true in
87 the field of rehabilitation research. As a result, carrying out a process evaluation alongside a
88 complex rehabilitation research trial can be seen as a daunting task, leading some researchers
89 to discard the idea of embarking on one or organising them unsystematically [14].

90 To date, only one piece of guidance has been published about undertaking process
91 evaluations, which was published whilst this research was underway [15]. The Medical
92 Research Council (MRC) guidance aims at providing guidance about how to carry out process
93 evaluations of public health interventions, and is considered by its authors as relevant to
94 evaluating complex interventions. The guidance summarises why there is a need for process
95 evaluations alongside current health research, and it then proposes a framework, which is
96 highly informed by the MRC guidance on complex interventions [3]. It discusses process
97 evaluation theory and then presents a practical section on how to carry out a process
98 evaluation. The guidance covers issues of implementation, mechanisms of impact and
99 influences and role of context. It also incorporates how the function and focus of a process
100 evaluation will vary according to the stage at which is conducted and the particular type of
101 complex intervention [16]. Each process evaluation will be different, but, the MRC guidance
102 was created in order to facilitate its planning and conducting [13,16]. According to several

103 authors [17,18] the tailoring of guidelines to particular contexts is of vital importance and can
104 strongly influence their uptake by the end user. Rehabilitation research, as previously
105 discussed, presents a particular set of challenges. Current guidelines such as the MRC
106 guidance although relevant to complex interventions often do not address these challenges
107 and therefore might present a number of limitations when applied to this context. This paper
108 reports on the development of consensus guidelines that build on current ones and aim to
109 solve their limitations tailoring their content to the individual challenges that define complex
110 rehabilitation intervention research and its process evaluation.

111 **METHODS**

112 **Formal consensus – study design**

113 A formal consensus development process was undertaken by the researcher based on a
114 modified nominal group technique (NGT) and informed by previous work carried out by
115 Rycroft-Malone [19]. A formal consensus process was chosen over an informal one since it
116 has been argued that guidelines produced as a result of informal consensus often formulate
117 recommendations without drawing from research evidence [20]. Also, an informal process
118 often follows unsystematic criteria and therefore resulting guidelines are not robust and can
119 be highly subjective [19].

120 NGT is an interdisciplinary collaborative approach and this can work at enhancing the
121 credibility of a guideline produced using this method. In other words, when end users of a
122 guideline (in this case rehabilitation researchers) have been involved in its creation, this can
123 have a positive influence on the future uptake of the guideline [19, 21, 22]. A number of
124 strengths of this method have been identified. First, it allows for participants to discuss

125 recommendations face to face, and, due to its highly structured nature, it can maximize the
126 chances for all participants to contribute in an equal way [23]. Secondly, it is a technique that
127 has been successfully used in the fields of health and rehabilitation research [24].

128 Participants were purposively sampled to reflect specialist knowledge and experience in
129 rehabilitation research. Participants were asked to take part due to their status as ‘experts in
130 rehabilitation and complex intervention research’. Invited participants worked in different
131 universities in the United Kingdom and covered a range of demographic characteristics and
132 career progressions. They qualified for selection based on their expertise on the matter under
133 discussion [25] but also because they had the seniority in their field to implement the findings.
134 The expert panel was expected to comprise 5-9 participants. Limited research in this area has
135 shown that this range is appropriate, with less than 5 decreasing reliability and more than 9
136 causing coordination problems [26].

137 Ethical approval to carry out this work was obtained from the Coventry Research Ethics
138 Committee (Reference: 09/H1210/88). Written and/or verbal informed consent to take part
139 in this study was obtained from all participants.

140 *Statements under consideration*

141 The evidence available for these guidelines came from one source: the systematic review on
142 the current state of process evaluation research in neurological rehabilitation research
143 carried out by the main author [27]. This systematic review resulted in a number of provisional
144 statements for carrying out process evaluations in neurological rehabilitation research. These
145 statements were identified via the individual analysis and consequent overarching synthesis
146 of two evidence streams: stream 1, published process evaluations of neurological

147 rehabilitation interventions and stream II, published guidelines and methodology on process
 148 evaluation. Stream I included 124 studies reporting on 106 interventions and stream II
 149 included 30 studies. The review concluded firstly, that there is a need for process evaluations
 150 to explore the role that intervention staff, their experience and set of skills play in the trial.
 151 Secondly, that it is vital for a process evaluation to address the nature and influence of context
 152 over time by monitoring staff’s learning effects and the possible impact on trial outcomes.

153 A total of 57 initial statements about process evaluation in rehabilitation research were
 154 identified. These 57 statements were grouped in 9 areas (Table 1) (for a complete list of
 155 statements please refer to Additional file 1). Each area was accompanied by a rationale
 156 providing a summary of the supporting information (Figure 1 shows an example of one of
 157 these interest areas – context). The paperwork included explanations and supporting
 158 information for each of the areas under discussion.

159 **Table 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

160

161 *Phase I - Nominal group meeting*

162 The nominal group meeting was organised following the standards reported by Rycroft-
 163 Malone [19]. In this meeting participants had the chance to discuss face to face, critique and

164 rate each of the proposed statements (Additional file 1). Also, they could voice their opinions
165 on the relevance of each of the suggested recommendations.

166 A suitable and convenient place for the meeting was chosen in order to increase the chances
167 of participant's availability. The lead author was the nominal group meeting facilitator. Prior
168 to the meeting, all participants received via email a document including all statements to be
169 discussed in the meeting (Additional file 1), and another document including a summary of
170 the results from the systematic review [27]. Making this evidence available increased the
171 chances of reducing bias as participants' opinions are then influenced not only by their own
172 personal experiences but also by the evidence provided [28].

173 Prior to the meeting, a participant information sheet was sent to all participants and written
174 informed consent was obtained from all those attending the meeting. The complete
175 meeting was audio recorded to assure that all information was captured. During the
176 meeting, following a strict order, each of the 57 statements and supporting information
177 were considered (Additional file 1). Firstly, participants were encouraged to discuss their
178 opinions regarding the statement. Participants were then asked to privately rate the
179 statement taking into account the research evidence, their expert opinion and the current
180 state of rehabilitation research in this area of the UK. The participants were asked to rate
181 the statement from 1-9 according to the following question: *How important is it for this*
182 *statement to be included in the future guidelines?* This process was followed for the 57
183 statements allowing participants to take a break when necessary.

184 Data analysis

185 Although there is no agreement on what is the best method to mathematically analyse this
186 type of rating response [23, 28] the frequency of responses to each statement was calculated.
187 For each statement, the median was calculated using SPSS for Windows. If the median score
188 of the statement was 7-9 this meant that consensus had been reached and that the statement
189 would be developed into the guidance recommendation. If the median was less than 2.99
190 then that would mean rejection of that statement. Finally, those statements with a median in
191 the middle ground were retained for further discussion during telephone interviews and post
192 nominal group meeting feedback (Phase II).

193 Data obtained from the audio-recording during Phase I was transcribed in full. In order to
194 analyse this set of qualitative data a thematic analysis approach was taken following the
195 method described by Braun and Clarke [29]. This method was chosen as it provides a rich and
196 detailed account of the data whilst being flexible. First, the main author (PMA) re-read the
197 transcription in order to gain familiarity with the data, which was then coded in order to
198 capture conceptual meanings. Crosschecking by the co-authors was carried out with 10% of
199 transcribed data to identify codes where there was lack of clarity. All codes were collated with
200 their relevant data extracts. Themes were then identified as meaningful patterns across
201 coded data.

202 *Phase II - Second round of feedback*

203 Once results from Phase I were analysed a summary was emailed to all participants. This
204 included a summary of main identified themes and a revised version of the proposed guidance
205 recommendations according to the results from the nominal group meeting.

206 Phase II of the NGT involved telephone in-depth interviews with a set of expert participants
207 in order to provide further feedback and critique the proposed revised version of the
208 guidance recommendations. Verbal informed consent to take part in this study was
209 obtained from all participants.

210 In line with ethical approvals, verbal informed consent was obtained from all participants and
211 audio recorded at the start of each interview. Prior to the telephone interview, participants
212 were asked to read the revised version of the guidelines. This allowed participants to see the
213 spread of agreement and how their response related to the results from the group meeting.
214 Certain items were selected for discussion with the focus primarily on statements where
215 agreement had not been reached. These semi-structured telephone interviews focused
216 primarily on those statements that were the source of the most disagreement during Phase
217 I. Participants were asked about both, the overall structure of the guideline and specific
218 aspects such as the role of theory in informing process evaluations and issues around tailoring
219 and context (for the interview schedule please refer to Additional file 2).

220 Data analysis

221 All Phase II in depth interviews were transcribed in full; the same process as in Phase I was
222 followed and thematic analysis was carried out following Braun and Clarke's method [29].
223 Themes were identified and collated with those that emerged during Phase I. Finally, the main
224 author, firstly independently and then, through discussion with the rest of the team members
225 (co-authors), produced a final version of the guidelines which was in line with identified
226 themes.

227 **RESULTS**

228 *Expert panel*

229 The researcher contacted a total of 23 potential participants. 10 agreed to take part in this
 230 consensus work. Due to work commitments and difficulty timetabling mutually convenient
 231 dates, 5 out of the 10 participants attended the nominal group meeting (Phase I) and the
 232 remaining 5 participants took part in Phase II. Table 2 provides information regarding the
 233 professional characteristics of the participants and their involvement in the research process.
 234 5 of the participants were professors in their field and therefore had high level of expertise.
 235 2 of the participants were working towards completing their PhD studies. Participants’
 236 backgrounds were varied; one was a physiotherapist, three nurses, one an exercise
 237 physiologist, one a speech pathologist, one a psychologist and two were medical doctors.

238 **Table 2** Professional characteristics and involvement of members of the consensus expert panel

Current research role	Background	Phase I	Phase II
Professor of Clinical Biostatistics	Biostatistics	√	
Doctoral Research Fellow	Speech pathology and therapy	√	
Professor of Stroke and Older People’s Care	Nursing	√	
Honorary Research Associate	Nursing	√	
Senior Research Fellow	Nursing	√	
Professor in Exercise Physiology	Exercise physiology		√
Reader in Psychology	Psychology		√
Clinical Senior Lecturer	Medical sciences		√
Professor of Stroke Medicine	Medical sciences		√
Research Officer	Physiotherapy		√

239

240 The results of the ratings were calculated for each of the statements. The median value for
 241 the statement together with the highest score and lowest score were calculated. 5 statements
 242 (n.1, n.9, n.14, n.16 and n.17) were excluded since consensus was not reached. The remaining
 243 53 statements met the criteria to be included in the guidelines; however, participants
 244 expressed these needed further editing, clarifying and grouping in order to reduce the
 245 number of recommendations. As a result of the formal consensus process (Figure 2), the

246 initial 57 proposed statements were edited in order to incorporate comments and feedback
247 from participants. These edits included changes in the use of terminology and in the order
248 and grouping of the statements as well as general corrections to increase the clarity of the
249 language. In addition, this revised version included an introduction section stating the
250 underlying *standpoint* of the researchers regarding the nature of complexity.

251 Four themes were identified during the formal consensus process as having a significant
252 influence on participants' ways of thinking at the time of discussing statements and the need
253 for them to be included in the proposed guidelines (Table 3). The data gathered during both
254 phases was key in order to understand what the rehabilitation research community think
255 about process evaluations. Participants openly discussed issues around the practicalities and
256 the challenges of process evaluation research. This consensus work became a platform for
257 researchers to voice their understanding about what is and what should be the aim of a
258 process evaluation. Table 3 provides a summary of themes that were identified during the
259 formal consensus process. These themes describe a number of issues in regards to the
260 guidance and its potential use for rehabilitation researchers which participants suggested
261 needed addressing.

262

263 **Table 3** Identified themes across Phase I and II

Theme	Description
The practicalities of doing research – being realistic about what 'can be done'	All participants agreed that there is a degree of compromise which impacts on what can realistically be achieved at the time of evaluating processes. Participants expressed their desire to not only rate recommendations in terms of the need for them to be included in the guidelines, but also to rank these statements in terms of their relative importance.

<i>Stand point</i> – role of theory, concepts and roles	Participants expressed how it is important for any guidelines to include an explanation of the assumptions that underpin it. The participants’ epistemological and ontological stance highly influenced their views regarding proposed recommendations and their understanding of the guidelines’ content. Likewise, participants expressed different views in regards of the role that theory plays at the time of designing and carrying out a process evaluation. Participants considered that for guidelines to work, they need to clearly explain their underlying assumptions. In this way, the rehabilitation researcher can make an informed decision at the time of following the proposed guidelines.
Investigating <i>tailoring</i> and ‘making connections’	Participants identified the need for a process evaluation to investigate the level of tailoring and its impact on outcomes. They discussed in depth the challenges in assessing the degree of tailoring taking place at the time of trialling a rehabilitation intervention. 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.
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. The proposed guidelines need to state who the end users are; rehabilitation researchers will then be responsible for tailoring its recommendations to best fit their evaluation aim. Participants agreed that the process evaluation guidelines would need to be tailored, not only to a particular process evaluation, but also to end users’ needs.

264

265 *The consensus guidelines*

266 The guidelines for carrying out process evaluations within complex interventions
 267 rehabilitation research were produced (Table 4) from findings from Phase I and Phase II. The
 268 proposed guidelines include a number of clarifying points in regards to: firstly, who are the
 269 guidelines’ target audience and how they should be used and adapted by rehabilitation
 270 researchers according to the design, type and the timing of the trial under evaluation.
 271 Secondly, a brief explanation clarifying the underlying assumptions underpinning the
 272 consensus guidelines and linked recommendations. Finally, seven sections in which the
 273 recommendations are grouped. These sections represent different aspects or stages, which
 274 the rehabilitation researcher will face throughout the evaluation process. The following
 275 describes the domains including an illustrative example for each.

- 276 • *Theoretical work*: addressed issues in relation to the theoretical underpinnings of the
277 trialled intervention. Researchers are guided to review the theoretical underpinnings
278 not only of the rehabilitation intervention but also the implementation approach. For
279 example, Byng et al. [30] carried out the process evaluation of an intervention to
280 improve primary healthcare for patients with long-term mental illness following a
281 realist evaluation approach. They reported that through realist evaluation the team
282 was able to identify the interactions taking place, not only between intervention
283 components, but also with the embedded external context.
- 284 • *Design and methods*: this describes a number of steps aimed at treating a process
285 evaluation as a piece of research in its own right. Researchers are advised to provide
286 a clear definition of chosen process evaluation terminology, define clear aims and
287 objectives and provide a detail description of selected data collection methods and
288 timings. Finally, the guidelines recommend researchers addressing the interactions
289 between process and outcome measures. For example, a number of protocols for
290 process evaluations have been published alongside the main trial's protocol [31, 32].
- 291 • *Context*: this section addresses the importance of understanding and accounting for
292 contextual factors, their role and their potential impact on process and outcomes over
293 time For example, the process evaluation of a randomized controlled trial (RCT)
294 looking at the benefits of a programme for caregivers of inpatients after stroke (TRACS
295 study) [33]. This evaluation investigated the impact that contextual factors had during
296 the process of embedding the intervention into the routine practice of a stroke unit.
297 The researchers explored in detail contextual factors such as organisational history
298 and policies, team relationships, responsibility sharing and staff engagement.

- 299
- *Recruitment and retention.* The process evaluation should review the outcome
300 evaluation's recruitment and retention procedures in order to identify potential
301 barriers and facilitators. It should also clearly describe the strategies and criteria
302 informing the recruitment of participants into the process evaluation. Scianni et al [34]
303 reviewed in detail their recruitment procedures and identified transport to and from
304 the health setting as the main barrier to participation in a trial investigating the impact
305 of gait training for stroke survivors.
 - *Intervention staff.* This section firstly addresses the need to investigate the
306 characteristics of staff in charge of delivering the intervention and identify how these
307 can potentially have an effect on intervention implementation and impact. Secondly,
308 it recommends the process evaluation to review the training provided to intervention
309 staff in order to identify possible impact on outcomes. For example, Chung [35], in his
310 study assessing the impact of a reminiscence programme for older adults with
311 dementia provided a detailed description of the training component and expected
312 learning outcomes. Intervention staff's knowledge on delivering the programme was
313 assessed using quizzes and questionnaires.
 - *Delivery of the intervention.* The guidelines recommend that process evaluation
315 researchers should focus on tailoring and investigate the strategies in place in order
316 to guide it and measure it. In addition, researchers should investigate barriers and
317 enablers to implementation by reviewing strategies in place to improve or support the
318 fidelity of the rehabilitation intervention. The process evaluation should review
319 strategies in place to measure 'dose delivered' and 'dose received'. Finally,
320 participant's experiences and acceptability of the intervention should be investigated.
321

322 To date, it is rare for research studies to provide intervention providers with clear
323 guidance on how to assess which is the 'right amount' of tailoring [27]. However,
324 studies such as Mayo et al. [36] set an example by investigating how an exercise
325 programme post-stroke was tailored to patients needs whilst keeping to the protocol
326 guidelines.

- 327 • *Results*. This section addresses the need to describe in detail the synthesis of process
328 and outcome evaluation results. This synthesis should be informed by the theoretical
329 underpinnings behind both, the outcome evaluation and its implementation. For
330 example, in their study looking at a rehabilitation intervention for adults with brain
331 injury, Letts and Dunal [37] developed a logic model through consensus work, which
332 integrated information on process and outcomes.

333 **DISCUSSION**

334 This paper presents a set of consensus guidelines for carrying out process evaluations within
335 complex rehabilitation research. These guidelines allow sufficient flexibility in order to be
336 adapted accordingly depending on the research design and study type and they work on the
337 assumption that complex rehabilitation interventions are those made up of a number of
338 components, which interact with each other to bring about changes in outcomes.
339 Furthermore, these guidelines consider that the impact of the complex intervention is greater
340 than the sum of the effects of their component parts and is a product of not only the changes
341 embedded in the intervention hypothesis but also the implementation approaches informing
342 it [38,39]. The aim of these guidelines is to update and contribute to the published evidence
343 by extending its coverage to rehabilitation research, its processes and theoretical

344 underpinnings. These guidelines provide a new lens for rehabilitation researchers attempting
345 to carry out a process evaluation and they build on published work such as the UK MRC
346 guidance [15] in an attempt to address the difficulties and challenges faced, in particular, by
347 those researchers dealing with complex rehabilitation interventions. For example, one of
348 these challenges is in regards to participant recruitment into rehabilitation trials which often
349 follows a criteria that is therapeutically based and therefore more complex, instead of based
350 on a screening tool [40]. The proposed guidelines acknowledge this and propose a number of
351 recommendations that guarantee the close exploration of the trial's recruitment procedures
352 in order to identify potential barriers and facilitators and their impact on outcomes.
353 Furthermore, these guidelines recommend in depth review of the strategies implemented
354 during the outcome evaluation in order to maximise participant retention (e.g. transportation
355 to and from research base). A further challenge faced by rehabilitation researchers planning
356 an RCT is making sure that treatment differentiation is kept throughout the study. This can be
357 extremely hard considering the role that tailoring often plays throughout the delivery of the
358 trialled intervention. The proposed guidelines address this challenge by advising on the need
359 to firstly, investigate strategies to guide, inform and measure the tailoring, and secondly,
360 assess the quality of any implementation strategy aimed at improving or supporting the
361 fidelity of the rehabilitation intervention. Finally, these guidelines understand the further
362 challenges that rehabilitation trials face in terms of recruiting intervention staff. The skills,
363 previous experience and knowledge of those administering the intervention can influence
364 intervention impacts [7]. This issue is particularly addressed in these guidelines with a number
365 of recommendations focussing on what the process evaluation should investigate in regards
366 to intervention staff characteristics, training provided and possible impact on outcomes.

367 In these guidelines, outcome evaluation and process evaluation are considered to be
368 inextricably linked. With this in mind, these guidelines work towards a consensus in regards
369 to how rehabilitation researchers should go about carrying out process evaluations and how
370 this evaluation should be linked into the proposed trials. Additionally, these guidelines are
371 innovative, in addressing the importance of learning effects and contextual changes with
372 time, when evaluating the processes that take place as part of a research trial. Finally, the
373 guidelines here presented stress the vital importance of describing in detail the components
374 of the rehabilitation interventions and their interactions. This demand is in line with the
375 requirements of other highly accepted published tools such as The Consolidated Standards
376 for Reporting Trials (CONSORT) 2010 statement [41] or the more recent Template for the
377 Intervention Description and Replication (TIDieR) checklist and guide [42].

378 As the data here presented shows, researchers are aware of how their decisions in terms of
379 process evaluation will be closely influenced by the type and stage of the study. As put by
380 Moore et al. [16], "*the focus of process evaluation will vary according to the stage at which it*
381 *is conducted*" (p.2). Thus, in line with what other authors [13,43] have stated, the guidelines
382 here presented will need to be tailored to rehabilitation researchers' particular needs, since
383 there is no single way to carry out a process evaluation. Issues around the design, the phase,
384 the timing of the study or a number of contextual factors will play a major role at the time of
385 designing and carrying out a process evaluation. Furthermore, as expressed by Moore et al.
386 [16], even when the feasibility trial has been under a process evaluation, there will still be the
387 need to carry out another one, alongside the full trial, because it is likely that the intervention,
388 and this is particularly true for rehabilitation interventions, will face new problems and new
389 challenges will emerge when implementing at a larger scale. Finally, the guidelines here

390 presented incorporate the idea that changes in contextual factors, responsible for triggering
391 intervention mechanisms [44], are likely to take place throughout the research period and
392 will therefore need to be addressed by the process evaluation.

393 One of the challenges faced by rehabilitation researchers planning an RCT is making sure that
394 treatment differentiation is kept throughout the study. In addition to this, several authors
395 [45, 46] have identified addressing ‘the science of client centred replication’ as a major
396 challenge for today’s health care research. Thus, it is of vital importance to address the issue
397 of tailoring of the intervention if the researcher aims to investigate its fidelity in depth [47,
398 48]. The proposed guidelines address this need by advising on the need to firstly, investigate
399 strategies to guide, inform and measure the tailoring, and secondly, assess the quality of any
400 implementation strategy aimed at improving or supporting the fidelity of the rehabilitation
401 intervention. In this way, and in answer to a need that has been previously identified by
402 several authors [13, 14], these guidelines allow for sufficient flexibility and room for
403 manoeuvre in order to be tailored to the type of intervention and the type of study design,
404 whilst facilitating standardisation of research practice. Furthermore, these guidelines are in
405 tune with the challenges that rehabilitation trials face in terms of recruiting intervention staff.
406 The skills, previous experience and knowledge of those administering the intervention can
407 influence intervention impacts [7]. This is particularly addressed in these guidelines with a
408 number of recommendations focussing on what the process evaluation should investigate in
409 regards to intervention staff characteristics, training provided and possible impact on
410 outcomes.

411 The data here presented show, and as it has been discussed in the literature [16], that there
412 are arguments for both the separation and the integration of process evaluation and outcome

413 evaluation teams. These guidelines assume some integration between outcome and process
414 evaluation. The guidelines we here propose consider that data on implementation should be
415 integrated into the analysis of outcomes and that emerging process issues identified in the
416 process evaluation should be integrated into trial data design and collection. Also, the authors
417 understand that by considering outcome and process evaluation to be inextricably linked, the
418 rehabilitation researcher might avoid duplication of efforts and reduce the burden on
419 participants at data collection stages. As raised by O’Cathain et al. [49], effective integration
420 and addressing the links between process and outcome evaluations will take place only when
421 members of both teams value each other’s contribution and when the principal investigator
422 understands and agrees with the value of integration. Closely linked to this, authors such as
423 Audrey et al. [50] have identified that one of the main challenges of implementing process
424 evaluation within clinical trials is the overlapping roles within the team and distinguishing
425 between the intervention and its evaluation. The proposed consensus guidelines support the
426 need for close integration of process and outcome evaluations.

427 The modified consensus NGT method [19], used in the creation of this guideline, proved to
428 be straightforward. The nominal group meeting was demanding upon participants because
429 there were a large number of recommendations to discuss. Also, it was hard for the
430 researcher to judge how successfully ‘group dynamics’ were controlled and how much the
431 personality and compliance of the participants impacted on the cooperation of the panel of
432 experts. However, there are a number of additional strengths in this piece of work. This
433 consensus work provided an opportunity for the researcher to be involved in collaborative
434 working amongst a number of rehabilitation researchers from a number of different
435 disciplines. Finally, as Rycroft-Malone [19] points out, the use of a collaborative approach, by

436 listening to experts in the field, could have a positive impact on the ultimate uptake of the
437 guideline as it is seen as being more credible.

438 *Limitations*

439 The number of participants who took part in both phases of the consensus work was lower
440 than originally anticipated. However, all participants were highly experienced in carrying out
441 rehabilitation research and were all academics. The statements under consideration during
442 the consensus process were drawn from a systematic review that focussed on neurological
443 rehabilitation and a small number of experts in the panel had a neurological research
444 background as well. This neurological focus could have influenced the outcome of this
445 consensus work. Finally, all expert participants were based in the UK and are likely to be more
446 familiar with the challenges and nuances of the British healthcare research context. The
447 authors understand firstly, that further work will be required to test the usefulness and
448 applicability of the proposed guidelines to the work that rehabilitation researchers are
449 currently undertaking not only in the UK but internationally. Secondly, that it is likely that
450 these guidelines will be read and used by those researchers who share its underpinning
451 assumptions in regards to the nature of complex interventions.

452 **CONCLUSIONS**

453 This paper has outlined the process of the development of new consensus guidelines for
454 designing and carrying out process evaluations of rehabilitation intervention trials. The aim
455 of these guidelines is to update and contribute to the published evidence by tailoring its
456 coverage to the particular challenges that define rehabilitation research, its processes and
457 theoretical underpinnings. The results here presented break new ground in terms of concepts

458 and theory and work towards a consensus in regards to how rehabilitation researchers should
459 go about carrying out process evaluations and how this evaluation should be linked into the
460 proposed trials. Although these guidelines are written from the perspective of researchers
461 with experience of carrying out trials of complex rehabilitation interventions, it is also relevant
462 and useful to stakeholders from other research domains such as funding agencies, when
463 making decisions regarding allocation of funding.

464

465 **DECLARATIONS**

466 **Consent for publication**

467 'Not applicable'

468 **Ethical approval and consent to participate**

469 Ethical approval to carry out this work was obtained from the Coventry Research Ethics
470 Committee (Reference: 09/H1210/88). A participant information sheet was sent to all
471 participants. Written informed consent was obtained from all those attending the nominal
472 group meeting. In line with ethical approvals, verbal informed consent was obtained from all
473 participants and audio recorded at the start of each interview.

474 **Availability of data and materials**

475 Data and materials are available from the corresponding author upon reasonable request.

476 **Competing interests**

477 "The authors declare that they have no competing interests"

478 **Author's contribution**

479 PMA made substantial contribution to the conception and design. PMA prepared the
480 manuscript and revised for important intellectual content. CRB and JRM made substantial
481 contribution to the design of the study and the revision of the manuscript for intellectual
482 content. All authors read and approved the final manuscript.

483 **Acknowledgements**

484 The authors would like to thank all researchers who contributed to the development of
485 these guidelines by providing their valuable opinions.

486

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610

611 **ABBREVIATIONS**

612 MRC – Medical research council

613 RCT – Randomized controlled trial

614 NGT – Nominal group technique

615 **FIGURES**

616 **Figure 1** Example of interest area (context) including statements and supporting information

617 **Figure 2** Formal consensus process

618 **TABLES**

619 **Table 1** Number of statements per area of interest

620 **Table 2** Professional characteristics and involvement of members of the consensus expert
621 panel

622 **Table 3** Identified themes across Phase I and II

623 **Table 4** Guidelines for carrying out process evaluations within complex rehabilitation
624 interventions research (uploaded as an Additional file)

625 **ADDITIONAL FILES**

626 **Additional file 1** Statements for consensus group

627 **Additional file 2** Interview schedule