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The role of Psychological Processes in acquired brain injury sequelae

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THE ROLE OF PSYCHOLOGICAL PROCESSES IN ACQUIRED BRAIN INJURY SEQUELAE

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The Role of Psychological Processes in Acquired Brain Injury Sequelae

Abstract

This thesis aimed to explore the pivotal role that psychological processes play in Acquired Brain Injury (ABI) sequelae at a both conceptual and interventional level.

Initially, a systematic review and meta-analysis examined the available evidence base for the efficacy of psychological interventions in reducing aggressive behaviour following an ABI. In line with the PRISMA guidelines, a literature search identified eleven studies that met the inclusion criteria. As many studies within the neurorehabilitation literature use single-case methodology, the current meta-analysis adopted a novel approach enabling the synthesis of empirical data from both group design and single-case experimental design studies. The results of the meta-analysis demonstrated moderate effect sizes across both types of research design, suggesting significant reductions in aggressive behavior following psychological intervention. Maintenance effects were also reported, but should be interpreted with caution.

A second cross-sectional study explored the discrepancy between subjectively reported cognitive impairment (SCI) and objectively measured cognitive impairment (OCI) following ABI, whilst highlighting the potential role of psychological factors. Twenty-four participants completed objective neuropsychological assessments and a series of psychometric questionnaires assessing psychological affect and perceived cognitive difficulties. A correlation analysis revealed no significant association between objective and subjective cognitive impairment. Conversely, psychological affect, such as anxiety and low mood, demonstrated a significant positive relationship with subjective cognitive impairment. An additional hierarchical regression analysis revealed psychological affect as a significant predictor of subjective cognitive impairment. The regression model found objective cognitive impairment to be non-significant. These findings suggest that an individual's subjective experience of their cognitive difficulties may not be associated with their actual objective cognitive impairment. Other psychological factors may play a more crucial role in patients' appraisals of their cognitive impairments.

The limitations and clinical implications for both papers are discussed.

Table of Contents

List of Tables

Page

List of Figures

Page

List of Abbreviations

ABI	Acquired Brain Injury
AQ-12	Buss and Perry Aggression Questionnaire-12
ASMT	Anger Self-Management Training
BAAQ	Brief Anger-Aggression Questionnaire
BDI	Beck Depression Inventory
CBT	Cognitive Behavioural Therapy
CFQ	Cognitive Failures Questionnaire
CI	Confidence Intervals
CVA	Cerebral Vascular Accident
DAFS	Direct Assessment of Functional Status
EBP	Evidence-Based Practice
GCS	Glasgow Coma Scale
HADS	Hospital Anxiety and Depression Scale
HAI	Health Anxiety Inventory
MRI	Magnetic Resonance Imaging
NHS REC	National Health Service Research Ethics Committee
OCI	Objective Cognitive Impairment
PTA	Post-Traumatic Amnesia
RBANS	Repeatable Battery for the Assessment of Neuropsychological Status
RCTs	Randomised Control Trials
SCEDs	Single-Case Experimental Designs Studies
SCI	Subjective cognitive Impairment
SD	Standard Deviation
STAXI	State–Trait Anger Expression Inventory
TBI	Traumatic Brain Injury
WAIS-IV	The Wechsler Adult Intelligence Scale-Fourth Edition

Chapter 1 - Meta analysis and Literature Review

The Effectiveness of Psychological Interventions for Aggressive Behaviour Following Acquired Brain Injury

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The Effectiveness of Psychological Interventions for Aggressive Behavior Following Acquired Brain Injury: A meta-analysis and systematic review

Abstract

Background: The consequences of aggressive behavior following ABI have an impact at both an individual and systemic level. In contrast to other ABI sequelae, aggressive behavior has been shown to increase over time without appropriate timely interventions.

Objective: The current meta-analysis aimed to systematically review the current literature examining psychological interventions for aggressive behavior following ABI. The meta-analysis also aimed to provide a statistical synthesis of the available evidence.

Method: Following the PRISMA guidelines, an electronic and ancestral search of the available literature identified eleven studies (N=123) that met the inclusion criteria for the review. Non-overlap effect sizes (Tau-U) were calculated to synthesize the available evidence from single case experimental design studies (SCEDs; N=7). Standardised mean difference effect sizes (*d*) were calculated to synthesize the available evidence from group studies (N=4).

Results: A medium omnibus effect size (weighted *d*=-0.46, 95% CI:-0.69<>-0.24) was found for group studies. Similarly, the overall effect size (Tau-U) for SCEDs was -0.59 (95% CI:-0.72<>-0.46), indicating a 59% reduction in aggressive behaviour compared to baseline.

Conclusion: The findings of the meta-analysis suggest that psychological interventions for aggressive behavior are at least moderately effective at reducing aggressive behavior following ABI.

Keywords: Aggressive behavior, Acquired Brain Injury, Rehabilitation, Meta-analysis, Single Case Experimental Design, Evidence Based Practice, Psychological Interventions

1. Introduction

Acquired Brain Injury (ABI), defined as cerebral damage occurring after birth and not a result of congenital or progressive disease, produces a wide variety of physical and psychological sequelae (Cattelani, Zettin, & Zoccolotti, 2008). A common psychological consequence of ABI is impairment in behavioral regulation, which can often manifests as aggressive behavior (Baguley, Cooper, & Felmingham, 2006).

The negative consequences of aggressive behavior have an impact at both an individual and systemic level. Individuals displaying aggressive behavior may become socially isolated (Kim *et al*., 1999), vulnerable to retaliatory assaults and subject to criminal charges. On a systemic level, carer stress (Hall *et al*. 1996), staff burnout, increased staffing costs and exclusion from vital services are also a common consequence (Kelly & Parry, 2008). Furthermore, in contrast to other ABI sequelae, aggressive behavior may worsen over time without appropriate intervention (Brooks *et al.,* 1986; Johnson & Balleny, 1996).

The prevalence rates for aggressive behavior following an ABI vary considerably. Sabaz *et al.* (2014) identified a wide range of prevalence rates, from as low as 11% to as high as 96%, within the literature. The wide ranging prevalence rates are likely due to heterogeneous nature of the population (i.e. different severity of brain injury, time since injury, intervention setting, age) and the diverse methods of outcome measurement used across the studies. In addition, there appears to be a lack of an accepted operational definition for aggressive behavior within the literature. Providing such an operational definition for aggressive behavior is a conceptual challenge. Previous definitions often imply the notion of intent. However, within the ABI population, where severe cognitive impairment is prevalent, intent may be extremely difficult to identify. Intent is covert and therefore cannot be directly observed making it difficult to objectively measure. Therefore, the current meta-analysis will use the following definition:

"Aggressive behavior is an overt act, involving the delivery of noxious stimuli to (but not necessarily aimed at) another organism, object or self. (Patel & Hope, 1992, p 212)

Due to the complex interaction between numerous brain structures that mediate aggressive behavior, the exact neurological aetiology of aggressive behavior following ABI is multifaceted. The majority of the literature emphasises the role of the frontal lobes. Historic case studies, such as the frequently cited case of Phineas Gage, provided the basis for this notion, although there is some debate about the exact nature of Gage's presentation (Macmillan, 2008). More recently, studies utilizing Magnetic Resonance Imaging (MRI) have demonstrated the importance of three major frontal-subcortical areas (dorsolateral, ventromedial and orbitofrontal) in aggressive behavior (Cattelani, Zettin & Zoccolotti. 2008). Empirical studies have associated lesions in the orbitofrontal cortex with impairments of executive control, resulting in disinhibited behavior and an inability to suppress automatic responses (Siever, 2008). The dorsolateral prefrontal cortex is also critically involved in moral decision-making, cognitive flexibility and the presence of apathy (Greene *et al.,* 2001; Cattelani, Zettin & Zoccolotti, 2010).

Characteristics such as disinhibited behavior, cognitive inflexibility and high impulsivity are a consistent part of the neurobehavioral profile of individuals who display aggressive behavior (Wood & Liossi, 2006). Furthermore, Grafman *et al.* (1996) demonstrated that patients with frontal ventromedial lesions have significantly higher aggression scale scores when compared to both healthy control participants and individuals with other anatomical lesions. However, although the literature highlights the importance of neuroanatomy, the presence of aggressive behavior is not exclusively dependent on biological lesions. Grafman *et al* (1996) also found that psychosocial factors, such as family disruption, were more associated with aggressive behavior compared to the total size of the lesion. This suggests that the behavioral expression of an injury may be related to factors other than the biological lesion alone. Factors such as premorbid personality and post-injury coping styles likely play a key role in the

presence of aggressive behavior following ABI. These factors are considered in Warriner & Velikonja (2006) conceptual model of the manifestation of emotional and behavioral difficulties following ABI. In addition to structural and pathological changes to the brain, the model also includes premorbid, post-injury and environmental variables that are specific to the individual.

Interventions for aggressive behavior can be can be broadly separated into two categories – pharmacological and non-pharmacological. A Cochrane Collaboration Review evaluated the efficacy of pharmacological treatments for aggressive behaviour following ABI (Fleminger, Greenwood & Oliver, 2006). In total, the review consisted of six Randomised Control Trials (RCTs): four studies investigated the efficacy of beta-blockers (propranolol and pindolol), one evaluated methylphenidate, and one evaluated amantadine (commonly used in Parkinson's disease). Of the six RCTs, two were found to demonstrate modest findings that supported the use of beta-blockers for the treatment of aggressive behaviour following ABI. However, it was noted that both studies used extremely large doses, which would have likely caused problematic side effects in the long-term. No effect was found for any other pharmacological treatment. It was concluded that there was no substantial evidence for the use of exclusive pharmacological treatment for aggressive behaviour following ABI, with the risks outweighing the potential benefits.

Aggressive behavior following ABI should be conceptualized as a multifaceted difficulty involving premorbid personality, post injury coping styles, pathological changes in the brain and environmental factors (Warriner & Velikonja, 2006). Interventions focusing solely on the organic factors will likely ignore the myriad of other contributing factors that play a crucial role in the presentation aggressive behavior. Alternative non-pharmacological interventions, which follow a more neurobehavioral paradigm, may provide a more holistic approach taking into account the relationship between the brain, behavior and an individual's environment (Alderman *et al*., 2013).

Behavioral interventions typically follow a combination of operant contingency management and antecedent management. Operant contingency management involves the use of contingencies to reduce maladaptive behaviors, whilst increasing adaptive behaviors through processes of reinforcement (positive and negative) or punishment (defined as a stimulus response that reduces the probability of a behavior occurring in the future). Antecedent management focuses on modifying the environmental and internal antecedents that are associated with a maladaptive behavior. Antecedent management may be considered useful in ABI populations when there are concerns regarding the ability for the individuals to learn through operant contingencies. For example, in the acute period of ABI where post-traumatic amnesia (PTA) and disorientation are frequently present (Slifer & Amari, 2009). Furthermore, there are currently no accepted neurobiological explanations for the commonly observed increase in aggressive behavior over time (Brooks *et al.,* 1986; Johnson & Balleny, 1996). However, a behavioral perspective can account for gradual increases in aggressive behavior through processes of reinforcement. For instance, aggressive behavior may become functional for an individual allowing them to gain access to desired tangibles or avoid aversive stimuli. Therefore behavioral interventions would be best suited to address this process, ultimately reducing the frequency of aggressive behavior.

Cognitive-behavioral interventions have also been suggested to offer benefit in reducing aggressive behavior within the ABI population (Medd & Tate, 2000; Walker *et al.* 2010; Aboulafia-Brakha *et al.,* 2012). Cognitive-behavioral interventions for aggressive behavior have demonstrated efficacy across a wide range of clinical and non-clinical populations, including those with; intellectual disabilities (Willner *et al.,* 2013), schoolchildren, adolescents, prison inmates, and college students (Beck & Fernandez, 1998). This approach contains elements of psychoeducation, self-monitoring, cognitive restructuring and self-talk training (Cattelani *et al.,* 2010). The structured and goal-based nature of CBT informed interventions may lend itself well to the ABI population where executive dysfunction is common impairment. However, some authors have suggested that CBT can be quite abstract and that in an ABI population some

negative beliefs may actually represent reality (Kangas & McDonald, 2011). At present, the evidence for CBT interventions for aggressive behavior following ABI is limited, but is growing.

Psychological interventions for aggressive behaviour, if effective, could offer many advantages over pharmacological therapies. For instance, psychological techniques taught to an individual, an individual's carer or an individual's staff team could be used in the long-term without any of the negative side effects associated with pharmacological treatments highlighted by the Cochrane Collaboration Review (Fleminger, Greenwood & Oliver, 2006). Furthermore, psychological interventions may be more economically viable in comparison to pharmacological treatment as the costs of medication accumulate throughout an individual's lifespan. In contrast, once the skills have been acquired, individuals would be able to carry on the techniques throughout their life.

There are two excellent systematic reviews (see Ylvisaker, 2006 and Cattelani, Zettin & Zoccolotti, 2010) within the current literature that have attempted to evaluate the effectiveness of psychological interventions for problematic behaviors following ABI. Both concluded that psychological interventions for behavioral disorders could be considered as evidence-based treatments. However, both reviews investigate a broad range of behavioral difficulties, grouping aggressive behavior with many other behavioral presentations. In addition, the reviews measure a wide range of outcomes such as quality of life (QoL), employability and emotional wellbeing. Recent meta-analyses investigating neurobehavioral interventions have also shown promising results at both reducing problematic behavior and increasing skill acquisition (Heinicke & Carr, 2014; Manolov & Rochat, 2015). However, similar to the before mentioned systematic reviews, previous meta-analyses have synthesized data from a wide range of challenging behaviors.

The lack of 'gold standard' research available within the current literature was highlighted by both Ylvisaker (2006) and Cattelani, Zettin & Zoccolotti (2010). This was also reiterated by Slifer & Amari (2009), who specifically commented

on the lack of Randomised Control Trials. The lack of RCTs may be due to the amount of confounding variables (spontaneous recovery, heterogeneity of participant, co-morbid difficulties, to list a few) that are often present and difficult to control in the ABI population (Ducharme, 2000). As a consequence, the majority of the evidence emanates from single-case experimental designs studies (SCEDs). This experimental design embraces the idiosyncratic differences demonstrated in this heterogeneous population. For this reason, the current meta-analysis aims to extend previous reviews by using a novel approach to statistically synthesize available evidence from both SCEDs and group design research within the literature. To the authors' knowledge no meta-analysis has attempted to statistically synthesize the available evidence in order to determine an overall effect size specifically for the reduction of aggressive behavior following psychological interventions.

2. Method

2.1 Search Strategy

To obtain and explore the literature, four electronic databases (Brain Injury, Web of Science, PubMed and PsychInfo) were searched in August 2015. The following search terms were used: ("Acquired Brain Injury*" OR "Brain Injury") AND "aggression*" "behavior disorders*" AND ("intervention*" OR "therapy*"). The search was restricted to English language articles and all publications post-1997. An ancestral search from the electronically identified studies was also conducted. In total the search yielded 236 journal articles.

2.2 Study selection

Following an initial screening process of 237 articles, which included abstract and title examination, 189 articles were excluded as they were found not to be relevant to the topic of interest. This left 48 full-text articles to be assessed using the following eligibility criteria:

- Studies must meet the current study's definition of a aggressive behavior: *"any overt act, involving the delivery of noxious stimuli to another organism, object or self, which is clearly not accidental"*
- No restriction on the age range or gender of participants.
- Interventions for aggressive behavior had to conform to the principles of a psychological model. For example, Applied Behavioral Analysis, Cognitive-Behavioral Therapy or Stress Inoculation Training.
- Pharmacological interventions were excluded.
- Interventions that used physical restriction were excluded.
- Studies had to follow an experimental design: randomized control trials (RCTs), SCEDs, a nonrandomized controlled design, or an uncontrolled group design (also termed single group design).
- All qualitative case studies, non-experimental case studies, and theoretical papers were excluded. Studies and/or participants within studies had to present sufficient data to allow effect size calculations.
- Studies must use an aggression related outcome measure.
- Group based studies must report both descriptive and inferential statistics. If the required descriptive statistics were not reported, the first name author of the study was contacted to acquire the descriptive data. Two authors were contacted by email to request the required data. Both authors provided the data.
- Single case experimental design studies should use a baseline with at least three time points.

Of the 48 full-text articles, 11 were identified as meeting the eligibility criteria for inclusion in the meta-analysis (see Figure 1 for study selection process). The designs of the selected studies consisted of three single group designs (Aboulafia-Brakha *et al*., 2012; Hart *et al*., 2012; Walker *et al.,* 2010), one Randomized Control Trial (Medd & Tate, 2000) and seven single case experimental designs (SCEDs) (Feeney & Ylvisaker, 2003; Gardner *et al.,* 2003; Alderman & Knight, 1997; Hegel & Ferguson, 2000; Guercio & McMorrow, 2002; Rothwell, LaVigna & Willis, 1999; Aeschleman & Imes, 1999).

---------- **Insert Figure 1 about here**----------

2.3 Study characteristics

Seven single case experimental designs studies (SCED), involving 16 participants, were included in the analysis**.** Medd and Tate's (2000) RCT consisted of 16 participants, with eight participants in each condition (treatment and waiting list control). The three single group designs consisted of 99 participants across the three studies. In total the current meta-analysis included 123 participants that received a psychological intervention for aggressive behavior. The characteristics of each study including the sample, adopted outcome measures, intervention, setting of intervention and quality rating for each study are summarized in *Table 1*.

2.4 Evidence-base practice

A crucial part of informing Evidence-Based Practice (EBP) is appraising not only the statistical results of a study, but also its methodological rigour. The current meta-analysis appraised the included studies using the Evaluative Method by Reichow, Volkmar & Cicchetti, (2008). This method allows the appraisal of both group and signal-case experimental designs, providing a single quality assessment score. The Evaluative Method tool has previously demonstrated good psychometric properties (Reichow *et al.,* 2008; Cicchetti, 2011) and has been shown to be superior when compared with several other quality appraisal tools (Wendt & Miller, 2012). For these reasons, the Evaluative Method was deemed the most appropriate appraisal tool for the current meta-analysis. The Evaluative Method consists of a three-stage process. Firstly, each individual study is appraised for quality guided by Reichow's (2011) primary and secondary indicators (i.e. quality of research design, use of statistical test, experimental control, attrition, treatment fidelity, social validity). Each indicator is then rated as high quality (H), acceptable quality (A) or unacceptable quality (U). Using the scoring criterion outlined by Reichow (2011), the indicators are then synthesized to provide an overall appraisal of quality for each individual

study – strong, adequate or weak (see *Table 1* for individual study results). Finally, the Evaluation Method also provides a formula to determine the overall strength of EBP status across all studies included in the meta-analysis:

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Based on the calculated Z score, three categories of EBP are provided: not an EBP (<30), promising EBP (>30) and established EBP (>60).

2.5 Outcome Measures

2.5.1 Single Case design

Single case experimental designs may be well suited for this particular research question due to the heterogeneity of the ABI population and the idiosyncratic nature of aggressive behavior. All SCED studies included in the current meta-analysis adopted a baseline-intervention (A-B) or multiple baseline (ABAB) design. The dependent variable for all SCED studies was the 'frequency of aggressive behavior' measured by behavioral observations. The topography of aggressive behavior varied across each study and participant. However, through further analysis, aggressive behavior could be separated in to three broad categories: Verbal aggression, Physical Aggression and Property Destruction. All three categories met the before mentioned definition for aggressive behavior.

2.5.2 Single group Designs and Randomized Control Trials

All single group design and RCT studies used psychometric self-report measures to examine aggression (the State–Trait Anger Expression Inventory [STAXI], Buss and Perry Aggression Questionnaire [AQ-12] & Brief Anger-Aggression Questionnaire [BAAQ]). The AQ-12 consists of four subscales that assess *Physical Aggression*, *Verbal Aggression*, *Anger* and *Hostility*. The *Physical* and *Verbal Aggression* subscales characterize the external behavioral components of aggression. In contrast, the *Anger* and *Hostility* subscales represent the internal

emotional and cognitive components of aggression. The AQ-12 has previously demonstrated good reliability and internal consistency. As the Aboulafia-Brakha *et al.* (2012) study consisted of a French speaking population the current meta-analysis used the reliability statistic (0.80) from the French Version of the AQ-12 (Genoud & Zimmermann, 2009) for the statistical analysis.

The STAXI and STAXI-2 also measure both internal and external components of aggression. The STAXI consists of five subscales: (1) *State Anger*, assessing the intensity of anger as an emotional state at a particular time, (2) *Trait Anger*, assessing how often anger feelings are experienced, (3) *Anger Expression-Out*, assessing the expression of anger externally towards others or objects, (4) *Anger Expression-In*, assessing the internalization of anger, and (5) *Anger Control,* assessing the ability to control the experience of anger. Subscales relating to *Anger Control* and *Anger Expression-Out* likely measure the external aspects of anger. *State Anger*, *Trait Anger* and *Anger Expression-In* all relate to the internal aspects of anger. Both the STAXI and STAXI-2 have demonstrated good reliability, with alpha coefficients ranging from 0.81 to 0.93 (STAXI) and 0.82 to 0.90 (STAXI-2) (Etzler, Rohrmann, & Brandt, 2014). The Brief Anger-Aggression Questionnaire (BAAQ) is a 6 item self-report measure examining anger related feelings and behaviors. High scores indicate higher aggressive feelings and behavior. The BAAQ has also demonstrated good test-retest reliability (r = 0.84; Nicholson, Anderson, Fox & Brenner, 2002).

2.6 Data Extraction and Analysis

2.6.1 Single Case Experimental Designs (SCED)

A visual analysis of the graphical data was completed to extract the relevant data for all participants in each SCED study. The extracted data was then inputted into the online application developed by Vannest, Parker, & Gonen (2011) (http://www.singlecaseresearch.org/calculators/tau-u). As SCED data rarely meets parametric assumptions (Parker *et al*. 2011a), a nonparametric statistical analysis was completed to calculate percentage of improvement in aggressive

behavior from the baseline phase. The Tau-U non-overlap effect size (Parker *et al*. 2011a) was chosen as it is considered to be a more comprehensive index of change between baseline and intervention phases (Rispoli *et al.* 2013). Tau-U also accounts for any baseline trend, is not affected by any ceiling or floor effects and is also considered to be a very powerful method of analysis (Parker *et al*. 2011a; 2011b). The Tau-U effect size ranges from 0 to 1, with a Tau-U of 0 indicating 0% improvement and a Tau-U of 1 indicating 100% improvement. Parker & Vannest (2009) have provided tentative guidelines for the interpretation of Tau-U effect sizes: strong effect (0.93 – 1.0), medium effect (0.66 – 0.92) and weak effect (<0.65).

2.6.2 Single Group & Randomized Control Trial designs

Standardized mean differences were calculated for both RCT and single group design studies. Due to the methodological difference between single group and RCT studies, a separate analysis was required to calculate the effect sizes for each design (see *Figure 3 & 4*). The means and standard deviations were extracted from each study. Where the descriptive statistics were not reported in the original paper, the first named author of the study was contacted to provide the required descriptive statistics. The descriptive statistics were then converted into a standardized mean difference (*d*), standardized by the standard deviation of difference scores, to establish the effect of the psychological intervention for aggression in each study. Following Cohen's (1988) conventions, the standardized mean differences can be interpreted as small (*d* = 0.2), moderate (*d* = 0.5) or large (*d* = 0.8).

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The standard deviation of pooled scores (SD_{pooled}) were not reported by Medd & Tate (2000), therefore, the SD of changed scores for each condition were calculated using formula displayed in *Figure 3a*. The reliability coefficient (*r*) for the psychometric measure used in the RCT (STAXI) was acquired using a separate study by Etzler, Rohrmann, & Brandt (2014). Following the calculation

of the effect size (*Figure 3b & 3c*), confidence intervals (95%) were than calculated for each effect size using the standard error (SEd_{adj}) (*Figure 3d & 3e*). The formula used to calculate the effect size for single group design studies differed slightly *(Figure 4).* Similarly, the reliability coefficients for the psychometric measures (STAXI, BAAQ and AQ-12) used for the single group designs studies were not reported. Therefore the analysis used previously established reliability coefficients (Etzler, Rohrmann, & Brandt, 2014; Genoud & Zimmermann, 2009; Nicholson, Anderson, Fox & Brenner, 2002).

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2.6.3 Overall summary effect size

To provide an overall synthesis of the available evidence an overall omnibus effect size was required. Following the calculation of effect sizes for each study, an omnibus effect size, weighted by the inverse of variance, was calculated using the formulas in *Figure 5*.

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3. Results

3.1 Description of studies

3.1.1 Single group studies

Three single group design studies were included in the analysis. The largest of which was Walker *et al.* (2010), which included 52 participants in the pre-post phase of the study. However, 21 participants did not partake in the follow-up phase of the study, leaving a sample of 31 for the final analysis. All participants were based in the community and attended a specialist tertiary rehabilitation service for individuals who have previously suffered a severe TBI. The intervention briefly consisted of weekly two-hours CBT informed psychoeducation session over a twelve-week period. The efficacy of the

intervention was measured using the STAXI. Both Aboulafia-Brakha *et al*. (2012) and Hart *et al*. (2012) used a sample of 10 participants, who were also based in the community and had moderate to severe TBI. One participant in the Aboulafia-Brakha *et al.* (2012) study did not complete the follow-up phase of the study. The intervention used by both Aboulafia-Brakha *et al*. (2012) and Hart *et al.* (2012) also followed a CBT paradigm. Hart *et al.* (2012) termed their intervention as '*Anger Self-Management Training'* (ASMT). This intervention broadly consisted of psychoeducation and skill building relating to self-awareness and self-monitoring. To measure the efficacy of the intervention Aboulafia-Brakha *et al* (2012) used the AQ-12. Hart *et al.* (2012) measured reductions in aggression through the BAAQ and two subscales of the STAXI (Trait Anger & Anger expression-Out). It should be noted that the time since injury and the age of participants was wide ranging within, and across, the three studies (see Table 1).

3.1.2 Randomized Control Trial

To date, only one RCT investigating the impact of psychological interventions for aggressive behavior following ABI has been completed. Medd & Tate (2000) randomly allocated 16 participants to either a treatment group (n=8) or a waiting list control group (n=8). Each participant in the treatment group received six-hourly session of individual anger management therapy. The therapy sessions broadly consisted of psychoeducation regarding brain injury, facilitation of anger awareness and skills training. The STAXI was used as the main outcome measure to examine reductions in aggression following the intervention. The time since post injury differed between the control group (mean = 74 months, SD=117.0) and treatment group (mean = 37.25 months, SD = 47.77). However, this difference was not found to be statistically significant ($p>0.05$).

3.1.3 Single Case Experimental Designs

Seven SCED studies, consisting of sixteen participants, met the inclusion criteria for the meta-analysis. Data that did conclusively meet the definition for

aggressive behavior (e.g. inappropriate sexual comments and swearing) were excluded.

Several methodological differences between SCED and group design studies were apparent. All SCED studies, with the exception of Feeney & Ylvisaker (2003), used samples from a residential setting. In addition, the majority (five out of seven) of SCED studies examined interventions that followed an exclusive behavioral paradigm (Rothwell, LaVigna & Willis, 1999; Alderman & Knight, 1997; Hegel & Ferguson, 2000; Guercio & McMorrow, 2002; Gardner *et al*., 2003). The behavioral interventions used across the SCED studies typically consisted of functional analysis, antecedent management and contingency management. In addition to the behavioral techniques described, Feeney & Ylvisaker (2003) also included a small cognitive element to their intervention in the form of a collaborative "goal-planning routine". Aeschleman & Imes (1999) examined the efficacy of a Stress Inoculation Training Program. This program consisted of approximately 20 sessions focusing on relaxation, self instructional and coping skills training.

A second major difference was the method of outcome measurement. In contrast to the RCT and single group studies, which adopted psychometric measures, the SCED studies used in-vivo observational methods to measure the frequency of an operationally defined aggressive behavior. This allowed for a further analysis of the topography of displayed aggressive behavior across SCED studies. The analysis revealed three broad categories of aggressive behavior: verbal aggression, physical aggression and property destruction. In many cases, the topography of a behavior was not mutually exclusive, with participants displaying more than one type of aggressive behavior.

The age of the sample used across SCED studies should also be noted. The studies consisted of a very wide age range, ranging from young children (6 years) to adults (58 years). Similar to the group design studies, there was a lack of studies examining the maintenance of the intervention at follow-up. Only one

study (Aeschleman & Imes, 1999) collected follow-up data to examine the maintenance effect after the intervention was withdrawn.

---------- Insert Table 1 about here----------

3.2 Meta-analysis

3.2.1 Single group and RCT design studies

The effect sizes and 95% confidence intervals (CI) for all outcomes are summarized in *Table 2*. In line with Cohen's (1988) conventions, two out of three group design studies obtained large effect sizes for both Trait Anger (*d* = -1.07 & -1.57) and Anger Expression-Out (*d* = -0.92 & -2.60) outcomes (Medd & Tate, 2000; Hart *et al.,* 2012). Similarly, Walker *et al.* (2010) measured these constructs but obtained small to moderate effect sizes (Anger Expression-Out, *d* = -0.40 and Trait Anger, *d* = -0.42). Walker *et al.* (2010) also demonstrated non-significant effect sizes for both State Anger (*d* = -0.12, CI, -0.39<>0.15) and Anger Expression-In (*d* = -0.13, CI -0.40<>0.14). When compared to other subscales in the Walker *et al.* (2010) study, both Trait Anger and Anger Expression-Out were shown to have the largest effect. Large and significant effect sizes were demonstrated across all STAXI subscale measures in both Medd & Tate (2000) and Hart *et al.* (2012) studies. In addition, Hart *et al.* (2012) measured anger using the separate outcome measure (BAAQ), which again demonstrated a large and significant effect (*d* = -0.99, CI -1.66<>-0.32). A small and non-significant effect (*d* = 0.30, CI -0.63<>0.03) was observed for general aggression as measured by the AQ-12 (Aboulafia-Braker *et al.,* 2012).

Aboulafia-Braker *et al.* (2012) and Walker *et al.* (2010) measured the maintenance of the interventions following its withdrawal. A small to moderate effect size (*d* = -0.48) was demonstrated by Aboulafia-Braker *et al.* (2012) at follow-up. However, this effect was found to be non-significant (CI -1.15<>0.19). Similarly, Walker *et al.* (2012) found the maintenance effect for Anger Control and State Anger to be small and non-significant. However, a small and significant

effect was observed for Trait Anger (*d* = -0.37, CI -0.72<>-0.01), Anger Expression-In (*d* = -0.37, CI -0.73<>-0.01) and Anger Expression-Out (*d* = -0.37, CI -0.73<>-0.02) at follow-up.

---------- Insert Table 2 about here----------

The summary effect sizes and 95% confidence intervals for each group design study are demonstrated in *Figure 6*. Medd & Tate (2000) demonstrated the largest effect size (*d* = 1.37, CI -2.18<>-0.57) out of all group design studies. The effect size observed in Aboulafia-Braker *et al* (2012) was the only effect found to be non-significant (*d* = -0.48, CI-1.15<>0.19) at post intervention. Overall, the omnibus effect size from all group design studies is suggestive of a significant and moderate effect (*d* = -0.46, CI -0.69<>-0.24) at post intervention. Two studies (Aboulafia-Braker *et al.* 2012; Walker *et al.* 2012) informed the calculation of the omnibus effect size at follow-up. Both studies separately demonstrated non-significant effect sizes. Subsequently, the overall omnibus effect size at follow-up was also observed to be non-significant (*d* = -0.30, CI-0.62 <> 0.01).

---------- Insert Figure 6 about here----------

3.2.2 Single case designs

The Tau-U effect sizes and 95% confidence intervals for each study are provided in *Table 3*. In addition, the results of a separate analysis examining the effect of the interventions for each type of aggressive behavior are also presented in *Table 4*. All studies, with the exception of Aeschleman & Imes (1999), demonstrated significant moderate-to-large effect sizes at the baseline-intervention phase. Aeschleman & Imes (1999) demonstrated a small (Tau-U = -0.10) and non-significant (95% CI -0.34<>0.15) effect size. However, Aeschleman & Imes (1999) were the only study to incorporate a follow up phase, which showed significant small-to-moderate effect sizes at both the baseline-follow up (Tau-U = -0.40, 95%, CI -0.62<>-0.19) and intervention-follow up (Tau-U = -0.32, 95% CI -0.53<>-0.11) phases. This suggests that psychological

intervention may prove to be beneficial in reducing aggressive behaviour over time. The overall summary Tau-U across all participants was -0.59 (95% CI -0.72<>-0.46), indicating a 59% improvement in aggressive behaviour over baseline.

The effects of the psychological interventions appear to be effective across the different topographies of aggressive behaviors. The largest effect was found for those who presented with both property destruction and physical aggression combined (Tau-U = -0.93, 95% CI -1.35<>-0.51). Physical aggression alone also demonstrated a significant and large effect (Tau-U = -0.87, 95% CI -1.11<>-0.63). Moderate effects were found for verbal aggression (Tau-U = -0.62, 95% CI -0.86<>-0.39) and property destruction (Tau-U = -0.71, 95% CI -1.09<>-0.35). A small but significant effect was found for those who presented with both physical and verbal aggression combined (Tau-U = -0.24, 95% CI -0.46<>-0.01).

---------- Insert Table 3 about here----------

---------- Insert Table 4 about here----------

3.2.3 Evidence Based Practice (EBP)

In accordance to Reichow's (2011) EBP criterion, a quality appraisal of the included studies was completed. One group study (Medd & Tate, 2000) and one SCED study (Feeney & Ylvisaker, 2003) met the criteria for "strong". The remaining SCED and group design studies included in the analysis met the "adequate" criteria. No studies were deemed to be "weak". The overall EBP status across studies was established using the previously outlined Reichow's (2011) formula (See *Figure 2*) ([1* 30] + [3* 15] + [1 * 4] + [5 * 2) = 89). Based on Reichow's (2011) conventions, the calculated EBP score ([1* 30] + [3* 15] + [1* 4] + [5 * 2) = 89) indicated that psychological interventions should be considered as an established EBP for aggressive behavior following ABI.

4. Discussion

As highlighted in previous reviews (Ylvisaker, 2006; Cattelani, Zettin & Zoccolotti, 2010), there are limited RCTs examining the efficacy of psychological interventions for aggressive behavior. For this reason, the current meta-analysis aimed to use a novel approach in order to synthesise the available evidence across research designs. The effect sizes from both types of research design appeared to be consistent suggesting significant and substantial reductions in aggressive behavior. These findings are in line with the evidence base for reducing aggressive behavior in other populations such as those with intellectual disabilities (Willner *et al*., 2013), schoolchildren, adolescents, prison inmates, and college students (Beck & Fernandez, 1998). In addition, the findings of the current meta-analysis are supportive of previous meta-analyses, which examined a broad range of challenging behaviours (Heinicke & Carr, 2014; Manolov & Rochat, 2015). The pre-post omnibus effect size across all group design studies was -0.46 (95% CI: -0.69<>-0.24). The effect size for SCEDs was -0.59, indicating a 59% reduction in aggressive behaviour. The slightly larger effect demonstrated by the SCED studies may reflect the nature of the interventions adopted. In contrast to most group design studies, which follow a specific standardised treatment procedure, interventions in the SCED research are typically tailored to the individual through a psychological formulation. This individualised approach would likely take into account the idiosyncratic differences seen across this population, subsequently increasing the efficacy of the intervention. However, this is purely conjecture and further investigation would need to be completed.

It was apparent that particular subscales of the STAXI demonstrated larger effect sizes than others. In particular, '*Anger Expression-Out*' was consistently found to display large effects across group design studies. In contrast, '*Anger Expression-In'* was found to have one of the smallest effect sizes. The *Anger Expression-Out* subscale of the STAXI assesses the expression of anger externally, whereas the *Anger-Expression-In* subscale assesses the internalization of anger. This may

suggests that psychological interventions may be more effective at addressing the externalized aspects of aggressive behavior compared to the internalized features. Further examination of the different constructs of aggressive behavior, and how they respond to psychological interventions, would be of benefit for future research.

The current meta-analysis also examined the long-term maintenance of the interventions following their withdrawal. For group design studies, a small but non-significant effect was found at follow-up (*d* = -0.30, 95% CI: -0.62<>0.01). This suggests that reductions in aggressive behavior may not be maintained over time. The potential clinical implication of this finding might be that 'maintenance' or 'booster' interventions may be indicated to ensure therapeutic gains after anger interventions are maintained in this population. Only one SCED study included a follow up phase in its design. Aeschleman & Imes (1999) found a significant and small effect (Tau-U = -0.40, 95% CI: -0.62<>-0.19). Caution should be taken when interpreting these findings as only two group design studies and one SCED informed the pre-follow up analysis. Further research in this area should examine the maintenance of psychological interventions over time.

There were several limitations to the present study. The majority of the empirical studies available within the current literature examine dependent variables such as emotional wellbeing, employability, QoL and employment. These studies were subsequently excluded from the current meta-analysis as no aggression specific outcome measure was available. This significantly reduced the number of studies used in the current meta-analysis. Future research investigating the efficacy of psychological interventions for aggressive behavior should adopt aggression related outcome measure. As more studies become available, further analyses to separate the efficacy of different type of psychological interventions would be possible. Due to the small number of studies, and therefore limited amount of data, the current meta-analysis was unable to perform such an analysis at this time. The present study included data from participants across a wide age range (6 – 58 years), which may to some extent influence the generalizability of the findings to all populations with ABI.

As with all meta-analyses, another limitation is the possibility of type I publication bias towards research demonstrating positive findings. As highlighted in Zakzanis (2001), there may be a tendency within the scientific population to publish statistically significant findings and abandon non-significant results. This is largely due to the general notion that non-significant results are less publishable when compared to results of statistical significance. Rosenthal (1979) previously acknowledged this issue labeling it the "file drawer problem". This problem can be partly addressed by calculating the number of hypothetical studies needed to confirm the null hypothesis. This has been previously termed as "a fail safe" (Cooper, 1979; Zakzanis, 2001). Orwin (1983) has provided such a formula for this calculation:

---------- Insert Figure 7 about here----------

Employing Orwin's (1983) formula in the current meta-analysis, the estimated number of hypothetical studies supporting the null hypothesis (small and non-significant effect) required to decrease the obtained effect to a negligible effects size (d = 0.2) would be 18. This should also be taken into consideration when interpreting the results of the current meta-analysis. The distinction between a statistically significant effect size and a clinically relevant outcome should also be considered. Although the pre-post omnibus effect size for group design studies was found to be statistically significant, we cannot determine whether the reduction in aggression scores were below the clinical threshold, as defined by the specific psychometric measures (i.e. BAAQ, AQ-12 or the STAXI).

In conclusion, to the authors' knowledge, this is the first meta-analysis to investigate the efficacy of psychological interventions specifically for aggressive behavior following ABI. The current meta-analysis also uses a novel statistical analysis to synthesize the available evidence across all types of quantitative research designs. As a large proportion of evidence in neuropsychological research stems from single case studies, the inclusion of SCED studies within the analysis is considered a particular strength of the current meta-analysis. The

findings of the meta-analysis suggest that psychological interventions for aggressive behavior are at least moderately effective at reducing aggressive behavior following ABI. In addition, the further conceptual analysis of the separate constructs of aggressive behavior (externalized v internalized anger) demonstrated a potential discrepancy in effect. Externalized anger may be more sensitive to psychological intervention in comparison to internalized anger. This observation warrants further exploration in future research.

5. Declaration of Interest

This research paper is submitted in partial fulfillment of the requirements for a Doctorate Degree in Clinical Psychology. Neither author has any personal or financial relationships with other people or organizations that could influence the outcome of the work.

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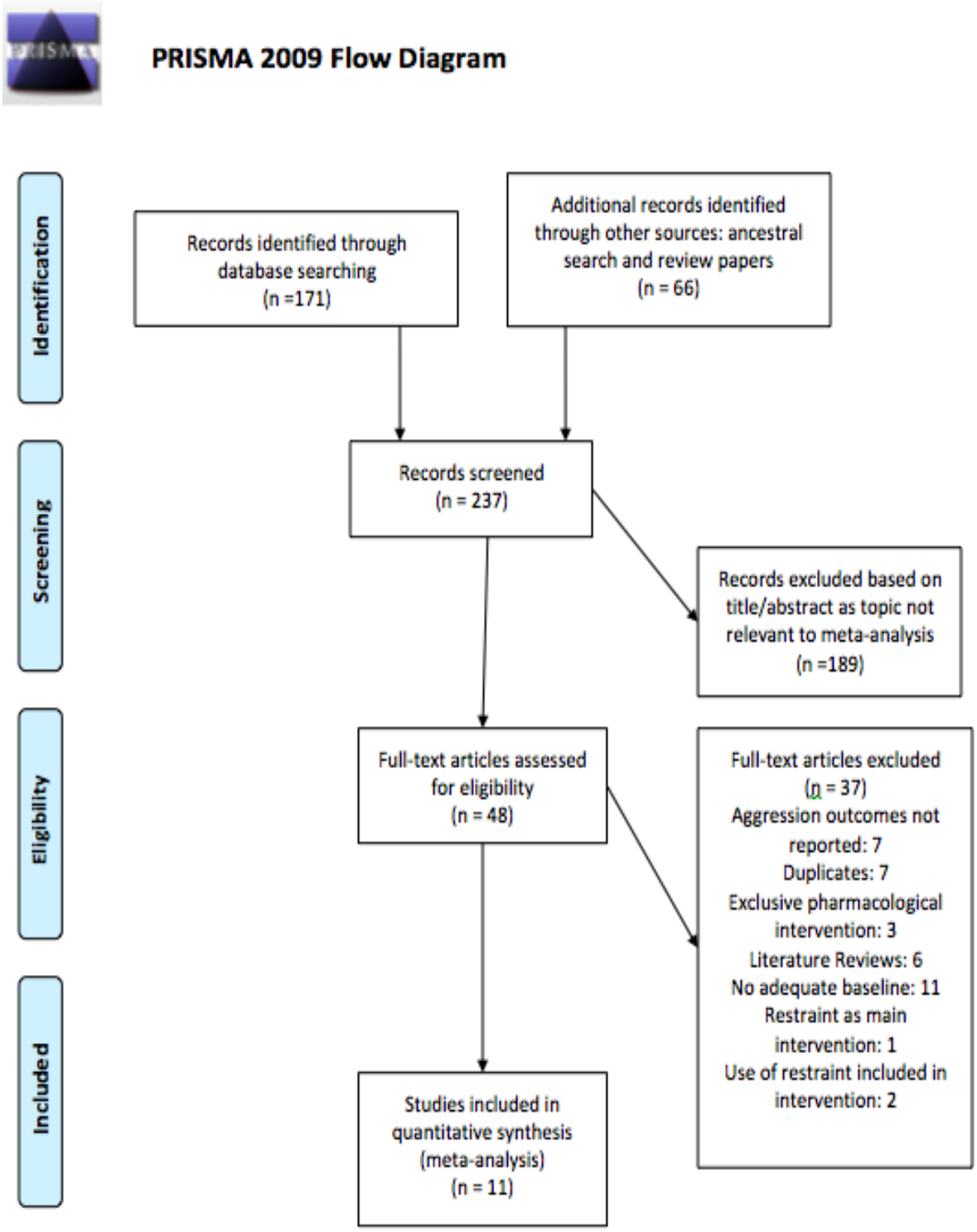

Figure 1. PRISMA (2009) *Flow Diagram For Decision Process For Included Studies*

$$(Group_S * 30) + (Group_A * 15) + (SCED_S * 4) + (SCED_A * 2) = Z$$

$Group_S$ refers to the total number of group studies that met the strong criteria. $Group_A$ refers to the total number of group studies that met the adequate criteria. $SCED_S$ refers to the total number of SCED studies that met the adequate criteria. $SCED_A$ refers to the total number of SCED studies that met the strong criteria

Figure 2. *Reichow's (2011) Evidence Based Practice Formula*

a) $$SD_{tr.change} = \sqrt{SD^2_{tr.pre} + SD^2_{tr.post} - \left(2 * r * SD_{tr.pre} * SD_{tr.post}\right)}$$

b) $$SD_{pooled} = \sqrt{\frac{(n_1 - 1)SD_1^2 + (n_2 - 1)SD_2^2}{(n_1 + n_2) - 2}}$$

c) $$d_{adjusted} = \frac{M_{treatment\ (post-pre)} - M_{comparison\ (post-pre)}}{Sd_{pooled\ of\ change\ scores}}$$

d) $$SE_{d_{adj}} = \sqrt{\frac{(n_1 + n_2)(1 - r^2)}{n_1 n_2} + \frac{d^2}{2(n_1 + n_2)}}$$

e) $$95\%CI = ES \pm 1.96\ se$$

Figure 3. *Effect Size Formula (Cohen's d) for studies consisting of two groups*

a) $$SD_{tr.change} = \sqrt{SD^2_{tr.pre} + SD^2_{tr.post} - (2 * r * SD_{tr.pre} * SD_{tr.post})}$$

b) $$d = \frac{M_{post} - M_{pre}}{SD_{difference}} \sqrt{2(1-r)}$$

c) $$SE_{d_t} = \sqrt{\frac{1}{n} + \frac{d^2}{2n}\, 2(1-r)}$$

d) $$95\%CI = ES \pm 1.96\, se$$

Figure 4. *Effect Size Formula for single group design studies*

a) $$weight_i = \frac{1}{variance_i} = \frac{1}{SE_i^2}$$

b) $$\overline{ES} = \frac{\sum(weight_i ES_i)}{\sum weight_i}$$

c) $$SE_{\overline{ES_w}} = \sqrt{\frac{1}{\sum weight_i}}$$

d) $$95\%CI = ES \pm 1.96\, se$$

Figure 5. *Summary effect size formula*

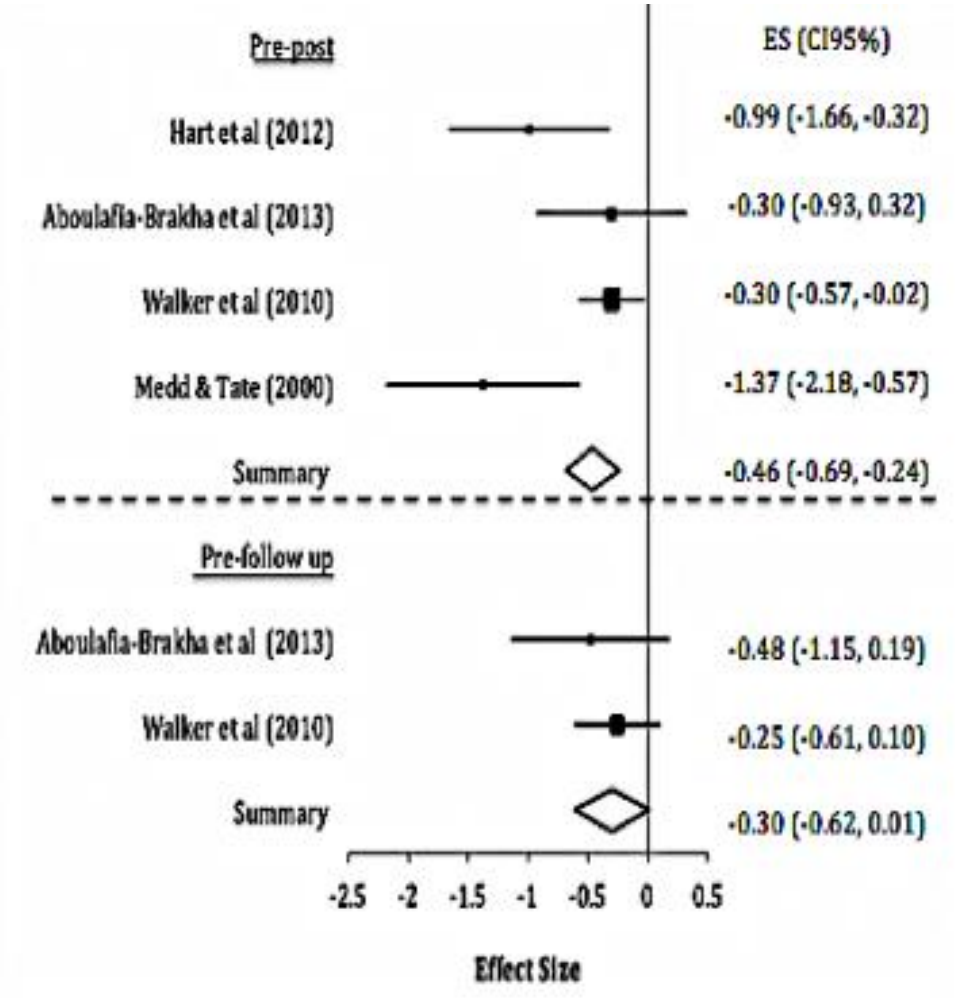

Figure 6. *Forest Plot demonstrating effect size and 95% confidence intervals*

$$N_{fs} = \frac{N(d - d_c)}{d_c}$$

N_{fs} = number of hypothetical studies needed to reverse the conclusion of the meta-analysis, N = the number of studies included in the meta-analysis, d = the average effect size for the meta-analysis, and d_c = the criterion value (Cohen's convention of d = 0.2)

Figure 7. *Orwin's (1983) Fail-safe N formula*

Table 1. Characteristics of studies included within the current meta-analysis

Author/Year	Design	N (pre)	N (post)	Follow-up	Age (sex)	Time since injury	Gender	Measured Outcome	Summary of Intervention	Findings	Setting	Quality rating (Reichow et al., 2008)*
Feeney & Ylvisaker (2003)	Single Case Design	2	2	0	6 & 7 years	TBI 1 & 2 years	1m, 1f	Frequency of operationally defined aggressive outbursts.	A multicomponent behavioral and cognitive intervention for improving the behavioral self-regulation.	Targeted aggressive behaviours were reduced to near zero with decreased intensity. Long-term beneficial outcomes were also maintained.	Community (educational setting)	S
Gardner et al (2003)	Single Case design	2	2	0	12 & 13 years	Unknown – 6 years	2m	Frequency of operationally defined aggressive behaviour.	The intervention included; functional analysis, functional communication training, antecedent management and contingency management.	The targeted aggressive behaviours were reduced to zero in both participants. In addition, domains of activity increased and self-management improved even as supports were systematically withdrawn.	Residential	A
Alderman & Knight (1997)	Single Case Design	3	3	0	58, 35 & 33	2, 3 & 7 years	2m, 1f	Frequency of verbally aggressive behaviour. The frequency of throwing behaviours was also measured in one of the participants	Differential reinforcement of low rates of aggressive behaviour (DROL), Differential reinforcement of other behaviours (DRO) & Differential reinforcement of incompatible	Target behaviours significantly reduced. An increase In independence was also demonstrated. The reduction in target behaviours were also maintained at	Residential	A

									behaviour (DRI).	follow-up		
Hegel & Ferguson (2000)	Single Case Design	1	1	0	28	10 years	1m	Frequency of operationally defined aggressive behaviour.	Differential reinforcement of other behaviour (DRO).	Differential reinforcement of more adaptive behaviours successfully reduced the frequency of aggressive behaviours by up to 74%. The Reductions in aggressive behaviour was also maintained at one-month follow-up.	Residential	A
Guercio & McMorrow (2002)	Single Case Design	1	1	0	20	Not stated	1m	Frequency of operationally defined target behaviours: physical aggression and property destruction.	Positive behaviour interventions and antecedent control.	The targeted aggressive behaviours (physical aggression and property destruction) were reduced to zero towards the end of the intervention. No follow-up data was collected.	Residential	A
Rothwell, LaVigna & Willis (1999)	Single Case Design	2	2	0	33 & 42	Not stated	1m, 1f	Frequency of target behaviours: physical aggression and verbal aggression.	A five component behavioural intervention: (1) functional analysis, (2) skill training (3) ecological changes, (4) focused treatment (using behavioural contingencies [DRO] for target behaviour) & (5) reactive	In both cases, aggressive behaviour reduced to zero towards the end of the intervention. No data was provided to suggest that reductions were maintained at follow-up.	Residential	A

								strategies (employing consistent reactive strategies)				
Aeschleman & Imes (1999)	Single Case Design (Multiple Baseline)	5	5	5	20, 24, 27, 30 & 29 years	16 months to 12 years	5m	Overall frequency of several aggressive impulse behaviours: Verbal, gestural, physical and other.	Stress inoculation training program consisting of relaxation, self instructional training, and coping skills training	Across all five participants a small, but consistent, reduction in aggressive impulse behaviours was demonstrated.	Residential setting	A
Aboulafia-Brakha, Greber-Buschbeck, Rochat & Annoni (2012)	Single Group Design	10	9	9	Mean = 47 years (range = 24 – 58)	27.5 (16–166) months	8m, 2f	Buss and Perry Aggression Questionnaire (AQ-12) (Buss & Perry, 1992).	A cognitive-behavioural group programme focusing on anger and aggressiveness.	A significant reduction in AQ-12 scores at T3, when compared to T1, was demonstrated. This reduction was found to have a large effect size.	Community	A
Medd & Tate (2000)	RCT	28	16	0	Mean 35.88 (S.D.= 12.40)		14m, 2m	Scores on the STAXI (Spielberger, 1988).were used as the main dependent variables.	The intervention consisted of five-to-eight weekly individual sessions using a cognitive behavioural informed approach.	A significant decrease anger, as measured by the STAXI, was found for the treatment group when compared to the control group at post-treatment.	Community	S
Walker et al (2010)	Single group design	52	52	31	Mean 32.3 (S.D. 11.3)	4.1 years (mean)	40m 12f	Scores on the STAXI (Spielberger, 1988) were used as the main dependent variables.	The intervention consisted of 12 weekly CBT informed group sessions. Modifications were made to account for TBI-related cognitive impairment.	Significant reductions were demonstrated in frequency of self-reported anger and frequency of anger expression (Anger Expression-Out). A significant increase in	Community	A

										attempts to control feelings of anger (Anger Control) was also demonstrated. These beneficial changes were maintained at follow-up.		
Hart et al (2012)	Single group design	10	10	0	Mean 43.3 (range 23 – 59)	6 months to 20 years	8m, 2f	Self-reported anger was measured pre and post treatment using selected scales from STAXI-2 and BAAQ.	A manualised, one-on-one psychoeducational intervention called Anger Self-Management Training (ASMT) .	Significant improvements were demonstrated on all dependent variables. Authors concluded that the ASMT treatment model warranted further investigation in relation to efficacy.	Community	A

*** The quality appraisal of included studies was based on Reichow *et al.,* (2008) evaluation method. Three categories of quality is provided: weak (W), Adequate (A) and Strong (S).**

Table 2. *Effect sizes and 95% confidence intervals (CI) for all outcomes across group design studies*

Study	Design	Outcome	Pre-post Effect Size (d)	95% Confidence Intervals	Pre-Follow-up Effect Size	95% Confidence Intervals
Aboulafia-Brakha et al (2012)	Single Group	General aggression	d=-0.30	-0.63 <> 0.03	d=-0.48	-1.15<>0.19
Medd & Tate (2000)	RCT	Trait Anger	d = -1.57	-2.28 <> -0.73	-	-
		Anger Expression-In	d = -1.26	-1.98 <> -0.54	-	-
		Anger Expression-Out	d= -2.60	-3.67 <> -1.53	-	-
		Anger Control	d = 0.91	0.26 <> 1.57	-	-
		Summary	**d = -1.37**	**-2.18<>-0.57**	**-**	**-**
Walker et al (2010)	Single Group	State Anger	d = -0.12	-0.39<>0.15	d = 0.17	-0.18<>0.52
		Trait Anger	d = -0.42	-0.70<>-0.14	d = -0.37	-0.72<>-0.01
		Anger Expression-In	d = -0.13	-0.40<>0.14	d = -0.37	-0.73<>-0.01
		Anger Expression-Out	d = -0.40	-0.68<>-0.12	d = -0.37	-0.73<>-0.02
		Anger Control	d = 0.43	0.16<>0.71	d = 0.33	-0.02<>0.69
		Summary	**d = -0.30**	**-0.57<>-0.02**	**d = -1.37**	**-2.18<>-0.57**
Hart et al (2012)	Single group	Trait Anger	d = -1.07	-1.76<>-0.39	-	-
		Anger Expression-Out	d = -0.92	-1.59<>-0.26	-	-
		BAAQ	d = -0.98	-1.64<>-0.31	-	-
		Summary	**d = -0.99**	**-1.66<>-0.32**	**-**	**-**

Table 3. *The Tau-U effect sizes and 95% confidence intervals for SCED studies*

Study	Baseline - Intervention			Baseline – Follow up*			Intervention – Follow up*		
	n	Effect Size (TAU-U)	Confidence Intervals (95%)	n	Effect Size (TAU-U)	Confidence Intervals (95%)	n	Effect Size (TAU-U)	Confidence Intervals (95%
Alderman & Knight (1997)	4	-0.61	-0.83<>-0.39	-	-	-	-	-	--
Rothwell, LaVigna & Willis (1999)	3	-0.88	-1.22<>-0.55	-	-	-	-	-	-
Aeschleman & Imes (1999)	5	-0.10	-0.34<>0.15	5	-0.40	-0.62<>-0.19	5	-0.32	-0.53<>-0.11
Hegel & Ferguson (2000)	1	-1.00	-1.49<>-0.50	-	-	-	-	-	-
Guercio & McMorrow (2002)	1	-0.72	-1.09<>-0.36	-	-	-	-	-	-
Feeney & Ylvisaker (2003)	2	-1.00	-1.42<>-0.57	-	-	-	-	-	-
Gardner et al (2003)	2	-0.93	-1.35<>-0.57	-	-	-	-	-	-
Summary weighted Tau-U across participants	16	-0.59	-0.72<> -0.46	5*	-0.40	-0.62<>-0.19	5*	-0.32	-0.53<>-0.11

* *'Baseline - Follow up' and 'Intervention – Follow up' data was solely provided by Aeschleman & Imes (1999*)

Table 4. *The Tau-U effect sizes and 95% confidence intervals for each topography of aggressive behaviour.*

Outcome	Baseline - Intervention			Baseline – Follow up*			Intervention – Follow up*		
	n	Effect Size (TAU-U)	Confidence Intervals (95% 0	n	Effect Size (TAU-U)	Confidence Intervals (95% 0	n	Effect Size (TAU-U)	Confidence Intervals (95% 0
Physical Aggression	6	-0.87	-1.11<>-0.63	-	-	-	-	-	--
Verbal Aggression	4	-0.62	-0.86<>-0.39	-	-	-	-	-	-
Physical and Verbal Aggression	6	-0.24	-0.46<>-0.01	5*	-0.40	-0.62<>-0.19	5*	-0.32	-0.53<>-0.11
Property Destruction	1	-0.71	-1.09<>-0.35	-	-	-	-	-	-
Property Destruction and Physical aggression	2	-0.93	-1.35< >-0.51	-	-	-	-	-	-

**'Baseline - Follow up' and 'Intervention – Follow up' data was solely provided by Aeschleman & Imes (1999)*

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Chapter 2 – Empirical Paper

Investigating the Discrepancy Between Subjective and Objective Cognitive Impairment In Acquired Brain Injury: The Role of Psychological Affect

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Investigating the Discrepancy Between Subjective and Objective Cognitive Impairment In Acquired Brain Injury: The Role of Psychological Affect

Abstract

The current study aimed to examine the potential discrepancy between subjective and objective cognitive impairment in a sample individuals with an acquired brain injury (ABI). Twenty-four participants, recruited from a community brain injury service, completed an objective neuropsychological assessment and a series of psychometric questionnaires assessing psychological affect and perceived cognitive difficulties. Correlational analyses revealed no association between objective cognitive impairment and self reported subjective cognitive impairment. Conversely, psychological affect, such as anxiety and depression, was found to be highly correlated with subjective cognitive impairment. A hierarchical regression analysis revealed psychological affect as a significant predictor of subjective cognitive impairment. Objectively measured cognitive impairment was found to be non-significant. These findings suggest that an individual's subjective experience of their cognitive difficulties following ABI are not associated with their actual objective cognitive impairment. Clinicians may benefit from considering other possible psychological factors that may play a more crucial role in a patient's appraisals of their cognitive impairments.

Keywords: Cognitive Impairment, Psychological affect, Subjective Impairment, Neuropsychological Rehabilitation, Cognitive Discrepancy

Introduction

Difficulties with mood and anxiety are a common experience for individuals following an Acquired Brain Injury (ABI) (Gracey, 2002). Prevalence rates reaching 61% have been demonstrated for depression (Kim *et al.* 2007), and up to 70% for anxiety (Rao & Lyketsos, 2002). In addition to negative affect, impairments in cognitive functioning are also a frequently reported and challenging difficulty for those with ABI (Whyte *et al.* 2011).

Whilst Magnetic Resonance Imaging (MRI) can reveal potential structural issues within the brain, it cannot provide more in-depth knowledge of cognitive functioning. For these data, we rely upon subjective and objective methods of neuropsychological assessments to investigate the extent and nature of the cognitive impairment. Due to time constraints, and the practical requirements of objective neuropsychological testing, it is often an individuals' subjective self-report of their cognitive impairment that is used to screen for further assessment or treatment decisions. However, previous research examining the use of self-report as a reliable predictor of actual objective cognitive impairment (OCI) has provided mixed results. Longitudinal studies by Hohman, Beason-Held, Lamar & Resnick (2011) and Dufouil, Fuhrer, & Alperovitch, (2005) have offered support for the validity of subjectively reported cognitive impairment (SCI) as a reliable indicator of OCI in both clinical and non-clinical populations. However, significant discrepancies between SCI and OCI have been demonstrated in various populations, including those with; multiple sclerosis (Middleton, Denney, Lynch & Parmenter, 2006), schizophrenia (Homayoun, Nadeau-Marcotte, Luck, & Stip, 2011), insomnia (Orff, Drummond, Nowakowski, & Perils, 2007) and gulf war veterans (Spencer, Drag, Walker, & Bieliaskas, 2010). This suggests that factors other than OCI play a mediating role in the occurrence of SCI.

It is generally recognised that psychological factors play an influential role in behavioural outcomes following ABI (Warriner & Velikonja, 2006). Subsequently, it is not unreasonable to suggest that psychological factors may play a mediating role in the level of reported SCI. Empirical evidence has

demonstrated that a large proportion of variance in broader post-ABI cognitive symptoms (i.e. poor concentration, forgetfulness, insomnia, decreased coordination) have been accounted for by factors other than actual injury severity (Stulemeijer, Vos, Bleijenberg & Van der Werf, 2007; Trahan, Ross & Trahan, 2001). Trahan, Ross & Trahan (2001) found a strong positive correlation (r= 0.68) between scores on measures of SCI and the Beck Depression Inventory (BDI-II). A significant positive correlation (r= 0.64) was also demonstrated between SCI and anxiety. Spencer *et al*. (2010) provided further support, finding positive correlations between SCI and psychological affect in a sample of Gulf War veterans with traumatic brain injury (TBI). Furthermore, an additional post hoc analysis revealed that anxiety, above several other psychological symptoms (such as post traumatic stress disorder and depression), to be the main mediating variable predicting SCI. More recently, French, Lange & Brickell (2014) replicated the strong associations between SCI and psychological affect seen in previous studies. However, an additional analysis investigating the relationship between SCI and performance on objective neuropsychological assessment revealed no significant correlation. These findings suggest that psychological factors may play a more principal role in SCI, than the actual objective impairment itself. However, it should be noted that both Spencer *et al.* (2010) and French, Lange & Brickall (2014) used samples from a military population, adding to the many confounding variables that are already present in such a heterogeneous population. It was highlighted that factors such as litigation and the prospect of medical discharge should be considered when interpreting these results. Therefore, further studies from non-military populations may prove beneficial in generalising the above findings to civilian clinical settings. Empirical evidence from non-military populations are now becoming more established. Lamb *et al.* (2013) recently examined the impact of negative affect, fatigue and OCI as potential predictors of SCI in 25 older adults following ischemic stroke. The overall statistical model, which included all three predictor variables (depression, fatigue and OCI), accounted for 61% of the total variance of SCI. However, depression was the only variable found to significantly predict SCI.

Investigating potential psychological factors that play an influential role in SCI may help to provide clinicians with a broader knowledge and understanding to address the underlying processes mediating high SCI in the absence of OCI. Identification of these key factors may be beneficial at both the screening and rehabilitation stage of a patient's care. For instance, should anxiety play a significant role in SCI, clinicians may work within a more evidenced-based psychological paradigm (e.g. CBT) to reduce anxiety, which may in turn reduce SCI, as opposed to using cognitive rehabilitation strategies in the first instance. The aim of the current study is to examine the potential discrepancy between SCI and OCI, and to determine what role psychological factors play in SCI.

Method

Participants

The participant sample consisted of 24 individuals with various aetiologies of ABI. All participants were aged between 36 and 72 years and were receiving ongoing support from a National Health Service community brain injury service based in a rural part of the United Kingdom. All participants were referred to the service due to cognitive, emotional or physical difficulties as a result of their ABI. The date of injury ranged from 8 months to 17 years. Further demographic information is outlined in *Table 1*.

----------Insert table 1----------

Diagnoses of ABI were confirmed through clinical imaging (e.g. MRI or computerized tomography) and neurological examination. The nature and severity of the ABI was determined in accordance with Malec *et al.* (2007) through retrospective examination of medical notes, which included scan reports, Glasgow Coma Scale (GCS) scores, Post-Traumatic Amnesia (PTA) and period of loss of consciousness where available. The nature of the injuries can be separated into three categories: 'Traumatic Brain Injury (TBI)', 'Cerebral

Vascular Accident (CVA)' and 'Other'. Participants with TBI could be further separated into three classifications of TBI: Mild (n = 1), Moderate (n = 1) and severe (n = 9). A third aetiological category was developed (Other), as the nature of injury for two participants did not meet criteria for TBI or CVA: one participant acquired their brain injury through infection, and the other through a brain tumor.

In order to control for confounding variables exclusion criteria were employed. Participants were excluded from the study if they had ongoing difficulties with drug and alcohol abuse, a co-morbid neurodegenerative disease or a previous diagnosis of intellectual disability.

Measures

Objective Measure of Cognitive Impairment

Objective cognitive impairment was measured using the Repeatable Battery for the Assessment of Neuropsychological Status (RBANS; Randolph, 1998). Although originally developed for the neuropsychological assessment of dementia in older adults, the RBANS has shown internal validity, ecological validity and test-retest reliability for the assessment of cognitive impairment in those with TBI (McKay, Casey, Wertheimer & Fichtenberg, 2007), CVA (Larson *et al.* 2005) and Concussion (Moser & Schatz, 2002). The RBANS comprises of 12 subtests, providing a composite score for 5 cognitive domains: Immediate Memory, Visuospatial/Constructional, Language, Attention and Delayed memory. A total scale score is also provided, which provides a general measure of cognitive functioning. Comparable to the WAIS-IV, scores on the RBANS can be translated into standardised scores with a mean of 100 and a standard deviation of 15. Subsequently, standardised scale scores of 70 or below would imply a "borderline to low range" performance equal to, or lower than, the second percentile of age matched peers.

Measure of subjective cognitive impairment

The Cognitive Failures Questionnaire (CFQ; Broadbent *et al*., 1982) was used as a psychometric measure of SCI. The CFQ is a 25-item psychometric questionnaire examining self-reported everyday lapses in cognitive functioning (e.g. Do you forget where you put something like a newspaper or a book?). The CFQ has demonstrated excellent reliability and internal consistency (Cronbach's α = 0.90; Bruce, Ray & Carlson, 2007). The CFQ was initially developed to provide a general SCI score, however, recent factor analyses have revealed multiple subscales: Attention, Memory and Motor Function (Payne, & Schnapp, 2014). Items are rated on a five-point Likert scale ranging from 0 (never) to 4 (very often). Total CFQ scores range from 0 to 100, with higher scores reflecting higher levels of SCI.

Measures of Psychological Affect

The Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983) was used as a measure of depression and anxiety. The HADS is a 14-item psychometric scale with 7 items relating to both anxiety and depression. Items are rated on a 4-point Likert Scale, with higher scores reflecting higher levels of depression and anxiety. Subscale scores between 0 – 7 are considered to be 'normal', 8 – 10 'borderline', and 11 – 21 are within the 'abnormal/clinical' range. The HADS has been found to be a valid and reliable scale for the psychometric assessment of anxiety (Cronbach's α from .68 to.93, mean α=.83) and depression (Cronbach's α from .67 to.90, mean α=.82) in a variety of populations (Bjelland, Dahl, Haug & Neckelmann, 2002), including ABI (Whelan-Goodinson, Ponsford, & Schönberger, 2009).

In addition to a general measure of anxiety, a specific measure of health anxiety was used to examine whether health anxiety symptoms have a lesser or greater effect on SCI. The Health Anxiety Inventory (HAI-18; Salkovskis, Rimes, Warwick, & Clark, 2002) was used to measure levels of health anxiety. The HAI-

18 is an 18-item psychometric questionnaire, which measures cognitive factors associated with health anxiety (Salkovskis *et al*. 2002). Items on the HAI-18 are rated on a 4-point Likert Scale with higher scores reflecting higher levels of health anxiety. Previous literature has found mean scores of 37.9 (±6.8) to reflect populations with clinical levels of health anxiety (Salkovskis *et al*. 2002). The HAI-18 has been shown to be a valid and reliable scale (r = 0.90) for the assessment of health anxiety (Salkovskis *et al*. 2002), independent of physical health status (Abramowitz, Deacon & Valentiner, 2007).

Procedure

Ethical approval was sought from the National Health Service Research Ethics Committee (NHS REC) and The School of Psychology, at Bangor University. Following ethical approval, potential participants who met the inclusion criteria were identified and approached by their lead clinician within the community brain injury service to determine their potential interest in participating in the current study. Following an expression of interest, the principal researcher contacted the participant to arrange a suitable time and date to complete the psychometric questionnaires and neuropsychological assessment. All participants who agreed to partake in the study provided written and verbal consent. The neuropsychological assessment was completed in clinic rooms local to the participant or in their own home. To control for potential confounding environmental factors, the administration of the assessment was completed in a quiet environment with little distractions. The duration of the assessment ranged between 60 to 90 minutes. All participants were then debriefed following the completion of the psychometrics and neuropsychological assessment.

Statistical Analysis

The statistical software package IBM SPSS version 22 (IBM Corp, 2012) was used to perform the statistical analyses. A Shapiro-Wilks test of normality was initially completed to further examine if the data met parametric assumptions. As the

data appeared to be normally distributed (p>0.05) a logarithmic transformation of variable data was not required. An independent samples t-test was initially completed to test for any statistically significant differences between the CVA and TBI aetiology groups on measures of anxiety, depression, SCI and OCI. As the third group ('Other') consisted of only two participants, it was not deemed meaningful to complete an ANOVA to examine differences between all three groups.

A second analysis, using Pearson's correlation coefficients, was completed to examine potential relationships between OCI, SCI and psychological variables. As there was no significant difference between CVA and TBI groups, the correlational analysis was completed for the whole participant sample (n=24). Following examination of the correlation coefficients, a 'post hoc' analysis using Stieger's (1980) equations was completed to determine whether the correlation between SCI and anxiety was significantly larger than the correlation between SCI and depression.

Finally, a three stage hierarchical regression analysis, with SCI as the dependent variable, was completed in order to identify the main predictors of SCI. Demographic variables were entered at stage one (Model 1) of the regression in order to control for demographic factors such as age, type of injury, educational history, gender and time since injury. Objective impairment, as measured by total RBANS score, was entered at stage two (model 2). Psychological factors such as health anxiety, anxiety and depression were entered at stage three of the model (model 3).

Results

The mean score for depression and anxiety measures lay within the 'normal' to 'borderline' range. However, five participants within the sample possessed scores that met the clinical threshold for depression. Eight participants also reached clinical ranges for anxiety. All health anxiety scores fell below the

clinical threshold (Salkovskis *et al*. 2002). An independent samples *t*-test revealed no statistically significant differences ($p < 0.05$) between CVA and TBI groups across all measures of cognitive impairment (SCI and OCI) and psychological factors (Health Anxiety, Anxiety and Depression). The descriptive and inferential statistics for all measures are outlined in *Table 2.*

----------Insert Table 2 ----------

As expected, the RBANS subtests (Immediate Memory, Attention and Delayed Memory) were all reciprocally correlated (r= .48 to .79, p<0.05). This is likely due to the high internal consistency of the neuropsychological assessment (McKay *et al.,* 2007). Similarly, CFQ subscales measuring SCI in Attention, Memory and Motor function were also highly correlated (r= .83 to .96, p<0.05). However, no statistically significant relationship between CFQ subscales and RBANS subtest scores (r= .01 to .28, p>0.05) were revealed. In addition, the relationship between the 'RBANS Total score' and 'CFQ Total score' was found to be non-significant (r_{22} = -.096, p = .656), suggesting little to no association between objective and subjective cognitive impairment. The results of the correlational analysis are summarized in *Table 3*.

----------Insert Table 3 ----------

Psychological factors

The correlation analysis indicated that participants who reported higher levels of anxiety and depression demonstrated higher levels of SCI (see *figure 1 & 2*). Large positive correlations were found between scores on the HADS Anxiety Scale and all CFQ measures: CFQ total score (r_{22}= .821, p<.000), CFQ Memory (r_{22}= .810, p<.000), CFQ Attention (r_{22}= .749, p<000), and CFQ Motor Function, (r_{22}= .832, p<000). Likewise, scores on the HADS Depression scale significantly correlated with total CFQ scores, (r_{22}= .505, p= .012), CFQ Attention subtest, (r_{22}= .518, p= .010), CFQ Motor function subtest (r_{22}= .509, p= .011), and RBANS Immediate memory score (r_{22}= .457, p= .025). A strong positive correlation was

found between health anxiety and depression (r_{22}= .600, p= .002). No other significant correlations were demonstrated between psychological variables. Health Anxiety, as measured by the HAI-18, did not show any statistically significant correlation with measures of SCI and OCI.

----------Insert Figure 1 and Figure 2 ----------

The strength of the correlation between anxiety and SCI (r_{22}= .821) was notably larger than the correlation between depression and SCI (r_{22}= .505). A post hoc analysis, using Stieger's (1980) equations, revealed that the observed difference between the two correlations was statistically significant (z=2.17, p=0.016).

Hierarchical regression analysis

The regression analysis revealed that demographic variables did not significantly contribution to the regression model ($F_{(6,17)}$ = .933, p= .497), accounting for only 1.8% of the variance in SCI. Furthermore, the introduction of OCI at stage 2 (model 2) was also shown to be non-significant ($F_{(7,16)}$ = .767, p= .622), explaining 7.6% of variation in SCI. However, the introduction of psychological variables at stage three (model 3) were found to significantly increase the variance of the model to 81% ($F_{(10,13)}$ = 10.55, p= .000). Further examination of the psychological variables revealed that anxiety ($t_{(23)}$=5.24, p<.000) was the most significant predictor of SCI, followed by depression ($t_{(23)}$=3.78, p= .002). Health anxiety was found to be non-significant ($t_{(23)}$=-1.95, p=.074).

----------Insert Table 4 ----------

Discussion

The primary aim of the current study was to examine the potential discrepancy between SCI and OCI, and to determine the extent psychological factors may play in the presence of SCI following ABI. Initially, as the sample consisted of a

mixture of ABI aetiologies, an analysis to examine for differences between aetiology types was completed. The rationale for this analysis stems from previous literature highlighting the potential differences in cognitive profile for those with TBI and CVA (Tateno, Murata & Robertson, 2002). In contrast to previous findings, the current study did not reveal any differences between CVA and TBI aetiology on measures of OCI, SCI or measures of psychological affect. Due the small sample size, the lack of significant differences between CVA and TBI groups may be a result of a type II error, therefore caution should be taken when interpreting this finding.

With the exception of Health Anxiety and Depression, no other correlations between psychological factors were found to be significant. This finding is inconsistent with previous literature (Bjelland, *et al*., 2002), which has demonstrated large correlations between the two HADS subscales (HADS-A and HADS-D, r = 0.80). Similarly, there was a small and non-significant correlation between the HAI and HADS-A subscale. The lack of correlations between psychological factors may again be attributed to a type-II error. However, the content of the HAI and the HADS are intrinsically different, which may also explain the lack of correlation between the two measures. The HAI predominately focuses on somatic symptoms related to health, whereas the HADS predominately focuses on general anxiety symptoms.

The use of the RBANS to measure OCI allowed the assessment of specific cognitive domains (immediate memory, delayed memory, attention) in addition to 'total cognitive impairment' (total RBANS score). Similarly, as previous factor analyses (Payne, & Schnapp, 2014) of the CFQ have revealed specific SCI domains, the current study was able to measure specific self-reported impairments in attention, motor function and memory. Further analysis of the relationship between specific OCI and SCI domains revealed no significant interaction. Therefore, specific self reported complaints in memory and attention did not correspond with objective measurement of these cognitive domains. Equally, overall SCI, as measured by the total CFQ score, demonstrated no association with total OCI (r = -.096). These finding are in line with previous

research that have observed similar discrepancies between OCI and SCI in those with multiple sclerosis (Middleton, Denney, Lynch & Parmenter, 2006), schizophrenia (Homayoun, Nadeau-Marcotte, Luck, & Stip, 2011), and gulf war veterans with TBI (Spencer, Drag, Walker, & Bieliaskas, 2010).

Conversely, measures of psychological affect were found to significantly correlate with SCI. Depression demonstrated large positive correlations with two out of three SCI domains (attention and motor function), in addition to total SCI. The key finding was that anxiety demonstrated the largest correlation across all SCI domains; the most notable being between anxiety and total SCI (r= .821). Subsequently, individuals with higher levels of anxiety are likely to report higher rates of SCI. The post hoc analysis revealed that the correlation between anxiety and SCI was significantly larger that the correlation between depression and SCI. This suggests that anxiety may play a more crucial role in SCI when compared to other psychological affect such as depression. This suggestion was further supported by the results of the hierarchical regression analysis. The regression analysis allowed the identification of key psychological variables that contribute to the prediction of SCI after the variance of OCI and demographic factors have been controlled (i.e. entered in to the preceding steps). At the first step of the model, demographic factors such as time since injury, age, gender and years of education were found to be non-significant in the prediction of SCI. Similarly, the inclusion of OCI at the second step was also found to be non-significant. However, the inclusion of the psychological variables at the third step of the hierarchy was found to make a significant contribution to the model. Further examination of the model revealed anxiety to be the main variable of interest in the prediction SCI, followed by depression. Health anxiety did not significantly contribute to the model suggesting that general anxiety symptoms, rather than a specific health anxiety, are more relevant for this population.

The results of the current study are consistent with the emerging ABI evidence base, which have also found discrepancies between OCI and SCI (Spencer *et al*., 2010; Lamb *et al.,* 2013). However, it should be noted that the findings from Lamb *et al.* (2013) somewhat differ from the current study. Lamb *et al.* (2013)

found depression to be the main psychological variable to play a contributing role in the prediction of SCI. This incongruence between findings may be due to the small sample sizes used in both studies. The modest sample size in the current study may have impeded the detection of all but the largest associations between variables (Type II error). Furthermore, it should be noted that the current study's sample did not reach the recommended minimum sample size of 42, as indicated by the power analysis (parameters: ß=0.80, alpha = 0.05, anticipated effect = 0.6). Further research using larger sample sizes may prove to be beneficial by offering more clarity on the key psychological factors, and provide more power to detect weaker associations between variables.

The cross-section correlational design of the study may also be considered as a further limitation. Although the design allowed the examination of associations between variables, it did not reveal the directions of causality or the temporal relationships. It is plausible that low mood and anxiety may be a normal reaction to a perceived impairment of ones' own cognitive ability. However, evidence from the health psychology literature indicates an opposite notion, in that those with high negative affect are more sensitive to subjective physical discomfort – '*the symptom perception hypothesis*' (Watson & Pennebaker, 1989). With this, could the *symptom perception hypothesis* be extended from the physical to the cognitive? Empirical studies using non-clinical populations have found that negative affect, particularly anxiety, negatively influences subjective appraisal of memory in absence of any objective impairment (Dux *et al.* 2008). Further studies, which adopt a more controlled experimental design, may offer benefit in investigating the impact of treating negative affect on reducing the level of SCI in those following ABI.

Due to the population under investigation, it would be imprudent to ignore the importance of insight and self-awareness of cognitive impairment. Individuals with an ABI display a wide range of awareness problems in relation to their physical, social and cognitive ability (Prigatono & Schacter, 1991). Furthermore, lack of awareness for cognitive impairment has been shown to be more prominent when compared to awareness for physical impairment (Sherer *et al.*

2003). The discrepancy between SCI and OCI likely reflects an individuals' insight into their current cognitive impairment. However, as the current study did not employ a standardised measure of insight, a test of association could not be performed. Future studies may benefit from adopting a more standardised measure of insight when examining the discrepancy between objective and subjective cognitive impairment.

In conclusion, the results of this study may have important implications for clinical practice. Firstly, actual objective cognitive performance on neuropsychological assessments should not be automatically interpreted as a reliable indicator of one's subjective experience of their cognitive difficulties. Clinicians should consider possible psychological factors that may play a more crucial role in patient's appraisals of their cognitive impairments. Consequently, a thorough assessment of mood and anxiety should be carried out and considered in response to self reported SCI. Clinicians may also consider psychological interventions as the primary rehabilitation strategy to address negative affect in those who report high SCI in absence of any objective impairment, instead of cognitive rehabilitation interventions.

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Table 1. *Demographic characteristics of participants*

	All Participants	CVA	TBI	Other
Number of participants	24	13	9	2
Age *(M, [S.D])*	56.3 (8.37)	56.6 (7.33)	58.9 (7.27)	42.0 (8.48)
Gender (N, %)				
Male	18 (75%)	10 (76.9%)	7 (77.8%)	1 (50%)
Female	6 (25%)	3 (23.1%)	2 (22.2%)	1 (50%)
Time since injury (N, %)				
8 months – 2 years	6 (25%)	4 (30%)	2 (22.2%)	0
2 – 4 years	6 (25%)	5 (38.5%)	0	1 (50%)
4 – 6 years	3 (12.5%)	2 (15.4%)	1 (11.1%)	0
6 – 10 years	4 (16.7%)	1 (7.7%)	3 (33.3%)	0
10+ years	5 (20.8%)	1 (7.7%)	3 (33.3%)	1 (50%)
Education (N, %)				
<12 years	9 (37.5%)	6 (42.2%)	2 (22.2%)	1 (50%)
12 – 14 years	6 (25%)	2 (15.4%)	3 (33.3%)	1 (50%)
14 – 17 years	8 (33.3%)	5 (38.5%)	3 (33.3%)	0
17+ years	1 (4.2%)	0	1 (11.1%)	0

Table 2. *Results of t-test for aetiological differences and descriptive statistics for psychological factors, subjective and objective cognitive impairment.*

Measure	All Participants			Type of Injury									t-test of statistical difference between CVA and TBI		
				CVA			TBI			Other					
	n	M	S.D.	n	M	S.D.	n	M	S.D.	n	M	S.D.	95% CI for mean Difference	t	df
Objective Impairment															
Immediate Memory	24	74.54	20.85	13	76.69	20.48	9	72.89	23.31	2	68.00	21.21	-15.78, 23.39	.41	20
Visuospatial/ Constructional	24	89.96	17.44	13	84.69	13.27	9	98.44	17.56	2	86.00	36.77	-27.48, -0.02	-2.09	20
Language	24	88.42	14.56	13	90.77	13.66	9	86.67	17.06	2	81.00	9.90	-9.56, 17.73	.62	20
Attention	24	80.75	19.73	13	77.92	16.74	9	87.56	20.82	2	68.50	36.06	-26.34, 7.08	-1.20	20
Delayed Memory	24	78.00	19.51	13	71.92	20.31	9	85.33	17.80	2	84.50	14.85	-30.90, 4.08	-1.60	20
Total Score	24	77.42	15.37	13	74.92	12.80	9	82.11	17.25	2	72.50	27.58	-20.52, 6.14	-1.12	20
Subjective Impairment															
Memory	24	15.39	8.07	13	14.31	5.53	9	17.00	10.32	2	15.00	15.55	-9.75, 4.34	-.80	20
Attention	24	20.38	8.70	13	19.38	7.24	9	22.56	10.21	2	17.00	14.14	-10.90, 4.56	-.86	20
Motor Function	24	13.62	7.54	13	12.61	6.31	9	14.44	9.00	2	16.50	12.02	-8.62, 4.96	-.56	20
Total CFQ Score	24	53.79	24.42	13	50.85	18.83	9	58.22	30.36	2	53.00	42.42	-29.18, 14,44	-.71	20
Psychological Factors															
HAI	24	17.37	9.10	13	16.46	8.14	9	20.56	10.41	2	9	0	-12.24, 4.15	-1.04	20
HADS Anxiety	24	8.62	5.05	13	8.62	3.52	9	9.11	6.77	2	6.5	7.78	-5.09, 4.10	-.23	20
HADS Depression	24	6.88	4.15	13	5.84	2.41	9	8.56	5.90	2	6.00	2.83	-6.48, 1.06	-1.50	20

Note: CVA = Cerebral Vascular Accident; TBI = Traumatic Brain Injury; RBANS = Repeatable Battery for the Assessment of Neuropsychological Status; CFQ = Cognitive Failures Questionnaire, HAI = Health Anxiety Index, HADS = Hospital Anxiety and Depression Scale; CI = Confidence Intervals.
*p = <0.05. **p = <0.01.

Table 3. *Pearson correlation coefficients of key variables*

	Objective Impairment (RBANS)				Subjective Impairment (CFQ)				Psychological Factors		
	Immediate Memory	Attention	Delayed Memory	Total Score	Memory	Attention	Motor function	Total CFQ	Health Anxiety	Anxiety	Depression
Objective Impairment											
Immediate Memory	1	.488*	.526**	.792**	.099	.118	.014	.104	.325	-.111	.457*
Attention	.488*	1	.492*	.736**	-.309	-.160	-.286	-.224	.215	-.473*	.253
Delayed Memory	.526**	.492*	1	.757**	-.168	-.077	-.067	-.098	.179	-.163	.279
Total Score	.792**	.736**	.757**	1	-.129	-.028	-.198	-.096	.190	-.373	.306
Subjective Impairment											
Memory	.099	-.309	-.168	-.129	1	.898**	.870**	.958**	.195	.810**	.385
Attention	.118	-.160	-.077	-.028	.963**	1	.837**	.963**	.366	.749**	.518**
Motor function	.014	-.286	-.067	-.198	.870**	.837**	1	.934**	.205	.832**	.509*
Total CFQ	.104	-.224	-.098	-.096	.958**	.963**	.934**	1	.276	.821**	.505*
Psychological Factors											
HAI	.325	.215	.179	.190	.195	.366	.205	.276	1	.307	.600**
HADS Anxiety	-.111	-.473*	-.163	-.373	.810**	.749**	.832**	.821**	.307	1	.281
HADS Depression	.457*	.253	.279	.303	.385	.518**	.509*	.505*	.600**	.281	1

Note: RBANS = Repeatable Battery for the Assessment of Neuropsychological Status; CFQ = Cognitive Failures Questionnaire, HAI = Health Anxiety Index, HADS = Hospital Anxiety and Depression Scale.
*p = < 0.05, **p = < 0.01.

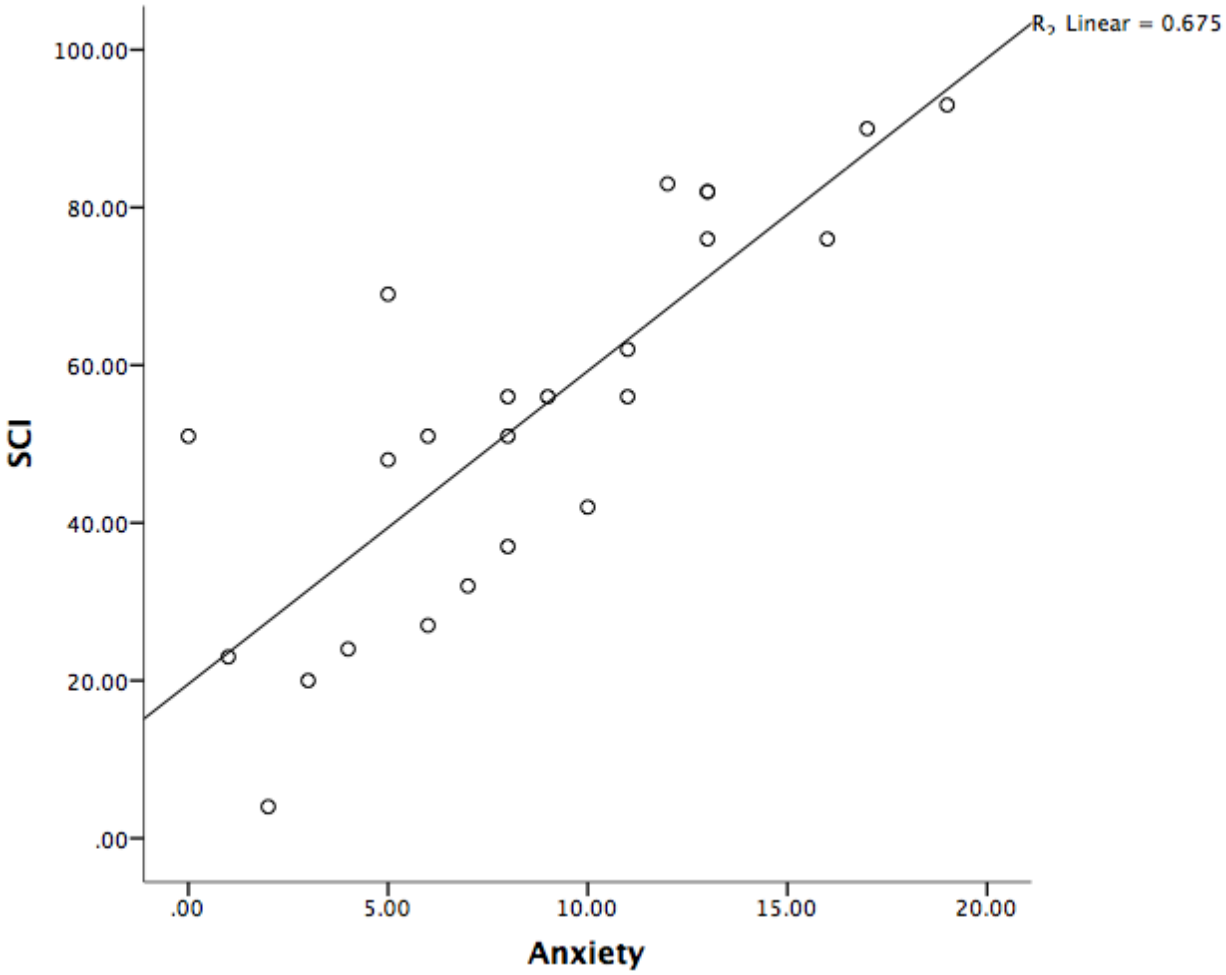

Figure 1. *Scatter plot demonstrating the positive relationship between Anxiety and SCI*

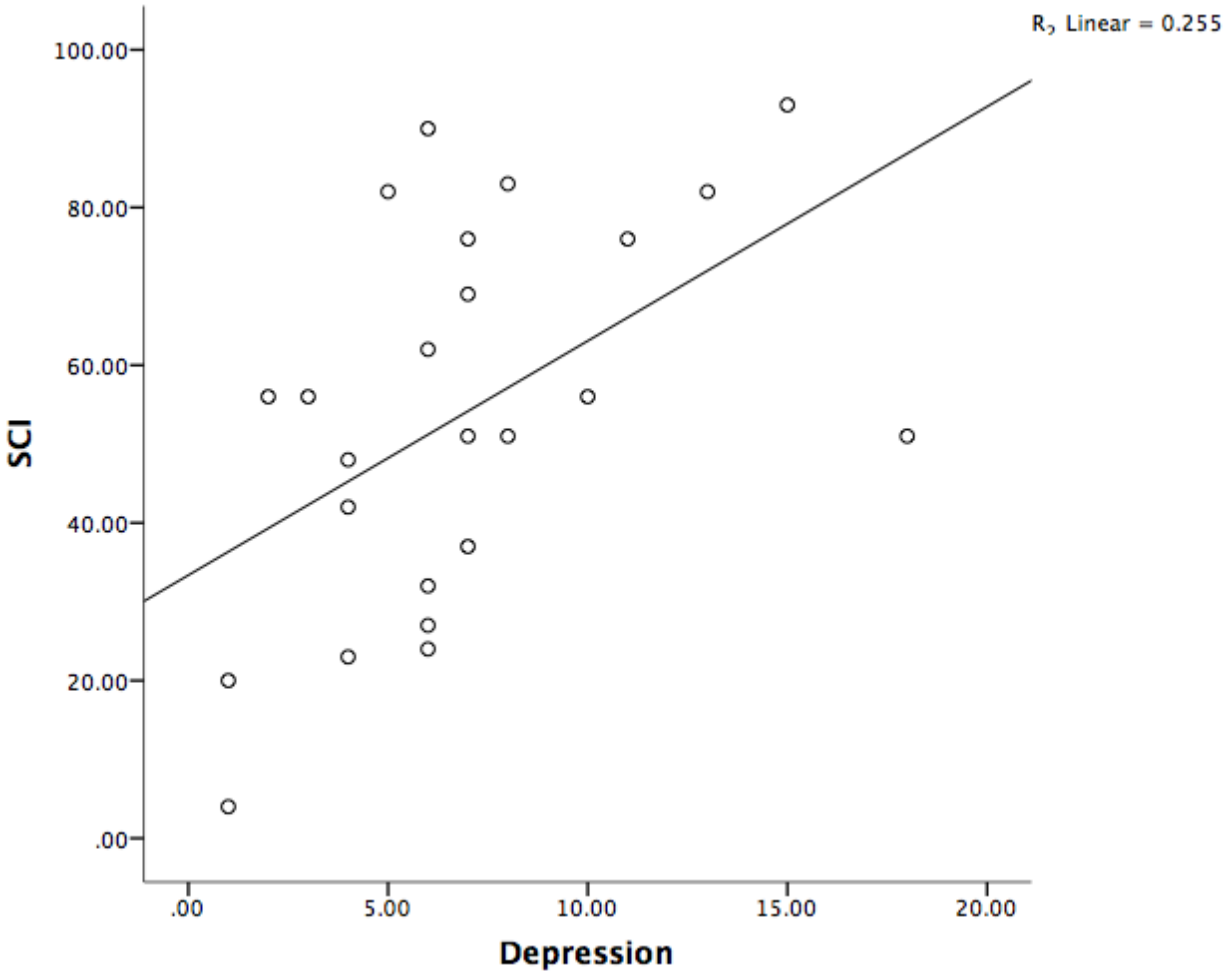

Figure 2. *Scatter plot demonstrating the positive relationship between Depression and SCI*

Table 4. *Summary of Hierarchical regression analysis for predictors of SCI*

	Model 1 (Demographics)			Model 2 (Objective Cognitive Impairment)			Model 3 (Psychological Factors)		
Variable	*B*	*SE b*	*β*	*B*	*SEB*	*β*	*B*	*SEB*	*β*
Type of Injury									
CVA (Constant)	44.35	45.78	-	41.22	48.38	-	11.47	21.99	-
TBI	.29	12.16	.01	-.49	12.81	-.01	-5.53	5.79	-.11
Other	-15.60	22.12	-.18	-17.49	23.73	-.20	-10.47	11.00	-.12
Age	-.39	.74	-.13	-.49	.84	-.17	-.48	.36	-.16
Gender	13.12	11.94	.24	13.31	12.30	.24	-.53	5.52	-.01
Time since injury	6.34	3.79	.40	6.68	4.03	.42	4.32	1.96	.27
Years of Education	-.96	5,72	-.04	-1.57	6.27	-.06	-7.25	3.01	-.28
RBANS Total Score	-	-	-	.12	.44	.08	.45	.20	.28
Anxiety	-	-	-	-	-	-	3.36	.64	.69**
Depression	-	-	-	-	-	-	3.33	.88	.57**
Health Anxiety	-	-	-	-	-	-	-.66	.34	-.25
Adjusted R^2		-.018			-.076			.81**	
R^2 Change		.248			.004			.64**	
F		.933			.767			10.55**	

Note: Type of Injury was represented as three dummy variables with CVA serving as the reference group (Constant)
**p = <0.01.

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Chapter 3 – Contributions to Theory & Clinical Practice

Contributions to Theory and Clinical practice

The current thesis aimed to explore the pivotal role that psychological processes play in Acquired Brain Injury (ABI) sequelae at a both conceptual and interventional level. This thesis can be separated into three distinct but topically related chapters. The first chapter consisted of a comprehensive literature review and meta-analysis that systematically appraised the current literature on psychological interventions for aggressive behaviour following ABI. A statistical synthesis of the available evidence using a novel methodology was also provided. The second chapter consisted of an empirical paper that examined the discrepancy between subjectively reported cognitive impairment (SCI) and objectively measured cognitive impairment (OCI) following ABI, whilst highlighting the role that psychological factors play in SCI. This third and final chapter will discuss the implications of both research papers on psychological theory and clinical practice. An additional reflective commentary is also provided.

Contributions to theory and practice - The meta-analysis and systematic review

There continues to be uncertainty surrounding many aspects of aggressive behaviour following ABI. In particular, the theoretical underpinnings for the development of aggressive behaviour are vague and ambiguous. There are currently two distinct, but not necessarily mutually exclusive, models that attempt to explain aggressive behaviour development in those with an ABI: the biomedical and psychosocial model. The biomedical model attempts to link neuroanatomical pathology to the development of aggressive behaviour (Cattelani, Zettin & Zoccolotti. 2008). However, although neuroanatomy plays a crucial role (Cattelani, Zettin & Zoccolotti. 2008), the empirical evidence has consistently shown that neuropathology alone does not significantly predict the presence of aggressive behaviour in those with ABI (Grafman *et al.,* 1996). It is likely that other psychosocial factors such as premorbid personality, post-injury coping styles and environment variables play a significant role in the behavioural expression of an individuals' ABI (Warriner & Velikonja, 2006). Furthermore, aggressive behaviour following ABI has been shown to frequently increase over time (Brooks *et al.* 1986; Johnson & Balleny, 1996). Exclusively biological models may struggle to explain this increase as, unlike degenerative or progressive disorders, the course of an ABI in the adult population following the acute period is often that of some recovery, before reaching a plateau at a level below pre-morbid functioning. Therefore, observed increases in aggressive behaviour do not correlate with any deterioration of neuroanatomical regions of the brain (Grafman *et al.,* 1996). Subsequently, although anatomical lesions may act as a key predisposing factor, psychosocial processes may mediate increases in aggressive behaviour over time, through processes such as behavioural reinforcement.

Experimentally controlled studies that differentiate between effective and ineffective interventions enable us to construct casual inferences, which further inform hypotheses development (Hagmayer, Sloman, Lagnado & Waldmann, 2007). As the evidence base for the exclusive use of pharmacological therapy has shown to be ineffective (Cochrane Collaboration Review; Fleminger, Greenwood & Oliver, 2006), psychopharmacological hypotheses that attempt to explain increases in aggressive behaviour following ABI are not substantiated. Conversely, there is a robust evidence base for behavioural

interventions (Rothwell, LaVigna & Willis, 1999; Alderman & Knight, 1997; Hegel & Ferguson, 2000; Medd & Tate, 2000; Walker *et al.* 2010; Guercio & McMorrow, 2002; Gardner *et al*., 2003; Ylvisaker, 2006; Cattelani, Zettin & Zoccolotti, 2010; Aboulafia-Brakha *et al.* 2012; Byrne & Coetzer, in press). This suggests that processes of reinforcement may play a crucial role in the development, maintenance, and/or increase of aggressive behaviour following ABI. Admittedly, this suggestion is conjecture at this time. It is likely that the causes for the observed increase in aggressive behaviour are multifaceted. However, examining the evidence base for effective interventions is conducive for further theory development into the mechanisms of problematic behavior following ABI.

Aggressive behaviour is considered to be one of the most challenging neurobehavioural difficulties following ABI (Alderman, 2001; Aboulafia-Brakha *et al.* 2012). The presence of aggressive behaviour can restrict an individual's access to rehabilitation services, which inevitably contribute to poor rehabilitation outcomes. It is therefore important for all ABI services to provide evidence-based interventions to manage those who display aggressive behaviour. Evidence based practice (EBP) is informed by the best available research within the current literature. Typically, the results from systematic reviews of 'gold standard' research are considered to be the best source of evidence. Systematic reviews examining the efficacy of interventions for aggressive behaviour following ABI have been broadly separated into two categories – pharmacological and non-pharmacological. As discussed, there is currently little evidence for the exclusive use of pharmacological treatment for aggressive behaviour following ABI (Cochrane Collaboration Review; Fleminger, Greenwood & Oliver, 2006). This suggests that exclusive pharmacological treatments are not warranted in clinical practice. However, there are two excellent systematic reviews that support the use of psychological interventions to reduce aggressive behaviour following ABI (Ylvisaker, 2006; Cattelani, Zettin & Zoccolotti, 2010). Furthermore, the current meta-analysis (Byrne & Coetzer, in press) was able to build upon previous systematic reviews by providing a statistical synthesis of the available data across research designs. Subsequently, the current evidence base indicates that aggressive behaviour following ABI may be best managed using a psychological paradigm.

It should be noted that EBP is not exclusively dependent on the best research evidence. It is an interaction between the research evidence, clinical judgment and patients' idiosyncratic characteristics (values, choices and context) (American Psychological Association, 2002). Therefore, although the current meta-analysis addresses one aspect of EBP (research evidence), psychological interventions may not be indicated in every incidence of aggressive behaviour. The realities of clinical practice are influenced by many factors; one of which is the availability of resources to complete an intervention. In the current economic climate, resources within the National Health Service are often limited. The current meta-analysis did not examine the health economics of using psychological interventions to reduce aggressive behaviour in persons with ABI. Further studies examining the economic benefits of both psychological and pharmacological interventions may offer further clarity when informing services that manage aggressive behaviour in those with ABI. In addition, the current meta-analysis was also unable to determine the effectiveness of specific psychological interventions (e.g. environmental contingency management, cognitive behavioural therapy). This was due to the limited number of studies available within the neurorehabilitation literature. However, as the literature expands, further research may attempt to establish which model of psychological intervention is the most effective.

A novel element within the current meta-analysis was the synthesis of both group design and single case experimental design (SCED) data. Although SCED methodology has a long history within psychological science (Sidman, 1960), it has previously been undervalued as a robust source of evidence (Evans, Gast, Perdices, & Manolov 2014). This may be partly due to the poor methodological rigor of many SCED studies (Tate *et al*., 2010). Tate *et al*. (2010) examined a random sample (n=253) of single case design studies within the neurorehabilitation literature. The results demonstrated that only 44% of studies had adopted an experimental control, 48% possessed baseline data over three time points, 54% reported inter-rater reliability and 26% completed a subsequent statistical analysis. These findings highlight the validity issues that may place doubt on single case research as a reliable source of evidence.

However, with the recent development of quality appraisal tools, such as the Evaluation Method (Reichow, Volkmar & Cicchetti, 2008), the methodological rigor of SCED studies

has improved (Evans *et al.*, 2014). Evans *et al.* (2014) highlighted the use of quality appraisal tools as one of several drivers that have increased recent interest in SCED research. Furthermore, the reclassification of systematic reviews that include 'n-of-1 trials' (comparable to ABAB designs) as Level 1 evidence by the Oxford Centre for Evidence Based Medicine (OCEBM) increases the empirical creditability of SCED research (Howick *et al*., 2011). Rigorously designed SCED studies have the ability to empirically investigate the effects of various interventions on heterogeneous populations such as those with ABI. It is hoped that the current meta-analysis, which includes both synthesised evidence from group and single case design studies will help contribute to the resurgence of SCED methodology by challenging the scientific dogma surrounding SCED as an inferior form of evidence.

Contributions to theory and practice - The empirical paper

Contrary to previous findings (Hohman, Beason-Held, Lamar & Resnick, 2011; Dufouil, Fuhrer & Alperovitch, 2005), the results of the current empirical paper suggest that one's subjective experience of their cognitive difficulties following ABI are not associated with their actual objective cognitive impairment (OCI). These findings are consistent with anecdotal reports and empirical findings from other clinical populations, such as those with Multiple Sclerosis (Middleton *et al.,* 2006), schizophrenia (Homayoun *et al.,* 2001) and veterans with TBI (Spencer *et al*., 2010). In addition, the examination of psychological variables revealed negative affect to be the only significant predictor of self reported subjective cognitive impairment (SCI). Further analyses revealed that anxiety demonstrated the strongest correlation with SCI, when compared with other psychological (depression and health anxiety) and OCI variables. The crucial role of psychological factors have been demonstrated in previous studies that have attempted to examine the aetiological factors of SCI in non-clinical populations (Dux *et al.,* 2008; Hanninen *et al*., 1994).

Two theoretical models, adapted from the health psychology literature, may provide the theoretical foundations for the current study's findings: the *disability hypothesis* and the *symptom perception hypothesis* (Watson and Pennebaker, 1989). The *disability hypothesis* suggests that health difficulties are the causal factor leading to specific behavioural or

personality changes, including increases in negative affect. From a cognitive perspective, the d*isability hypothesis* would suggest that objective and subjective cognitive impairments following an ABI are the direct cause for high negative affect. Conversely, the opposite causal mechanism is proposed by the *symptom perception hypothesis*. This suggests that those with high negative affect are more likely to perceive, report and struggle with reported health difficulties. Again, from a cognitive impairment perspective, those with high negative affect would be more likely to report cognitive difficulties, even in absence of any objective cognitive impairment.

For the *disability hypothesis* to be supported, it is expected that both SCI and negative affect would be significantly associated with actual OCI (i.e. a disability). However, these associations were not demonstrated. Conversely, negative affect was found to be positively correlated with self reported SCI. These findings offer tentative support for the *symptom perception hypothesis*. As such, it could be proposed that the *symptom perception hypothesis* may be extended from physical health complaints to cognitive complaints. Similar proposals have been made by *Dux et al.,* (2008), who demonstrated comparable findings in healthy individuals.

There were a few limitations to the current study, which will now be considered. It is important to not draw definitive conclusions from the current study's findings. The cross-section correlational design of the study restricts the conclusion of both the temporal relationship and direction of cause between variables. In line with Reichenbach's (1956) common cause principle, there are three possible explanations for an observed relationship between two variables: (i). Variable A causes Variable B, (ii). Variable B causes Variable A, or (iii). Another variable, or set of variables, are causing both variable A and B. For example, in the context of cognitive impairment, it may be that a third variable, such as environmental demands, may act as a moderator for the relationship between SCI and anxiety in those with ABI. Further research examining potential moderator variables would offer more clarity. Nevertheless, the current study provided a valuable insight into the relationships between OCI, SCI and negative affect. These findings suggest that clinicians may benefit from considering possible psychological factors that may play a crucial role in a patient's appraisals of their cognitive impairment. Clinicians may choose to work within an evidence base paradigm

(e.g. cognitive behavioural model; see figure 1) to address negative affect in those individuals who present with high SCI, in absence of actual OCI.

------- Insert Figure 1 -------

The ecological validity of the neuropsychological assessments employed to measure actual OCI in the current study may be considered as a potential limitation. Ecological validity can be conceptually separated into two approaches: verisimilitude and veridicality (Franzen & Wilhelm, 1996). Verisimilitude refers to the similarity between the cognitive demands required by neuropsychological test and the cognitive demands of the real world environment for an individual. Veridicality refers to the extent to which the results of a neuropsychological test can predict functioning in real world environment. It could be argued that the neuropsychological test employed to measure OCI in the current study (RBANS; Randolph, 1998) would be less sensitive to measuring real world cognitive difficulties, when compared to subjective self report measures such as the Cognitive Failures Questionnaire (CFQ; Broadbent *et al*., 1982). This may subsequently give rise to the observed discrepancy between SCI and OCI in the current study. However, a study by Keil (2005) found that self-report measures of cognitive impairment were not a reliable indicator of everyday functioning, as measured by the Direct Assessment of Functional Status (DAFS). Conversely, the RBANS was found to account for the majority of variance in the DAFS when compared to other cognitive and self report tests, ultimately supporting its use as an ecologically valid measure of objective cognitive impairment.

A Reflective Commentary

Why did I choose ABI as an area of research for my thesis? As I ask myself this question the answer is surprisingly simple – I am interested and curious. Yet, the question of what has generated this curiosity is not so simple: Is it the challenging nature of working clinically with this population? Was I inspired by a lecture during my undergraduate degree? Is it a natural fascination with the inner workings of the brain and how it relates to behaviour? Or is it all of the above? However, on reflection, the answer likely stems from my early experiences as a child - I was once a part of the system that I am currently

working hard to help. It is from my early experience of having a parent with an ABI that has shaped my interest and curiosity. I have experienced first hand the consequences of an ABI on a social, emotional and physical level. As I further reflect on the specific topics of my thesis, my early childhood experiences of brain injury start to emerge. I believe it is my early experiences have unconsciously shaped my clinical and research interests.

The process of writing this thesis was predominantly an enjoyable one. However, at times, it was an emotional rollercoaster. And like all rollercoasters, it is the plunges from the highs to the lows that evoke the most anxiety: the first dip – the ethics panel, second dip – recruitment, third dip – statistical analyses and so on. Thankfully, the peak and troughs of the rollercoaster were not especially "bumpy" and the process went smoothly. A large part of this can be due to the support network who were 'riding the rollercoaster' along side me.

A major step in both conducting research, and working clinically, within a brain injury service was grasping the language. I initially found the many diagnostic terms, acronyms and neuroanatomical regions totally foreign. Consequently, I had to approach this challenge as I would approach learning a new language; I familiarized myself to the language of an evening, and practiced it during my working day. From a research perspective, trawling through medical notes and deciphering scan reports in an attempt to comprehend the nature and extent of a participants' ABI was an additional challenge. However, although time consuming, this task was crucial in not only ensuring that the sample met the inclusion criteria, but also in helping develop my vocabulary within this specialist area of clinical psychology.

When I think about both the most valuable and most tedious aspects of completing this thesis I arrive at the same answer – the recruitment process. Given the large geographical location covered by the brain injury service, I would frequently spend a large majority of my time driving to various locations to administer psychometric tests. This was extremely frustrating, and I would often ruminate on how this time would be better spent working clinically with patients. However, when I finally met the participant, my frustration would be replaced by my natural curiosity to hear their story. When designing the study, it was estimated that the duration of the assessment would

last no longer than 90 minutes. I soon realized that 90 minutes would often become three hours. I felt the need to hear each participant's story and to validate his or her experience of living with an ABI. This again evoked strong emotions, as I often found it difficult to separate my role as a researcher and as a clinician.

The struggle between different roles was further extended into my life, not only as a Trainee Clinical Psychologist, but also as a parent. Working within a brain injury service made me become more aware of the fragility of life. I was frequently meeting both children and adults whose life had catastrophically changed in the blink of an eye. These humbling experiences encouraged reflection into my own life. I soon became more mindful of the many evenings I would spend working, in place of spending time with my own children. Subsequently, completing this research has been a process of both professional and personal development.

To conclude this reflective section, I feel the need to acknowledge how struck I was by the altruistic nature of each participant who voluntarily gave their time to partake in the study. In deciding to use a quantitative research design, my anxiety about recruiting enough participants without any monetary incentive was high. However, despite all the idiosyncrasies of each participant, I soon found one commonality: they all wanted to "give something back". The eagerness shown by each participant to "give something back" is likely a testament to the care they received from the brain injury service. I will be forever grateful to both the brain injury service and those who participated in the study. I hope this current study will contribute to the scientific literature, subsequently allowing the participants to "give something back" on a wider level.

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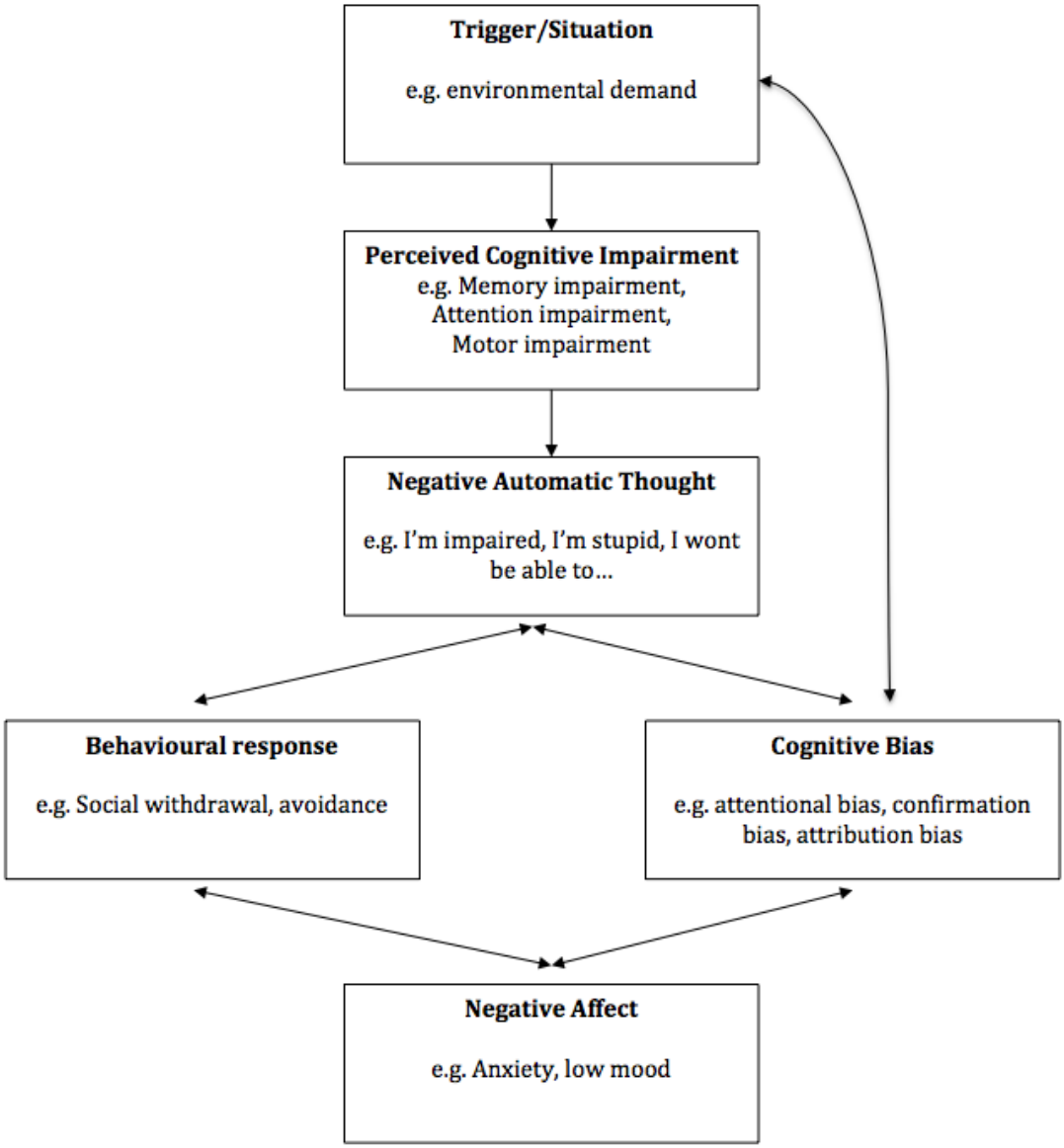

Figure 1. *Cognitive behavioural model of anxiety relating to subjective cognitive impairment.*

Appendices

I. Bangor University, School of Psychology Ethics Committee Approval

II. NHS IRAS Research Ethics Committee Form

III. Research Ethics Committee Approval Letter

IV. Research & Development Approval Letter

V. Participant Consent Form – English

VI. Participant Consent Form – Welsh

VII. Participant Information Sheet – English

VIII. Participant Information Sheet – Welsh

IX. Cognitive Failures Questionnaire (CFQ)

X. Hospital Anxiety and Depression Scale (HADS)

XI. Health Anxiety Inventory (HAI-18)

Appendix I.

Bangor University, School of Psychology Ethics Committee Approval

Everil McQuarrie 15 April 2015 at 11:25

To: Christopher Byrne LSRP

Ethical approval granted for 2015-15027 Investigating the role of psychological factors in the perception of cognitive impairment following Traumatic Brain Injury.

Dear Christopher,

2015-15027 Investigating the role of psychological factors in the perception of cognitive impairment following Traumatic Brain Injury.

Your research proposal number 2015-15027
has been reviewed by the Psychology Ethics and Research Committee
and the committee are now able to confirm ethical and governance approval for the above research on the basis described in the application form, protocol and supporting documentation. This approval lasts for a maximum of three years from this date.

Ethical approval is granted for the study as it was explicitly described in the application

If you wish to make any non-trivial modifications to the research project, please submit an amendment form to the committee, and copies of any of the original documents reviewed which have been altered as a result of the amendment. Please also inform the committee immediately if participants experience any unanticipated harm as a result of taking part in your research, or if any adverse reactions are reported in subsequent literature using the same technique elsewhere.

Appendix II.

NHS IRAS Research Ethics Committee Form

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
Psychological factors in subjective CI in TBI

1. Is your project research?

(•) Yes ( ) No

2. Select one category from the list below:

( ) Clinical trial of an investigational medicinal product
( ) Clinical investigation or other study of a medical device
( ) Combined trial of an investigational medicinal product and an investigational medical device
( ) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
( ) Basic science study involving procedures with human participants
(•) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
( ) Study involving qualitative methods only
( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
( ) Study limited to working with data (specific project only)
( ) Research tissue bank
( ) Research database

If your work does not fit any of these categories, select the option below:

( ) Other study

2a. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation?	( ) Yes	(•) No
b) Will you be taking new human tissue samples (or other human biological samples)?	( ) Yes	(•) No
c) Will you be using existing human tissue samples (or other human biological samples)?	( ) Yes	(•) No

3. In which countries of the UK will the research sites be located? *(Tick all that apply)*

☐ England
☐ Scotland
☑ Wales
☐ Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

- ○ England
- ○ Scotland
- ◉ Wales
- ○ Northern Ireland
- ○ This study does not involve the NHS

4. Which review bodies are you applying to?

- ☑ NHS/HSC Research and Development offices
- ☐ Social Care Research Ethics Committee
- ☑ Research Ethics Committee
- ☐ Confidentiality Advisory Group (CAG)
- ☐ National Offender Management Service (NOMS) (Prisons & Probation)

For NHS/HSC R&D offices, the CI must create Site-Specific Information Forms for each site, in addition to the study-wide forms, and transfer them to the PIs or local collaborators.

5. Will any research sites in this study be NHS organisations?

◉ Yes ○ No

6. Do you plan to include any participants who are children?

○ Yes ◉ No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

○ Yes ◉ No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

○ Yes ◉ No

9. Is the study or any part of it being undertaken as an educational project?

◉ Yes ○ No

Please describe briefly the involvement of the student(s):
This study will be part of the Clinical Psychology Doctorate. The student (Mr Christopher Byrne) will be the Chief Investigator supervised by Dr Karen Addy.

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

◉ Yes ○ No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

○ Yes ◉ No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

○ Yes ◉ No

Site-Specific Information Form (NHS sites)

Is the site hosting this research a NHS site or a non-NHS site? *NHS sites include Health and Social Care organisations in Northern Ireland. The sites hosting the research are the sites in which or through which research procedures are conducted. For NHS sites, this includes sites where NHS staff are participants.*

- (●) NHS site
- ( ) Non-NHS site

This question must be completed before proceeding. The filter will customise the form, disabling questions which are not relevant to this application.

One Site-Specific Information Form should be completed for each research site and submitted to the relevant R&D office with the documents in the checklist. See guidance notes.

The data in this box is populated from Part A:

Title of research:
Investigating the role of psychological factors in the perception of cognitive impairment following Traumatic Brain Injury

Short title: Psychological factors in subjective CI in TBI

Chief Investigator:

Title	Forename/Initials	Surname
Mr	Christopher	Byrne

Name of NHS Research Ethics Committee to which application for ethical review is being made:
Wales REC 4

Project reference number from above REC: 15/WA/0165

1-1. Give the name of the NHS organisation responsible for this research site

Betsi Cadwaladr Uuniversty Health Board

1-3. In which country is the research site located?

- ( ) England
- (●) Wales
- ( ) Scotland
- ( ) Northern Ireland

1-4. Is the research site a GP practice or other Primary Care Organisation?

( ) Yes (●) No

2. Who is the Principal Investigator or Local Collaborator for this research at this site?

Select the appropriate title: ○ Principal Investigator
○ Local Collaborator

	Title	Forename/Initials	Surname
	Mr	Christopher	Byrne
Post	Trainee Clinical Psychologist		
Qualifications	BSc (Hons) Psychologist		
Organisation	BCUHB		
Work Address	North Wales Clinical Psychology Programme		
	Brigantia Building, Bangor University		
	Bangor, Gwynedd		
PostCode	LL57 2DG		
Work E-mail	psp2c8@bangor.ac.uk		
Work Telephone	07805338006		
Mobile	07805338006		
Fax			

a) Approximately how much time will this person allocate to conducting this research? *Please provide your response in terms of Whole Time Equivalents (WTE).*
0.4 WTE

b) Does this person hold a current substantive employment contract, Honorary Clinical Contract or Honorary Research Contract with the NHS organisation or accepted by the NHS organisation? ◉ Yes ○ No

A copy of a current CV for the Principal Investigator (maximum 2 pages of A4) must be submitted with this form.

3. Please give details of all locations, departments, groups or units at which or through which research procedures will be conducted at this site and describe the activity that will take place.

Please list all locations/departments etc where research procedures will be conducted within the NHS organisation, describing the involvement in a few words. Where access to specific facilities will be required these should also be listed for each location.

Name the main location/department first. Give details of any research procedures to be carried out off site, for example in participants' homes.

	Location	Activity/facilities
1	North Wales Brain Injury Service (NWBIS)	Administartion of psychometric measures

5. Please give details of all other members of the research team at this site.

6. Does the Principal Investigator or any other member of the site research team have any direct personal involvement (e.g. financial, share-holding, personal relationship etc) in the organisation sponsoring or funding the research that may give rise to a possible conflict of interest?

○ Yes ◉ No

7. What is the proposed local start and end date for the research at this site?

Start date: 20/05/2015
End date: 01/06/2016

Duration (Months): 12

8-1. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. *(These include seeking consent, interviews, non-clinical observations and use of questionnaires.)*

Columns 1-4 have been completed with information from A18 as below:

1. *Total number of interventions/procedures to be received by each participant as part of the research protocol.*
2. *If this intervention would have been routinely given to participants as part of their care, how many of the total would have been routine?*
3. *Average time taken per intervention (minutes, hours or days)*
4. *Details of who will conduct the procedure, and where it will take place*

Please complete Column 5 with details of the names of individuals or names of staff groups who will conduct the procedure at this site.

Intervention or procedure	1	2	3	4	5
Participant approached to potentially be include in the research study	1	0	15 minutes	The participants lead clinician will initially approach potential participants with details regarding the study. If the potential participant is interested in participating in the study, permission will be sought by the clinician to pass their details onto the principle investigator. Further information (information sheet) regrading the study will be provided to the potential participant.	Lead clinician from NWBIS.
Consent	1	0	15 minutes	Principle investigator will gain informed consent from the willing participants. A convenient date, time and location (clinics within the participant's geographical location) will be set to complete the assessment.	principal investigator
Assessment	4	0	90 minutes (total)	The participant will initially complete a demographic questionnaire. Following the demographic questionnaire a Neuropsychological assessment (RBANS) will be carried out to objectively assess cognitive impairment. Psychometric measures including the Cognitive Failures Questionnaire, Hospital Anxiety and Depression scale, and the Health Anxiety Inventory will also be completed. The whole process should take no longer than 1 hour 30 minutes. The whole assessment process will be completed by the principle investigator.	principal investigator
Debrief	1	0	15 minutes	Participants will be debriefed on the study.	principal investigator

8-2. Will any aspects of the research at this site be conducted in a different way to that described in Part A or the protocol?

○ Yes ◉ No

If Yes, please note any relevant changes to the information in the above table.

Are there any changes other than those noted in the table?
No.

10. How many research participants/samples is it expected will be recruited/obtained from this site?

40

11. Give details of how potential participants will be identified locally and who will be making the first approach to them to take part in the study.

potential participants will be approached by their lead clinician. Potential participants may be approached via letters, phone calls and face-to-face after sessions. Only after permission is gained by the clinician, the principal investigator will contact the participant with further information about the study

12. Who will be responsible for obtaining informed consent at this site? What expertise and training do these persons have in obtaining consent for research purposes?

Name	Expertise/training
Christopher Byrne	BSc (Hons) Psychology DClin Psych training. I have been trained to obtain consent in an ethical manner.

15-1. Is there an independent contact point where potential participants can seek general advice about taking part in research?

Yes, potential participants can contact NWBIS or North Wales Clinical Psychology Programme. The contact details for the above sites are stated on the participant information sheet and consent form.

15-2. Is there a contact point where potential participants can seek further details about this specific research project?

Yes, potential participants can contact NWBIS or North Wales Clinical Psaychology Programme. The contact details for the above sites are stated on the participant information sheet and consent form.

16. Are there any changes that should be made to the generic content of the information sheet to reflect site-specific issues in the conduct of the study? *A substantial amendment may need to be discussed with the Chief Investigator and submitted to the main REC.*

No, the information sheet is appropriate for all participants.

Please provide a copy on headed paper of the participant information sheet and consent form that will be used locally. Unless indicated above, this must be the same generic version submitted to/approved by the main REC for the study while including relevant local information about the site, investigator and contact points for participants (see guidance notes).

17. What local arrangements have been made for participants who might not adequately understand verbal explanations or written information given in English, or who have special communication needs? *(e.g. translation, use of interpreters etc.)*

Participants are required to be fluent in English. The psychometric measures are only valid in English language. Any other other language would invalidate the study.

18. What local arrangements will be made to inform the GP or other health care professionals responsible for the care of the participants?

Clinicians that are responsible for the professional care of a participant will be made aware of the participants involvement in the study.

19. What arrangements (e.g. facilities, staffing, psychosocial support, emergency procedures) will be in place at the site, where appropriate, to minimise the risks to participants and staff and deal with the consequences of any harm?

Given the nature of the study, there are no significant risks of harm to both participants or staff. The principal

investigator will abide by the NHS lone working policies. see section A22 in R&D Form.

20. What are the arrangements for the supervision of the conduct of the research at this site? *Please give the name and contact details of any supervisor not already listed in the application.*

Dr Karen Addy is based at NWBIS.

21. What external funding will be provided for the research at this site?

- ○ Funded by commercial sponsor
- ○ Other funding
- ◉ No external funding

How will the costs of the research be covered?
No costs will occur.

23. Authorisations required prior to R&D approval

The local research team are responsible for contacting the local NHS R&D office about the research project. Where the research project is proposed to be coordinated centrally and therefore there is no local research team, it is the responsibility of the central research team to instigate this contact with local R&D.

NHS R&D offices can offer advice and support on the set-up of a research project at their organisation, including information on local arrangements for support services relevant to the project. These support services may include clinical supervisors, line managers, service managers, support department managers, pharmacy, data protection officers or finance managers depending on the nature of the research.

Obtaining the necessary support service authorisations is not a pre-requisite to submission of an application for NHS research permission, but all appropriate authorisations must be in place before NHS research permission will be granted. Processes for obtaining authorisations will be subject to local arrangements, but the minimum expectation is that the local R&D office has been contacted to notify it of the proposed research project and to discuss the project's needs **prior** to submission of the application for NHS research permission via IRAS.

Failure to engage with local NHS R&D offices **prior** to submission may lead to unnecessary delays in the process of this application for NHS research permissions.

Declaration:
☑ **I confirm that the relevant NHS organisation R&D office has been contacted to discuss the needs of the project and local arrangements for support services. I understand that failure to engage with the local NHS R&D office before submission of this application may result in unnecessary delays in obtaining NHS research permission for this project.**

Please give the name and contact details for the NHS R&D office staff member you have discussed this application with:
Please note that for some sites the NHS R&D office contact may not be physically based at the site. For contact details refer to the guidance for this question.

	Title	Forename/Initials	Surname
	Dr	Rossela	Roberts
Work E-mail	Rosella.Roberts@wales.nhs.uk		
Work Telephone	01248384877		

Declaration by Principal Investigator or Local Collaborator

1. The information in this form is accurate to the best of my knowledge and I take full responsibility for it.

2. I undertake to abide by the ethical principles underpinning the World Medical Association's Declaration of Helsinki and relevant good practice guidelines in the conduct of research.

3. If the research is approved by the main REC and NHS organisation, I undertake to adhere to the study protocol, the terms of the application of which the main REC has given a favourable opinion and the conditions requested by the NHS organisation, and to inform the NHS organisation within local timelines of any subsequent amendments to the protocol.

4. If the research is approved, I undertake to abide by the principles of the Research Governance Framework for Health and Social Care.

5. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to the conduct of research.

6. I undertake to disclose any conflicts of interest that may arise during the course of this research, and take responsibility for ensuring that all staff involved in the research are aware of their responsibilities to disclose conflicts of interest.

7. I understand and agree that study files, documents, research records and data may be subject to inspection by the NHS organisation, the sponsor or an independent body for monitoring, audit and inspection purposes.

8. I take responsibility for ensuring that staff involved in the research at this site hold appropriate contracts for the duration of the research, are familiar with the Research Governance Framework, the NHS organisation's Data Protection Policy and all other relevant policies and guidelines, and are appropriately trained and experienced.

9. I undertake to complete any progress and/or final reports as requested by the NHS organisation and understand that continuation of permission to conduct research within the NHS organisation is dependent on satisfactory completion of such reports.

10. I undertake to maintain a project file for this research in accordance with the NHS organisation's policy.

11. I take responsibility for ensuring that all serious adverse events are handled within the NHS organisation's policy for reporting and handling of adverse events.

12. I understand that information relating to this research, including the contact details on this application, will be held by the R&D office and may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 1998.

13. I understand that the information contained in this application, any supporting documentation and all correspondence with the R&D office and/or the REC system relating to the application will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.

This section was signed electronically by Mr Christopher Byrne on 23/04/2015 15:13.

Job Title/Post:	Trainee Clinical Psychology
Organisation:	BCUHB
Email:	psp2c8@bangor.ac.uk

III. Research Ethics Committee Approval Letter

Part of the research infrastructure for Wales funded by the National Institute for Social Care and Health Research, Welsh Government
Yn rhan o seilwaith ymchwil Cymru a ariannir gan y Sefydliad Cenedlaethol ar gyfer Ymchwil Gofal Cymdeithasol ac Iechyd, Llywodraeth Cymru

Wales REC 4
G1/G2 Croesnewydd Hall
Croesnewydd Road
Wrexham Technology Park
Wrexham LL13 7YP

Telephone : 01978 726377

E-mail : tracy.biggs@wales.nhs.uk

Website : www.nres.nhs.uk

28 May 2015

Mr Christopher Byrne
Trainee Clinical Psychologist
NHS
North Wales Clinical Psychology Programme
Brigantia Building, Bangor University
Bangor, Gwynedd
LL57 2DG

Dear Mr Byrne

Study title:	**Investigating the role of psychological factors in the perception of cognitive impairment following Traumatic Brain Injury**
REC reference:	**15/WA/0165**
IRAS project ID:	**168056**

Thank you for your letter of 22 May 2015, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered by a Sub-Committee of the REC at a meeting held on 28 May 2015. A list of the Sub-Committee members is attached.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager, Mrs Tracy Biggs, Tracy.Biggs@Wales.nhs.uk. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

IV. Research & Development Approval Letter

GIG CYMRU NHS WALES | Bwrdd Iechyd Prifysgol Betsi Cadwaladr University Health Board

Panel Arolygu Mewnol Y&D - Canolog
R&D Internal Review Panel

Betsi Cadwaladr University Health Board
Ysbyty Gwynedd
Clinical Academic Office
Bangor, Gwynedd
LL57 2PW

Chairman/Cadeirydd – Dr Nefyn Williams PhD, FRCGP
Email: rossela.roberts@wales.nhs.uk
debra.slater@wales.nhs.uk
sion.lewis@wales.nhs.uk
Tel/Fax: 01248 384 877

Mr Christopher Byrne
Trainee Clinical Psychologist
North Wales Clinical Psychology Programme
Brigantia Building, Bangor University
Bangor
LL57 2DG psp2c8@bangor.ac.uk

03rd June 2015

Dear Mr Byrne

Re: Confirmation that R&D governance checks are complete / R&D approval granted

Study Title	Psychological factors in subjective CI in TBI
IRAS reference	168056
REC reference	15/WA/0165

The above research project was reviewed at the meeting of the BCUHB R&D Internal Review Panel

Thank you for responding to the Panel's request for further information. The R&D office considered the response on behalf of the Panel and is satisfied with the scientific validity of the project, the risk assessment, the review of the NHS cost and resource implications and all other research management issues pertaining to the revised application.

The Internal Review Panel is pleased to confirm that all governance checks are now complete and to grant approval to proceed at Betsi Cadwaladr University Health Board (BCUHB) sites as described in the application.

The documents reviewed and approved are listed below:

Document:	Version	Date
R&D Form	V4.0.0	23/04/2015
SSI Form	V4.0.0	23/04/2015
Protocol	V1	23/04/2015
Participant Information Sheet	V1	23/04/2015
Consent Form	V1	23/04/2015
Questionnaire – Cognitive Failure		1982
Questionnaire – HADS (Hospital Anxiety and Depression Scale)		No date
Questionnaire – HAI (Health Anxiety Inventory)		No date
Client Service Receipt Inventory - Needs and Costs Form		
Summary CV: Byrne		Undated
Summary CV: Addy	V1	23/04/2015
Evidence of Insurance (UMAL)		Expires 31/07/2015
REC Provisional Opinion Letter		13/05/2015
Risk Assessment		23/04/2015

All research conducted at the Betsi Cadwaladr University Health Board (BCUHB) sites must comply with the Research Governance Framework for Health and Social Care in Wales (2009). An electronic link to this document is provided on the BCUHB R&D WebPages. Alternatively, you may obtain a paper copy of this document via the R&D Office.

Attached you will find a set of approval conditions outlining your responsibilities during the course of this research. Failure to comply with the approval conditions will result in the withdrawal of the approval to conduct this research in the Betsi Cadwaladr University Health Board.

If your study is adopted onto the NISCHR Clinical Research Portfolio (CRP), it will be a condition of this NHS research permission, that the Chief Investigator will be required to regularly upload recruitment data onto the portfolio database. To apply for adoption onto the NISCHR CRP, please go to: http://www.wales.nhs.uk/sites3/page.cfm?orgid=580&pid=31979. Once adopted, NISCHR CRP studies may be eligible for additional support through the NISCHR Clinical Research Centre. Further information can be found at:http://www.wales.nhs.uk/sites3/page.cfm?orgid=580&pid=28571 and/or from your NHS R&D office colleagues.

To upload recruitment data, please follow this link:
http://www.crncc.nihr.ac.uk/about_us/processes/portfolio/p_recruitment.
Uploading recruitment data will enable NISCHR to monitor research activity within NHS organizations, leading to NHS R&D allocations which are activity driven. Uploading of recruitment data will be monitored by your colleagues in the R&D office. If you need any support in uploading this data, please contact debra.slater@wales.nhs.uk or sion.lewis@wales.nhs.uk

If you would like further information on any other points covered by this letter please do not hesitate to contact me.

On behalf of the Panel, may I take this opportunity to wish you every success with your research.

Yours sincerely,

Dr Nefyn Williams PhD, FRCGP
Associate Director of R&D
Chairman Internal Review Panel

Copy to:

Sponsor:	Mr Hefin Francis School of Psychology Brigantia, Bangor University Bangor LL57 2AS	h.francis@bangor.ac.uk
Academic Supervisor:	Dr Karen Addy The North Wales Brain injury Service Hesketh Road Colwyn Bay LL29 8AY	karen.addy@wales.nhs.uk

V. Participant Consent Form – English

RESEARCH INFORMED CONSENT FORM

Title of Study - Investigating the role of psychological factors in the perception of cognitive impairment following Acquired Brain Injury.

Lead Researcher – Christopher Byrne email – psp2c8@bangor.ac.uk

Research Supervisor - Dr Rudi Coetzer email – Rudi.Coetzer@wales.nhs.uk

Please read the following statements and, if you agree, initial the corresponding box to confirm agreement:

I confirm that I have been provided with, read, and understand the information sheet for the above study. I have also had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason. ☐

I understand that my data will be treated confidentially and any publication resulting from this work will report only data that does **not** identify me. ☐

I understand that if I disclose any information that may suggest I or someone else is in danger then this information will be shared with the relevant authority. ☐

I consent to my lead clinician being informed of my participation in this study. ☐

I freely agree to participate in this study. ☐

Signatures:

Name of participant (block capitals)	**Date**	**Signature**
Researcher (block capitals)	**Date**	**Signature**

If you would like a copy of this consent form to keep, please ask the researcher.
If you wish to make a complaint about the study, you can either contact Betsi Cadwaladr University Health Board Concerns Team, Ysbyty Gwynedd, Bangor, Gwynedd, LL57 2PW. Email: ConcernsTeam.bcu@wales.nhs.uk, Tel: 01248 384194. Or Hefin Francis, School of Psychology, Adeilad Brigantia, Penrallt Road, Gwynedd LL57 2AS, Email: h.francis@bangor.ac.uk, Tel: 01248 388339

VI. Participant Consent Form – Welsh

FFURFLEN CYDSYNIAD GWYBODUS YMCHWIL

Teitl yr Astudiaeth - Ymchwilio i swyddogaeth ffactorau seicolegol wrth ganfod nam gwybyddol yn dilyn anaf i'r ymennydd.

Prif Ymchwilydd – Christopher Byrne e-bost – psp2c8@bangor.ac.uk

Goruchwyliwr Ymchwil - Dr Rudi Coetzer e-bost – Rudi.Coetzer@wales.nhs.uk

A fyddech cystal â darllen y datganiadau canlynol, ac os cytunwch, llofnodwch y bocs cyfatebol i gadarnhau hynny:

Rydw i'n cadarnhau fy mod wedi darllen a deall y daflen wybodaeth ar gyfer yr astudiaeth uchod. Rwyf hefyd wedi cael cyfle i ystyried y wybodaeth a gofyn cwestiynau, ac wedi cael atebion boddhaol.

Rydw i'n deall fy mod yn cymryd rhan yn wirfoddol ac y gallaf dynnu'n ôl unrhyw bryd, heb roi rheswm.
Rydw i'n deall y caiff fy nata eu trin yn gyfrinachol, ac y bydd unrhyw gyhoeddiad sy'n deillio o'r gwaith hwn yn adrodd data nad yw'n datgelu pwy ydwyf yn unig.

Pe bawn yn datgelu unrhyw wybodaeth a allai awgrymu fy mod i neu rywun arall mewn perygl, rwy'n deall wedyn y byddai'r wybodaeth hon yn cael ei rhannu gyda'r awdurdod perthnasol.

Rwy'n cydsynio i'm prif glinigwr gael gwybod fy mod yn cymryd rhan yn yr astudiaeth hon.

Rwy'n cytuno o'm gwirfodd i gymryd rhan yn yr astudiaeth hon.
Llofnodion:

Enw'r sawl sy'n cymryd rhan (priflythrennau)	**Dyddiad**	**Llofnod**
Ymchwilydd (priflythrennau)	**Dyddiad**	**Llofnod**

Os hoffech gael copi o'r ffurflen gydsynio hon, gofynnwch i'r ymchwilydd.
Os ydych chi'n dymuno cwyno am yr astudiaeth, gellwch gysylltu naill ai â Thîm Pryderon Bwrdd Iechyd Prifysgol Betsi Cadwaladr, Ysbyty Gwynedd, Bangor, Gwynedd, LL57 2PW. E-bost: ConcernsTeam.bcu@wales.nhs.uk). Ffôn: 01248 384194. Neu Hefin Francis, Ysgol Seicoleg, Adeilad Brigantia, Ffordd Penrallt, Gwynedd LL57 2AS, E-bost: h.francis@bangor.ac.uk, Ffôn: 01248 388339

VII. Participant Information Sheet – English

Investigating the role of psychological factors in the perception of cognitive impairment following Acquired Brain Injury.

Participant Information Sheet

This information sheet will help you understand why this study is being conducted and what is involved in taking part. Please read this information sheet carefully. You can take your time to read this information and talk to your friends, family and lead clinician before you make any decisions.

If you have any questions you can talk to your lead clinician. Alternatively you can contact the principle investigator (Christopher Byrne) or Dr Rudi Coetzer directly:
Christopher Byrne - psp2c8@bangor.ac.uk or Telephone: 01248 388365
Dr Rudi Coetzer – Rudi.Coetzer@wales.nhs.uk or Telephone (01492) 807770

PART A

We are asking if you would like to take part in a study to investigate how psychological factors influence the perception of cognitive impairment following an Acquired Brain Injury

What is cognitive impairment?
Cognitive impairment is when an individual may have trouble remembering, learning new things, concentrating, or making decisions that affect their everyday life.

Why are we doing this?
Lots of research has been conducted looking into the prognosis of those who have suffered different degrees of Acquired Brain Injury. It is hoped that this study may help to provide clinicians and patients with the knowledge and understanding to address crucial underlying factors associated with persistent perceived cognitive impairment.

Why have I been asked?

This study is being completed within the North Wales Brain Injury Service (NWBIS). We have asked you to take part in this study as you have been previously referred to or attend appointments at the NWBIS. .

Do I have to take part?
No. Your involvement in this study is completely voluntary. This study will be totally separate from the care you receive from the NWBIS. Therefore, any decision you make will not impact the care you receive.

If you do want to take part in the study then we will ask you for your written consent. At any time during the study you can choose to stop taking part without giving any reason. Again, this will not have any impact on your future care.

What will happen to me if I take part?
The researcher will contact you to organize a time and location to meet at your convenience. Once a time and place is organized, you will meet with the researcher to complete three short questionnaires and a series of puzzles. The whole process should take no longer than 1 hour 30 minutes. You may bring someone with you to the appointment if you would like.

Is there anything to be worried about if I take part?
There are some things that it is important to think about:

1. <u>The whole process may take up to 1 hour 30 minutes.</u>
   As you are required to answer questions and complete a series of tasks you may feel fatigued during the process. It is important to know that you can take short breaks whenever you choose. You can also choose to stop the process all together.

2. <u>Some of the questions relate to mental health difficulties such as anxiety and depression</u>
   If you feel distressed by the questions being asked you can choose to stop answering them. You can also highlight your distress with the researcher who will attempt to address your concerns.

What are the possible benefits of taking part?
We cannot promise that the study will have a direct benefit to you, but you may find the process of taking part in this study enjoyable. You may also find it rewarding to take part in a scientific study which is aimed at improving the understanding and knowledge in this area. It is hoped that this research can add to the scientific literature, ultimately helping those with persistent cognitive impairment following Acquired Brain Injury.

If you would like to receive a summary of the findings please let the researcher know. Following the completion of the study we will send you a letter outlining our findings.

PART B

Additional Information

What happens when the study stops?
The whole study is likely to stop in July 2016. If you choose to, you can be sent a summary of the findings when it is finished.

What about if I don't want to be in the study anymore but I have completed the questionnaire and tasks?
All your data from the study is completely anonymised and cannot be traced back to you. However, should you want your data removed from the study then you can contact the researcher – Christopher Byrne. This decision will have to be made before January 2016 as following this time the data will have been collated and analyzed. The anonymised and collated data will be securely held in the North Wales Clinical Psychology Programme for up to five years.

Will anyone else know I'm doing this?
You involvement in this study is completely confidential. However, if you say something that makes us think that you, or someone else, is in danger then we would have to share what you tell us with your clinical team for further discussion and possible action. This is unlikely but we would let you know if we needed to do this.

Who is organising and funding the study?

The study is being done as part of Christopher Byrne's (Principle Investigator) training to become a Clinical Psychologist. Therefore, the study is organised by the North Wales Clinical Psychology Programme, Bangor University. The study is also organized and supervised through the NHS.

Who has reviewed the study?
The study has been checked and approved by ethics departments in both Bangor University and the NHS Research Ethics Committee. This is to ensure that the research is fair to those who participate in the study.

Important contact details:
If you wish to make a complaint about the study, you can either contact Betsi Cadwaladr University Health Board Concerns Team, Ysbyty Gwynedd, Bangor, Gwynedd, LL57 2PW
Email: ConcernsTeam.bcu@wales.nhs.uk, Tel: 01248 384194.
Or Hefin Francis, School of Psychology, Adeilad Brigantia, Penrallt Road, Gwynedd LL57 2AS, Email: h.francis@bangor.ac.uk, Tel: 01248 388339

Thank you.

Christopher Byrne
Trainee Clinical Psychologist
Betsi Cadwalar University Health Board
North Wales Clinical Psychology Programme
School of Psychology
Bangor University
Bangor
LL57 2DG

VIII. Participant Information Sheet – Welsh

Ymchwilio i swyddogaeth ffactorau seicolegol wrth ganfod nam gwybyddol yn dilyn anaf i'r ymennydd.

Taflen Wybodaeth i Gyfranogwyr

Bydd y daflen wybodaeth hon yn eich helpu i ddeall y rheswm dros wneud yr astudiaeth hon a'r hyn fydd yn digwydd wrth gymryd rhan. Darllenwch y daflen wybodaeth hon yn ofalus. Gellwch gymryd eich amser i ddarllen y wybodaeth hon a'i thrafod â ffrindiau, teulu a'r prif glinigwr, cyn i chi wneud unrhyw benderfyniadau.

Os oes gennych unrhyw gwestiynau, gallwch siarad â'ch prif glinigwr. Fel arall, gellwch gysylltu â'r prif ymchwilydd (Christopher Byrne) neu Dr Rudi Coetzer yn uniongyrchol:
Christopher Byrne - psp2c8@bangor.ac.uk neu ffoniwch: 01248 388365
Dr Rudi Coetzer - Rudi.Coetzer@wales.nhs.uk neu ffoniwch (01492) 807770

RHAN A

Rydym yn gofyn a fyddech yn hoffi cymryd rhan mewn astudiaeth sy'n edrych ar sut mae ffactorau seicolegol yn dylanwadu ar ganfod nam gwybyddol yn dilyn anaf i'r ymennydd.

Beth yw nam gwybyddol?
Nam gwybyddol yw pan fo unigolyn o bosib yn cael anhawster cofio, dysgu pethau newydd, canolbwyntio, neu wneud penderfyniadau sy'n effeithio ar eu bywyd bob dydd.

Pam ydym ni'n gwneud hyn?
Mae llawer o ymchwil wedi'i chynnal sy'n edrych ar brognosis y rhai sydd wedi dioddef gwahanol raddau o anaf i'r ymennydd. Gobeithir y bydd yr astudiaeth hon yn helpu i roi gwybodaeth a dealltwriaeth i glinigwyr i ymdrin â ffactorau sylfaenol hollbwysig sy'n gysylltiedig â nam gwybyddol ymddangosiadol parhaus.

Pam y gofynnwyd imi gymryd rhan?
Mae'r astudiaeth yn cael ei gwneud o fewn Gwasanaeth Anaf i'r Ymennydd Gogledd Cymru (NWBIS). Rydym ni wedi gofyn i chi gymryd

rhan yn yr astudiaeth hon oherwydd i chi gael eich cyfeirio at NWBIS yn y gorffennol, neu'n mynd i apwyntiadau yno. .

Oes rhaid imi gymryd rhan?
Nac oes. Mae cymryd rhan yn yr astudiaeth hon yn hollol wirfoddol. Bydd yr astudiaeth hon yn gyfan gwbl ar wahân i'r gofal a dderbyniwch gan NWBIS. Felly, ni fydd unrhyw benderfyniad a wnewch yn effeithio ar y gofal a dderbyniwch.

Os ydych am gymryd rhan yn yr astudiaeth, byddwn yn gofyn am eich cydsyniad ysgrifenedig. Gellwch roi'r gorau i gymryd rhan unrhyw bryd yn ystod yr astudiaeth, a hynny heb roi rheswm. Eto, ni fydd hyn yn cael unrhyw effaith ar eich gofal yn y dyfodol.

Beth fydd yn digwydd i mi os byddaf yn cymryd rhan?
Bydd yr ymchwilydd yn cysylltu â chi i drefnu amser a lleoliad cyfleus i gyfarfod â chi. Ar ôl trefnu amser a lle, byddwch yn cyfarfod â'r ymchwilydd i gwblhau'r tri holiadur byr a chyfres o bosau. Ni ddylai'r broses gyfan gymryd mwy nag awr a hanner. Gellwch ddod â rhywun gyda chi i'r cyfarfod os dymunwch.

Oes yna unrhyw beth i boeni amdano os bydda i'n cymryd rhan?
Mae yna rai pethau y mae'n bwysig meddwl amdanyn nhw:

1. <u>Gall y broses gyfan gymryd hyd at awr a hanner.</u>
   Oherwydd y gofynnir i chi ateb cwestiynau a chwblhau cyfres o dasgau, efallai y byddwch yn teimlo wedi blino yn ystod y broses. Mae'n bwysig gwybod y gellwch gymryd egwyl fer pryd bynnag yr ydych yn dewis. Gellwch hefyd ddewis rhoi'r gorau i'r broses yn gyfan gwbl.

2. <u>Mae rhai o'r cwestiynau'n ymwneud ag anawsterau iechyd meddwl fel pryder ac iselder</u>
   Os ydych yn teimlo bod unrhyw rai o'r cwestiynau'n peri gofid ichi, nid oes raid i chi eu hateb. Gellwch hefyd sôn am eich gofid gyda'r ymchwilydd a fydd yn ceisio mynd i'r afael â'ch pryderon.

Beth yw'r manteision posibl o gymryd rhan?
Ni fedrwn addo y bydd mantais uniongyrchol i chi o'r astudiaeth, ond efallai y byddwch yn gweld cymryd rhan yn yr astudiaeth yn brofiad

pleserus. Efallai hefyd y bydd cymryd rhan mewn astudiaeth wyddonol sydd â'r nod o wella'r ddealltwriaeth a'r wybodaeth yn y maes hwn yn rhoi boddhad i chi. Gobeithir y bydd yr ymchwil hon yn gallu ychwanegu at ddeunydd darllen gwyddonol, gan helpu'r rhai sydd â nam gwybyddol parhaus yn dilyn anaf i'r ymennydd yn y pen draw.

Os hoffech gael crynodeb o'r canlyniadau, a fyddech cystal â rhoi gwybod i'r ymchwilydd. Ar ôl cwblhau'r astudiaeth byddwn yn anfon llythyr atoch yn nodi ein canfyddiadau.

RHAN B

Gwybodaeth Ychwanegol

Beth fydd yn digwydd pan fydd yr astudiaeth yn gorffen?
Bydd yr astudiaeth gyfan yn debygol o ddod i ben ym mis Gorffennaf 2016. Os dewiswch hynny, gellir anfon crynodeb o'r canfyddiadau atoch pan fydd wedi gorffen.

Beth os na fydda'i eisiau bod yn rhan o'r astudiaeth mwyach, ond fy mod i wedi llenwi'r holiadur ac wedi gwneud y tasgau?
Bydd eich holl ddata o'r astudiaeth yn hollol ddienw, ac ni ellir ei olrhain yn ôl i chi. Fodd bynnag, os dymunwch i'ch data gael ei dynnu o'r astudiaeth, yna gellwch gysylltu â'r ymchwilydd – Christopher Byrne. Bydd yn rhaid penderfynu hyn cyn Ionawr 2016, oherwydd ar ôl yr amser hwn bydd y data wedi cael ei gasglu a'i ddadansoddi. Bydd y data dienw a gasglwyd yn cael eu cadw'n ddiogel yn Rhaglen Seicoleg Glinigol Gogledd Cymru am hyd at bum mlynedd.

Fydd unrhyw un arall yn gwybod fy mod i'n gwneud hyn?
Mae eich rhan yn yr astudiaeth hon yn hollol gyfrinachol. Os byddwch yn dweud rhywbeth fydd yn gwneud i ni feddwl eich bod chi, neu rywun arall, mewn perygl, yna byddai'n rhaid i ni rannu'r hyn y gwnaethoch ei ddweud wrthym ni gyda'ch tîm clinigol i'w drafod ymhellach, ac o bosib gweithredu ar hynny. Nid yw hynny'n debyg o ddigwydd ond byddem yn rhoi gwybod i chi pe bai'n rhaid i ni wneud hynny.

Pwy sy'n trefnu a chyllido'r astudiaeth?
Mae'r astudiaeth yn cael ei gwneud fel rhan o hyfforddiant Christopher Byrne (Prif Ymchwilydd) i fod yn Seicolegydd Clinigol. Trefnir yr astudiaeth felly gan Raglen Seicoleg Glinigol Gogledd Cymru, Prifysgol

Bangor. Mae'r astudiaeth hefyd yn cael ei threfnu a'i goruchwylio drwy'r GIG.

Pwy sydd wedi adolygu'r astudiaeth?
Mae'r astudiaeth wedi cael ei hadolygu a'i chymeradwyo gan adrannau moeseg ym Mhrifysgol Bangor a chan Bwyllgor Moeseg Ymchwil y Gwasanaeth Iechyd Gwladol. Diben hyn yw sicrhau bod yr ymchwil yn deg i'r rhai sy'n cymryd rhan yn yr astudiaeth.

Manylion cysylltu pwysig:
Os ydych chi'n dymuno cwyno am yr astudiaeth, gellwch gysylltu â Thîm Pryderon Bwrdd Iechyd Prifysgol Betsi Cadwaladr, Ysbyty Gwynedd, Bangor, Gwynedd, LL57 2PW
E-bost: ConcernsTeam.bcu@wales.nhs.uk, Ffôn: 01248 384194.
Neu Hefin Francis, Ysgol Seicoleg, Adeilad Brigantia, Ffordd Penrallt, Gwynedd LL57 2AS, E-bost: h.francis@bangor.ac.uk, Ffôn: 01248 388339

Diolch.

Christopher Byrne
Seicolegydd Clinigol dan Hyfforddiant
Bwrdd Iechyd Prifysgol Betsi Cadwaladr
Rhaglen Seicoleg Glinigol Gogledd Cymru
Ysgol Seicoleg
Prifysgol Bangor
Bangor
LL57 2DG

IX. Cognitive Failures Questionnaire

The Cognitive Failures Questionnaire (Broadbent, Cooper, FitzGerald & Parkes, 1982)

The following questions are about minor mistakes which everyone makes from time to time, but some of which happen more often than others. We want to know how often these things have happened to your in the past 6 months. Please circle the appropriate number.

		Very often	Quite often	Occasion-ally	Very rarely	Never
1.	Do you read something and find you haven't been thinking about it and must read it again?	4	3	2	1	0
2.	Do you find you forget why you went from one part of the house to the other?	4	3	2	1	0
3.	Do you fail to notice signposts on the road?	4	3	2	1	0
4.	Do you find you confuse right and left when giving directions?	4	3	2	1	0
5.	Do you bump into people?	4	3	2	1	0
6.	Do you find you forget whether you've turned off a light or a fire or locked the door?	4	3	2	1	0
7.	Do you fail to listen to people's names when you are meeting them?	4	3	2	1	0
8.	Do you say something and realize afterwards that it might be taken as insulting?	4	3	2	1	0
9.	Do you fail to hear people speaking to you when you are doing something else?	4	3	2	1	0
10.	Do you lose your temper and regret it?	4	3	2	1	0
11.	Do you leave important letters unanswered for days?	4	3	2	1	0
12.	Do you find you forget which way to turn on a road you know well but rarely use?	4	3	2	1	0
13.	Do you fail to see what you want in a supermarket (although it's there)?	4	3	2	1	0
14.	Do you find yourself suddenly wondering whether you've used a word correctly?	4	3	2	1	0

		Very often	Quite often	Occasion-ally	Very rarely	Never
15.	Do you have trouble making up your mind?	4	3	2	1	0
16.	Do you find you forget appointments?	4	3	2	1	0
17.	Do you forget where you put something like a newspaper or a book?	4	3	2	1	0
18.	Do you find you accidentally throw away the thing you want and keep what you meant to throw away – as in the example of throwing away the matchbox and putting the used match in your pocket?	4	3	2	1	0
19.	Do you daydream when you ought to be listening to something?	4	3	2	1	0
20.	Do you find you forget people's names?	4	3	2	1	0
21.	Do you start doing one thing at home and get distracted into doing something else (unintentionally)?	4	3	2	1	0
22.	Do you find you can't quite remember something although it's "on the tip of your tongue"?	4	3	2	1	0
23.	Do you find you forget what you came to the shops to buy?	4	3	2	1	0
24.	Do you drop things?	4	3	2	1	0
25.	Do you find you can't think of anything to say?	4	3	2	1	0

References

Broadbent, D.E., Cooper, P.F., FitzGerald, P., & Parkes, K.R. (1982). The Cognitive Failures Questionnaire (CFQ) and its correlates. *British Journal of Clinical Psychology*, *21*, 1-16.

X. Hospital Anxiety and Depression Scale (HADS)

Hospital Anxiety and Depression Scale (HADS)

Tick the box beside the reply that is closest to how you have been feeling in the past week.
Don't take too long over you replies: your immediate is best.

D	A		D	A	
		I feel tense or 'wound up':			**I feel as if I am slowed down:**
	3	Most of the time	3		Nearly all the time
	2	A lot of the time	2		Very often
	1	From time to time, occasionally	1		Sometimes
	0	Not at all	0		Not at all
		I still enjoy the things I used to enjoy:			**I get a sort of frightened feeling like 'butterflies' in the stomach:**
0		Definitely as much		0	Not at all
1		Not quite so much		1	Occasionally
2		Only a little		2	Quite Often
3		Hardly at all		3	Very Often
		I get a sort of frightened feeling as if something awful is about to happen:			**I have lost interest in my appearance:**
	3	Very definitely and quite badly	3		Definitely
	2	Yes, but not too badly	2		I don't take as much care as I should
	1	A little, but it doesn't worry me	1		I may not take quite as much care
	0	Not at all	0		I take just as much care as ever
		I can laugh and see the funny side of things:			**I feel restless as I have to be on the move:**
0		As much as I always could		3	Very much indeed
1		Not quite so much now		2	Quite a lot
2		Definitely not so much now		1	Not very much
3		Not at all		0	Not at all
		Worrying thoughts go through my mind:			**I look forward with enjoyment to things:**
	3	A great deal of the time	0		As much as I ever did
	2	A lot of the time	1		Rather less than I used to
	1	From time to time, but not too often	2		Definitely less than I used to
	0	Only occasionally	3		Hardly at all
		I feel cheerful:			**I get sudden feelings of panic:**
3		Not at all		3	Very often indeed
2		Not often		2	Quite often
1		Sometimes		1	Not very often
0		Most of the time		0	Not at all
		I can sit at ease and feel relaxed:			**I can enjoy a good book or radio or TV program:**
	0	Definitely	0		Often
	1	Usually	1		Sometimes
	2	Not Often	2		Not often
	3	Not at all	3		Very seldom

Please check you have answered all the questions

Scoring:

Total score: Depression (D) _____ Anxiety (A) _____

0-7 = Normal

8-10 = Borderline abnormal (borderline case)

11-21 = Abnormal (case)

XI. Health Anxiety Inventory (HAI-18)

HAI

name: _____
date: _____

Each question is this section consists of a group of four statements. Please read each group of statements carefully and then select the one which best describes your feelings, over the past six months (or other agreed time period). Identify the statement by ringing the letter next to it, i.e. if you think that statement *a.)* is correct, ring statement *a.)*. It may be that more than one statement applies, in which case, please ring any that are applicable.

1. *a.)* I do not worry about my health.
b.) I occasionally worry about my health.
c.) I spend much of my time worrying about my health.
d.) I spend most of my time worrying about my health.

2. *a.)* I notice aches/pains less than most other people (of my age).
b.) I notice aches/pains as much as most other people (of my age).
c.) I notice aches/pains more than most other people (of my age).
d.) I am aware of aches/pains in my body all the time.

3. *a.)* as a rule I am not aware of bodily sensations or changes.
b.) sometimes I am aware of bodily sensations or changes.
c.) I am often aware of bodily sensations or changes.
d.) I am constantly aware of bodily sensations or changes.

4. *a.)* resisting thoughts of illness is never a problem.
b.) most of the time I can resist thoughts of illness.
c.) I try to resist thoughts of illness but am often unable to do so.
d.) thoughts of illness are so strong that I no longer even try to resist them.

5. *a.)* as a rule I am not afraid that I have a serious illness.
b.) I am sometimes afraid that I have a serious illness.
c.) I am often afraid that I have a serious illness.
d.) I am always afraid that I have a serious illness.

6. *a.)* I do not have images (mental pictures) of myself being ill.
b.) I occasionally have images of myself being ill.
c.) I frequently have images of myself being ill.
d.) I constantly have images of myself being ill.

7. *a.)* I do not have any difficulty taking my mind off thoughts about my health.
b.) I sometimes have difficulty taking my mind off thoughts about my health.
c.) I often have difficulty in taking my mind off thoughts about my health.
d.) Nothing can take my mind off thoughts about my health.

8. *a.)* I am lastingly relieved if my doctor tells me there is nothing wrong.
b.) I am initially relieved but the worries sometimes return later.

c.) I am initially relieved but the worries always return later.
d.) I am not relieved if my doctor tells me there is nothing wrong.

9. *a.)* if I hear about an illness I never think I have it myself.
b.) if I hear about an illness I sometimes think I have it myself.
c.) if I hear about an illness I often think I have it myself.
d.) if I hear about an illness I always think I have it myself.

10. *a.)* if I have a bodily sensation or change I rarely wonder what it means.
b.) if I have a bodily sensation or change I often wonder what it means.
c.) if I have a bodily sensation or change I always wonder what it means.
d.) if I have a bodily sensation or change I must know what it means.

[cont.]

11. a.) I usually feel at very low risk for developing a serious illness.
b.) I usually feel at fairly low risk for developing a serious illness.
c.) I usually feel at moderate risk for developing a serious illness.
d.) I usually feel at high risk for developing a serious illness.

12. *a.)* I never think I have a serious illness.
b.) I sometimes think I have a serious illness.
c.) I often think I have a serious illness.
d.) I usually think that I am seriously ill.

13. *a.)* if I notice an unexplained bodily sensation I don't find it difficult to think about other things.
b.) if I notice an unexplained bodily sensation I sometimes find it difficult to think about other things.
c.) if I notice an unexplained bodily sensation I often find it difficult to think about other things.
d.) if I notice an unexplained bodily sensation I always find it difficult to think about other things.

14. *a.)* my family/friends would say I do not worry enough about my health.
b.) my family/friends would say I have a normal attitude to my health.
c.) my family/friends would say I worry too much about my health.
d.) my family/friends would say I am a hypochondriac.

For the following questions, please think about what it might be like if you had a serious illness of a type which particularly concerns you (e.g. heart disease, cancer, multiple sclerosis & so on). Obviously you cannot know for definite what it would be like; please give your best estimate of what you *think* might happen, basing your estimate on what you know about yourself and serious illness in general.

15. *a.)* if I had a serious illness I would still be able to enjoy things in my life quite a lot.
b.) if I had a serious illness I would still be able to enjoy things in my life a little.
c.) if I had a serious illness I would be almost completely unable to enjoy things in my life.

d.) if I had a serious illness I would be completely unable to enjoy life at all.

16. *a.)* if I developed a serious illness there is a good chance that modern medicine would be able to cure me.
b.) if I developed a serious illness there is a moderate chance that modern medicine would be able to cure me.
c.) if I developed a serious illness there is a very small chance that modern medicine would be able to cure me.
d.) if I developed a serious illness there is no chance that modern medicine would be able to cure me.

17. *a.)* a serious illness would ruin some aspects of my life.
b.) a serious illness would ruin many aspects of my life.
c.) a serious illness would ruin almost every aspect of my life.
d.) a serious illness would ruin every aspect of my life.

18. *a.)* if I had a serious illness I would not feel that I had lost my dignity.
b.) if I had a serious illness I would feel that I had lost a little of my dignity.
c.) if I had a serious illness I would feel that I had lost quite a lot of my dignity.
d.) if I had a serious illness I would feel that I had totally lost my dignity.

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all groups are scored 0, 1, 2 or 3 depending on the statement selected; if more than statement is selected, use the highest-scoring statement of those chosen.

main section score (questions 1 to 14) =

negative consequences score (questions 15 to 18) =

total score =

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scoring the 18 item HAI

In the 2002 paper describing the development of both the full Health Anxiety Inventory and this current shortened 18 item version, the following scores were reported for the shortened form in a series of different populations. The table below gives means (and standard deviations):

	health anxiety	*anxiety sufferers*	*controls*	*students*	*gp patients*	*gastro patients*
main section	30.1 (5.5)	14.9 (6.2)	9.4 (5.1)	9.6 (4.5)	11.2 (4.6)	11.4 (6.3)
negative consequences	7.8 (2.8)	3.6 (2.2)	2.2 (2.1)	3.0 (1.8)	3.2 (2.0)	2.4 (1.9)
total score	37.9 (6.8)	18.5 (7.3)	12.2 (6.2)	12.6 (5.0)	14.5 (5.9	13.9 (7.4)

At an initial assessment, it is probably appropriate to ask these questions about the last six months. When monitoring treatment, applying the scale questions to the last week is more usual.

Salkovskis P.M., Rimes K.A., Warwick H.M.C. & Clark D.M. *The health anxiety inventory: development and validation of scales for the measurement of health anxiety and hypochondriasis* Psychological Medicine 2002;32:843-853

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