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The Psychosocial Impact and Outcomes of Brain Injury

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Declaration

I hereby declare that this thesis is the results of my own investigations, except where otherwise stated. All other sources are acknowledged by bibliographic references. This work has not previously been accepted in substance for any degree and is not being concurrently submitted in candidature for any degree unless, as agreed by the University, for approved dual awards.

Signed: ……

Date: ……

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Thesis Abstract

This thesis aimed to explore the psychosocial impact and outcomes following brain injury, and comprises of the following chapters;

The first chapter consists of a systematic literature review and meta-analysis, investigating the efficacy of Cognitive Behavioural Therapy (CBT) based interventions at reducing anxiety symptoms following traumatic brain injury (TBI). Ten randomised controlled trials met the identified inclusion criteria. The results of the meta-analysis revealed a small, but statistically significant main effect of CBT at reducing symptoms of anxiety in individuals who had sustained a TBI. The clinical implications and limitations of this review are discussed.

The second chapter contains an exploratory research study investigating potential associations between cognitive functioning, self-awareness and social isolation following acquired brain injury. Twenty-seven participants were recruited from a community brain injury rehabilitation service and completed questionnaires and neuropsychological measures investigating self-awareness, social isolation and cognitive functioning (i.e. working memory, mental flexibility and disinhibition). Results indicated that general cognitive functioning was not associated with self-reported experiences of social isolation, however increased disinhibition and reduced self-awareness were associated with greater quantity of family contact, but not acquaintances. Poor self-awareness, specifically the underestimation of difficulties, may be protective against emotional loneliness. Demographic factors, including rurality and marital status are likely also important. Clinical implications, considerations for future research and limitations of this study are discussed.

The final chapter explores the outcomes of the meta-analysis and empirical paper, considering implications for theory, research and clinical practice. A reflective commentary concludes the thesis.

List of Abbreviations

ABI	Acquired Brain Injury
ACT	Acceptance and Commitment Therapy
AQ	Awareness Questionnaire
CBT	Cognitive Behavioural Therapy
CVA	Cerebrovascular Accident
DJGLS-6	De Jong Gierveld Loneliness Scale (6-item)
DS	Digit Span
HSCT	Hayling Sentence Completion Task
LSNS-6	Lubbens Social Network Scale-6
MBCT	Mindfulness Based Cognitive Therapy
MI	Motivational Interviewing
PCS	Post-Concussion Syndrome
RCT	Randomised Control Trial
TBI	Traumatic Brain Injury
TMT	Trail Making Task
WAIS-IV	Wechsler Adult Intelligence Scale-IV

Chapter 1

Meta-Analysis and Systematic Literature Review

Instructions for Authors – Neuropsychological Rehabilitation

https://www.tandfonline.com/action/authorSubmission?show=instructions&journalCode=pnrh20

The Effectiveness of Cognitive Behaviour Therapy for Reducing Anxiety Symptoms following Traumatic Brain Injury: A Meta-Analysis and Systematic Review.

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This paper will be submitted to *Neuropsychological Rehabilitation* and will therefore follow the submission guidelines for the journal.

Abstract

Anxiety is a common neuropsychological sequalae following traumatic brain injury (TBI). Cognitive Behaviour Therapy (CBT) is a recommended, first-line intervention for anxiety disorders in the non-TBI clinical population, however its effectiveness after TBI remains unclear and findings are inconsistent. To the authors' knowledge, there are no current meta-analyses exploring the efficacy of CBT as an intervention for anxiety symptoms following TBI, using controlled trials. The aim of the current study, therefore, was to systematically review and synthesize the controlled evidence for the effectiveness of CBT for anxiety, specifically within the TBI population. A systematic review of intervention studies utilising CBT and anxiety related outcome measures in a TBI population was performed in December 2018. Baseline and outcome data were extracted from the 10 controlled trials that met the inclusion criteria and effect sizes were calculated. A random effects meta-analysis identified a small overall effect size of -0.26 (95% CI -0.41 to -0.11) of CBT interventions reducing anxiety symptoms following TBI. This meta-analysis tentatively supports the view that CBT interventions may be effective in reducing anxiety symptoms following TBI, however the effect sizes are smaller than in non-TBI clinical populations. Clinical implications and limitations of the current meta-analysis are discussed.

Key Words: Traumatic Brain Injury, Cognitive Behavioural Therapy, Anxiety, Meta-analysis

Introduction

Traumatic brain injury (TBI) is defined as an injury to the brain as a result of external force. There are many possible causes of TBI, but they are most commonly caused by road traffic accidents, falls and assaults (Hyder, Wunderlich, Puvanachandra, Gururaj, & Kobusingye, 2007). In the UK, reports estimate that someone is admitted to hospital every three minutes following a TBI (Headway, 2015). TBI is the leading cause of death and disability in the developed world and is currently considered to be a worldwide public health problem (McAllister, 2008; Roozenbeek, Mass, & Menon, 2013; Stocchetti, 2014).

TBI is associated with long-term disability, which can significantly impact daily functioning and quality of life (Hyder et al., 2007). The sequalae following TBI often includes physical and cognitive difficulties (McAllister, 2008) and an increased incidence of psychiatric illness (Deb, Lyons, Koutzoukis, Ali, & McCarthy, 1999; Koponen et al., 2002).

Anxiety and TBI

Anxiety is a commonly reported neuropsychiatric complaint following TBI and is the most prevalent psychiatric diagnosis within the first 12 months post-injury (Gould, Ponsford, Johnston, & Schonberger, 2011). Anxiety symptomology can manifest as apprehension, worry and fear, or as a diagnosable mental health disorder (Soo & Tate, 2012). Post-TBI, individuals are considered to be at increased risk of developing anxiety conditions (Hiott & Labbate, 2002) with the prevalence estimated to range between 11% and 70% (Rao & Lykestos, 2000; Rao & Lykestos, 2002). This wide range in prevalence is likely due to the heterogenous nature of the population and variability in outcome measurements used across studies. In terms of specific anxiety disorders, post-traumatic stress disorder (PTSD; 19%), obsessive compulsive disorder (OCD; 15%); panic disorder (14%), generalised anxiety

disorder (GAD; 9%) and phobias (10%) are most frequently diagnosed following TBI (Hibbard, Uysal, Kepler, Bogdany, & Silber, 1998).

Post-TBI anxiety can hinder the recovery process and result in up to four times poorer functional outcomes and increased impairment (Bryant et al., 2010). Patients who experience anxiety following TBI report significantly increased disability and reduced quality of life (Fann, Katon, Uomoto, & Esselman, 1995; Whitnall, 2006). Anxiety has also been associated with the subjective over-estimation of the severity of physical and cognitive impairments (Fann et al., 1995; Byrne, Coetzer, & Addy, 2017). Effective treatment of anxiety in this population may therefore reduce subjective reporting of physical and cognitive impairments.

Causes of Anxiety after TBI

Neurobiological damage, physical and psychological adjustment, coping style, feelings of grief, loss, and uncertainty regarding the future are all considered to contribute to the aetiology of anxiety following TBI (Williams, Evans, & Fleminger, 2003). Post-injury biopsychosocial models of adjustment consider both direct and indirect influences, in addition to a variety of mediating factors (Lishman 1973; Gainotti 1993; Kendall & Terry; 1996).

Treatments for Anxiety

In non-TBI clinical populations, anxiety is often treated effectively with pharmacotherapy (Murrough, Yaqubi, Sayed, & Charney, 2015; Bandelow et al., 2015). There is evidence however, that pharmacological interventions have limited efficacy in the TBI population. Individuals may be increasingly vulnerable to negative side effects (Warden et al., 2006) and the exacerbation of cognitive difficulties (Perna, Bordini, & Newman, 2001).

The development of effective alternative treatments, including psychological interventions is therefore vital.

Psychological Interventions

Despite the high prevalence of anxiety disorders following TBI and the negative impact they have on rehabilitation outcomes, in comparison to the general clinical population, there has been relatively little research into potential treatments. Within the TBI population, the evidence-base for psychological interventions for anxiety has been steadily expanding over the last 20 years. To date, the intervention that has had the most research within this population, is Cognitive Behaviour Therapy (CBT). CBT is based on the premise that cognitions influence behaviour and emotions, and a change in one of these areas will bring about reciprocal change in the others.

Over recent years there has been increased interest in developing and adapting alternative interventions for use within the TBI population. Such interventions that have been considered, include Acceptance and Commitment Therapy (ACT) and Mindfulness Based Cognitive Therapy (MBCT), which have shown promising results (Kangas & McDonald, 2011; Whiting, Deane, Simpson, & McLeod, 2017; Bedard et al., 2012). The role of exercise as an intervention to reduce anxiety symptoms has also been considered, and results are promising (Gordon et al., 1998; Rzezak et al., 2015; Weinstein, et al., 2017).

CBT for Anxiety in Non-TBI Populations

In the general population CBT is a recommended intervention for the treatment of a range of anxiety disorders (National Institute for Health and Care Excellence [NICE], 2011) There is a wealth of empirical evidence supporting the efficacy of CBT for reducing anxiety symptoms, including several reviews of high-quality meta-analyses (Deacon & Abramowitz,

2004; Norton & Price, 2007). Hoffman, Asnaani, Vonk, Sawyer and Fang (2012) conducted a large-scale review to examine CBT as a treatment for a variety of disorders, including anxiety. Large effect sizes for the treatment of OCD and medium effect sizes for social anxiety disorder, PTSD and panic disorder were reported consistently (Hoffman et al., 2012). In another meta-analysis of 108 clinical trials, Norton and Price (2007) considered the efficacy of CBT across a range of anxiety disorders. CBT resulted in significantly larger effect sizes in comparison to no treatment or control conditions across all the anxiety disorders, particularly GAD and PTSD.

CBT in TBI Populations

Over recent years, CBT has been increasingly used within TBI populations. It has been argued that its highly structured and goal-oriented approach, in addition to a focus on concrete thoughts and behaviours, means that it is an appropriate intervention for individuals with cognitive impairments (Hodgson, McDonald, Tate, & Gertler, 2005; Doering & Exner, 2011). Additional adaptations may also be beneficial to ensure that CBT is accessible to the TBI population. A recent review by Gallagher, McLeod and McMillan (2016) reported that increased socialisation to the CBT model and utilising external memory aids were the most common adaptations used.

In 2007, Soo and Tate conducted a systematic review of the available randomised control trials (RCTs) to investigate the efficacy of psychological treatment for anxiety following TBI. At the time, there were only three RCTs that met the inclusion criteria for their systematic review, examining the efficacy of CBT (Bryant, Moulds, Guthrie & Nixon, 2005; Tiersky et al., 2005) and interpersonal process recall therapy (IPRT; Helffenstein & Wechsler, 1982). They found evidence in support of the effectiveness of CBT for the treatment of acute stress disorder post-TBI and for the combination of CBT and

neurorehabilitation as an intervention for general anxiety symptoms following mild to moderate TBI. They reported limited evidence for the efficacy of IPRT and identified significant flaws in the methodology of this study. Soo and Tate (2007) highlighted the complexity of assessing anxiety within TBI populations; specifically, due to difficulties with differential diagnoses and diagnostic overshadowing.

Much of the current evidence-base is conducted on individuals who have experienced acquired brain injury (ABI), which includes TBI as well as cerebrovascular accidents (CVA). This is often due to difficulties with recruitment within the small TBI population. Although often resulting in similar neuropsychiatric sequalae, it could be argued that the aetiology of TBI and CVA are different (Tateno, Murata, & Robinson, 2002; Werner & Engelhard, 2007), therefore, this meta-analysis will focus on TBI populations only.

The current evidence-base examining the efficacy of treatments for anxiety post-TBI is conflicted and equivocal, with studies utilising a variety of sample sizes, outcome measures, severity of TBI and focus of the intervention. As a result, it is difficult to make comparisons across studies and there is a need to synthesise current research. To the authors' knowledge, there have been no previous meta-analyses of controlled trials specifically investigating CBT as an intervention to treat anxiety symptoms following TBI. The current meta-analysis therefore aims to answer the following question: *Is CBT an effective intervention to reduce anxiety symptoms following TBI?*

Method

Identification and Selection of Studies

Three electronic databases (Web of Science, PubMed and PsychInfo) were searched in December 2018, using the following search terms: ("Cognitive Behav* Therapy" OR "CBT") AND ("anxiety" OR "stress") AND ("traumatic brain injury" OR "TBI" OR "brain injury" OR "head trauma" OR "head injury" OR "brain damage"). The search was limited to English language articles, published since 1990. An ancestral search of the identified articles was also conducted. Articles were screened initially via examination of title and abstract, then full text articles were assessed according to the following eligibility criteria:

I. Participants must be over the age of 18
II. The sample must contain participants who have sustained a TBI of any severity (i.e. mild, moderate or severe)
III. Studies must be controlled trials
IV. Interventions must utilise CBT. For the purpose of this meta-analysis, studies were included if the intervention targeted cognitive and behavioural processes or was underpinned by CBT principles.
V. Studies must include an anxiety related outcome measure.
VI. Study data must be quantitative.

In the case of unreported data, authors were contacted via email, three email reminders were sent to non-responders.

Assessment of Study Quality

The quality of each study was assessed using Reichow, Volkmar and Cicchetti's (2008) criteria, a method with strong psychometric properties. Each individual study was initially appraised for quality using Reichow's (2011) primary and secondary indicators (e.g. participant characteristics, statistical analysis, randomised assignment, social validity) and each indicator was assigned a quality rating of high, acceptable or unacceptable. An overall strength rating of strong, adequate or weak, was then determined for each study (Reichow et al., 2008). Quality ratings are listed in Table 1.

Data Extraction and Analysis

The Metafor package for the statistical software environment, R (The R Foundation, 2018; Viechtbauer, 2010) was used to analyse all data in this meta-analysis. Data from anxiety related measures were extracted from each article by the first author. Email requests and reminders were sent for unreported data if necessary. Wherever possible, data from intention to treat (ITT) analyses were used as this is considered to provide a more pragmatic and unbiased comparison between conditions (Soares & Carneiro, 2002).

The mean change in anxiety score, from pre to post-intervention, divided by the baseline standard deviation, was used to calculate the effect sizes for each RCT. The difference between the effect sizes for the intervention and control group of each study were then analysed (Viechtbauer, 2010). For each outcome measure, correlation coefficients (test re-test reliability) were extracted from the current evidence-base.

Due to the anticipated heterogeneity of interventions and variability in methodological rigour within the identified studies, a random effects meta-analysis model was used. This model is based on the assumption that the true effect size varies between studies and therefore predicts the overall standardised mean change (SMC; Borenstein, Hedges, Higgins

& Rothstein, 2010). Negative effect sizes would indicate an average reduction in anxiety scores from pre to post-intervention. Each study's effect size was then weighted by its sample size and pooled to provide an overall effect size for the effectiveness of CBT at reducing anxiety symptoms. Using Cohen's (1988) criteria, an effect size of 0.2 is considered to be a small effect, 0.5 a medium effect, and 0.8 a large effect.

Results

An initial screening process yielded 938 articles. Following title and abstract examination 871 were excluded as they were found not to be relevant to the research question. The remaining 67 full-text articles were assessed and 11 were found to satisfactorily meet the above inclusion criteria. Unfortunately, one author did not respond to requests for data, therefore 10 studies were included in the meta-analysis. The selection of studies followed the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines (Moher, Liberatti, Tetlzaff & Altman, 2009). See Figure 1 for the PRISMA diagram demonstrating the search process. All 10 of the included studies were RCTs.

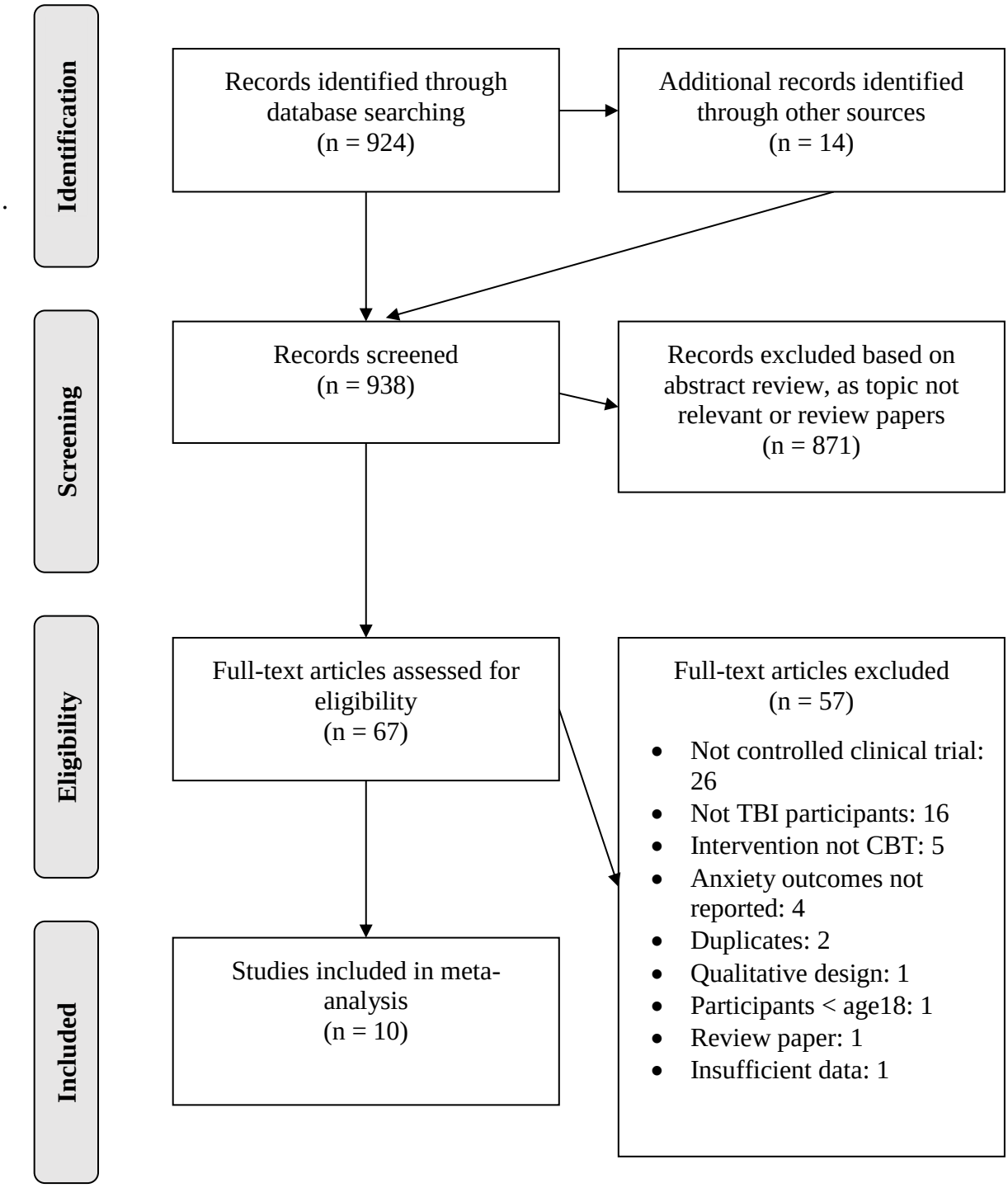

Figure 1. PRISMA diagram (Moher et al., 2009).

Study Characteristics

Methodological Quality

The quality of the included studies was considered to be 'Adequate' (Ashman, Cantor, Tsaousides, Spielman, & Gordon, 2014; Hsieh et al., 2012; Nguyen et al., 2017; Tiersky et al., 2005) or 'Strong' (Bell et al., 2016; Bryant, Moulds, Guthrie, & Nixon, 2003; Cooper et al., 2017; Ponsford et al., 2016; Potter, Brown, & Fleminger, 2016; Silverberg et al., 2013). Out of the 10 articles included, eight stated that they utilised ITT analysis. Tiersky et al. (2005) did not appear to use ITT and Potter et al. (2016) lost one participant to follow up but did not attempt to impute missing data.

Participants

All participants included in the current meta-analysis were over the age of 18 and gave informed consent to participate in the individual studies. All participants were recruited from community samples and had sustained TBIs of varying severity (i.e. mild, moderate or severe). The studies by Bell et al. (2016) and Cooper et al. (2017) used military samples, including only active service members.

Eight of the studies recruited from rehabilitation services, where TBI diagnoses and severity were confirmed by clinicians (Ashman et al., 2014; Bell et al., 2016; Bryant et al., 2003; Cooper et al., 2017; Hsieh et al., 2012; Ponsford et al., 2016; Potter et al., (2016); Silverberg et al., 2013). Nguyen et al. (2017) and Tiersky et al. (2005) relied on self-reported symptoms of loss of consciousness and post traumatic amnesia to confirm TBI.

All the included studies recruited participants that had experienced a TBI at least six months prior to participating in the study, with the exception of the studies by Silverberg et al. (2013) who recruited at six weeks and Bryant et al. (2003) who recruited at two weeks post-injury. In total, 359 participants were randomised to a CBT based intervention and 342

were randomised to a control condition. Several of the included studies required participants to have a diagnosed psychological disorder including anxiety (Hsieh et al., 2012; Ponsford et al., 2016), depression (Ashman et al., 2014; Ponsford et al., 2016), acute stress disorder (Bryant et al., 2003) or be at risk of developing postconcussion syndrome (PCS; Potter et al., 2016).

Trial Design

All of the studies included in the current meta-analysis were RCTs, where participants were randomly allocated to either an intervention or control arm of the trial. Seven of the studies utilised a two-group parallel trial (Ashman et al., 2014; Bell et al., 2016; Bryant et al., 2003; Nguyen et al., 2017; Potter et al., 2016; Silverberg et al., 2013; Tiersky et al., 2005) where participants were randomised to a CBT condition or a control condition. Hsieh et al. (2012) and Ponsford et al. (2015) utilised a three-group parallel trial, adding motivational interviewing (MI) or non-directive counselling (NDC) prior to CBT, in comparison to a control condition. To capture the effect of the CBT, data was extracted from the NDC and CBT condition and the control condition, pre and post-CBT (in the study by Ponsford et al., (2016) data were extracted from week three and week 12). Cooper et al. (2017) utilised a four-group parallel trial, comparing psychoeducation, to computerised cognitive rehabilitation, therapist implemented cognitive rehabilitation and CBT. Pre and post-data were extracted from the psychoeducation and the CBT condition for this study.

Control Conditions

Three of the studies utilised a wait list control (WLC; Potter et al., 2016; Ponsford et al., 2015; Tiersky et al., 2005), three utilised a treatment as usual (TAU) condition (Hsieh et al., 2012, Nguyen et al., 2017; Silverberg et al., 2013), two utilised a psychoeducation

condition; face-to-face (Cooper et al., 2017) or via telephone (Bell et al., 2016) and three studies used various forms of face-to-face counselling or psychotherapy (Ashman et al., 2014; Bryant et al., 2003).

Intervention Type

The studies all administered a CBT based intervention, however they varied in terms of session length, frequency and format of delivery. All the interventions were manualised, to ensure treatment fidelity. All interventions were conducted individually and face-to-face, except for the studies by Cooper et al. (2017) who used a combination of individual and group interventions and Bell et al. (2016) who conducted their CBT informed intervention via telephone call. The length of the interventions varied between 5 and 33 sessions which were delivered over a period of between 5 weeks and 6 months.

The primary focus of the CBT interventions included depression (Ashman et al., 2014; Ponsford et al., 2015), anxiety (Hsieh et al., 2012; Ponsford et al., 2015), acute stress disorder (Bryant et al., 2003), cognitive functioning (Bell et al., 2016; Cooper et al., 2017); postconcussional complaints (Potter et al., 2016; Silverberg et al., 2013), sleep disturbance (Nguyen et al., 2017) and psychological symptoms (Bell et al., 2016; Tiersky et al., 2005).

Despite the differing primary focus of interventions, all incorporated the basic underlying principles of CBT including; psychoeducation, cognitive restructuring, behavioural activation, problem solving and relapse prevention. All studies incorporated structure weekly homework activities, to support participants in the practice and generalisation of skills between sessions.

Adaptations

The studies by Ashman et al. (2014), Hsieh et al. (2012), Nguyen et al. (2017), Ponsford et al. (2016) and Potter et al. (2016) clarified the adaptations made to CBT interventions, to ensure accessibility for TBI populations. Adaptations included incorporating compensatory strategies such as written handouts, external memory aids, simplifying complex concepts, providing organisational support, implementing new strategies *in viv*o where possible. With the exception of Bell et al. (2016) and Cooper et al. (2017), all of the studies stated that their CBT interventions were delivered by professionals who had experience in delivering CBT to TBI populations.

Follow up

Five of the included studies included a follow up to determine maintenance effects. Follow ups took place at two months (Nguyen et al., 2017), 12 and 18 weeks (Cooper et al., 2017) and six months (Bell et al., 2016; Bryant et al., 2003). At 21 weeks, Ponsford et al. (2016) provided a top up CBT session to participant and then re-administered outcome measures at 30 weeks.

Outcome Measures

All the studies included in the current meta-analysis utilised anxiety related outcome measures. These included the Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983), the State Trait Anxiety Inventory (STAI; Spielberger, Gorsuch, Lushene, Vagg, & Jacobs, 1983), the Beck Anxiety Inventory (BAI; Beck, Epstein, Brown, & Steer, 1988), the Symptom Checklist-90-R, (SCL-90-R; Derogatis, 1994) and the PTSD checklist-military version (PCL-M; Weathers, Huska, & Keane, 1991). In the event that multiple anxiety measures were administered, measures were prioritised in the following order,

according to frequency of use across the studies to maximise the consistency of extracted data and improve homogeneity; HADS, BAI, STAI, SCL-90; PCL-M. The main characteristics of the 10 articles included in this meta-analysis are summarised in Table 1 and Table 2.

Table 1. Main Characteristics of Studies Included in the Meta-Analysis.

Author (Year)	Design	TBI Severity	Anxiety Measures	Other Outcome Measure(s)	CBT Intervention (led by)	Focus of the CBT intervention	Setting (location)	Quality rating†
Ashman et al. (2014)	RCT	Mild - Severe	STAI	BDI-II, Life-3, ISEL, LES	16 weekly sessions of manualised individual CBT based on CBT techniques for treating depression (postdoctoral fellows in clinical neuropsychology)	Depression	Community (USA)	Adequate
Bell et al. (2016)	RCT	Mild	PCL-M	BSI-18, RPQ, EuroQol, PSQI, PHQ-9, CD-RISC, B-IFE, AUDIT, SDS, SF-12, CSC	12 bi-weekly telephone sessions of problem-solving therapy based upon CBT principles (Master's level counsellors)	Psychological symptoms	Community, military sample (USA)	Strong
Bryant et al. (2003)	RCT	Mild	BAI	ASDI, IES, BDI, CAPS	5 weekly sessions of manualised individual CBT (clinical psychologists)	Acute stress disorder	Community (Australia)	Strong
Cooper et al. (2017)	RCT	Mild	SCL-90 PCL-M	PASAT, KBCI	10 weekly sessions of manualised individual and group integrated cognitive rehabilitation and CBT. Focus on cognitive restoration and anxiety/depression symptoms (doctoral level psychologists)	Cognitive difficulties.	Community, military sample (USA)	Strong
Hsieh et al. (2012)	RCT	Moderate - Severe	HADS-A DASS	CSA, SPRS-2, SADI,	12 weekly sessions of individual manualised CBT (clinical neuropsychologists)	Anxiety	Community (Australia)	Adequate
Nguyen et al. (2017)	RCT	Mild - Severe	HADS-A	PSQI, ISI, BFI, FSS, ESS	8 weekly sessions of individual manualised CBT (clinical neuropsychologist)	Sleep Disturbance	Community (Australia)	Adequate
Posnford et al. (2015)	RCT	Mild - Severe	HADS-A DASS	SPRS-2	9 weekly sessions of manualised CBT (clinical psychologist or neuropsychologist)	Anxiety and depression	Community (Australia)	Strong
Potter et al. (2016)	RCT	Mild - Moderate	HADS-A STAI	RPQ, BICRO-39, QOLAS, IES-R, CIS20R, MPQ, STAXI-2, EuroQol	12 weekly sessions of individual manualised CBT (clinical neuropsychologist)	Post-concussion complaints	Community (UK)	Strong
Silverberg et al. (2013)	RCT	Mild	HADS-A	RPQ, M2PI, IPQ	6 weekly sessions of individual manualised CBT (doctoral level psychologists with neuropsychology experience)	Post-concussion complaints	Community (Canada)	Strong
Tiersky et al. (2005)	RCT	Mild - Moderate	SCL-90R	PASAT, RAVLT, ACFI, Attention Questionnaire, CRI, SCL-90, CIQ	Individual CBT and cognitive remediation three times a week for 11 weeks (33 sessions) (clinical psychologist with experience in brain injury).	Psychosocial symptoms	Community (USA)	Adequate

† Reichow, 2011; ACFI – Aged Care Funding Instrument; ASDI – Acute Stress Disorder Interview; AUDIT – Alcohol Use Disorders Identification Test; BAI – Beck Anxiety Inventory; BDI – Beck Depression Inventory; BICRO-39 – Brain Injury Community Rehabilitation Outcome Scale; BDI-II – Beck Depression Inventory-II; B-IFE – Brief inventory for Functioning Evaluation; BSI-18 – Brief Symptom Inventory-18; CAPS – Clinician Administered PTSD Scale; CD-RISC – Connor-Davidson Resilience Scale-10; CIQ – Community Integration Questionnaire; CIS20R – Checklist of Individual Strength; CRI – Coping Response Inventory; CSA – Coping Scale for Adults; CSC – Client Satisfaction Scale; DASS – Depression Anxiety Stress Scales; ESS – Epworth Sleepiness Scale; EuroQol – European Quality of Life; GOSE – Glasgow Outcome Scale; HADS – Hospital Anxiety and Depression Scale; HISC – Head Injury Symptom Checklist; FSS - Fatigue Severity Scale; IES-R – Impact of Event Scale-Revised; ISEL – Interpersonal Support Evaluation List; IPQ-R – Illness Perception Questionnaire- Revised; ISI – Insomnia Severity Index; KBCI – Key Behaviour Change Inventory; LES – Life Experiences Survey; M2PI – Mayo-Portland Participation Index; MPQ – McGill Pain Questionnaire; PASAT – The Paced Auditory Serial Addition Task; PHQ-9 – Patient Health Questionnaire-9; PSQI – Pittsburgh Sleep Quality Index; QOLAS – Quality of Life Assessment Schedule; RAVLT – Rey Auditory Verbal Learning Test; RCT – Randomised Controlled Trial; RPQ – Rivermead Postconcussion Symptoms Questionnaire; SADI – The Self-Awareness of Deficits Interview; SPRS-2 – The Sydney Psychosocial Reintegration Scale; STAI – State-Trait Anxiety Inventory; STAXI-2 – State-Trait Anger Expression Inventory-2 SCL-90-R – Symptom Checklist-90-R; SDS – Sheehan Disability Scale; SF-12 – Short Form Health Survey; TBI – Traumatic brain injury; UCL – Utrechtse Coping List.

Table 2. Methodological Characteristics and Findings of Articles Included in the Meta-Analysis.

	Intervention Group					Control Group						
Author (Year)	**N (pre)**	**N (post)**	**Age (M, SD)**	**Gender (% M)**	**Time Since Injury (M, SD)**	**Control Condition**	**N (pre)**	**N (post)**	**Age (M, SD)**	**Gender (% M)**	**Time Since Injury (M, SD)**	**Findings**
Ashman et al. (2014)	39	22	47.1 (10.6)	37.8%	13.3 (16.7) years	Supportive psychotherapy (SPT)	38	21	48.1 (10.2)	48.6%	11.8 (16.9) years	Significant time effects for the BDI, STAI and QOL outcome measures, but no group effect. No significant difference between CBT and SPT intervention groups post-intervention.
Bell et al. (2016)	178	132	29.25 (7.20)	93.26%	Not reported	Psycho-education	178	160	29.44 (7.27)	93.36 %	Not reported	Post-intervention the PST/CBT group demonstrated greater reductions in psychological distress, and PTSD symptoms; but effects not sustained at 12m follow up.
Bryant, et al. (2003)	12	12	29.42 (13.93)	33.3%	< 2 weeks	Supportive counselling (SC)	12	12	33.00 (14.37)	33.3%	< 2 weeks	Significantly fewer participants in the CBT group met criteria for PTSD post-treatment than the SC group (8 % vs 58% respectively). Significant reduction on the BAI for the CBT group.
Cooper et al. (2017)	32	25	32.03 (8.98)	93.8%	306.63 (193.15) days	Psycho-education	32	25	30.09 (7.61)	91.2%	290.71 (161.08) days	Integrated CR and CBT reduced functional cognitive symptoms compared to education only. No statistical analysis for anxiety measure.
Hsieh et al. (2012)	10	10	36.4 (14.1)	70%	50.4 (89.7) months	Treatment as usual (TAU)	8	8	35.6 (9.8)	87.5%	23.0 (18.5) months	Significant reduction in HADS and DASS scores for the CBT groups compared to TAU.
Nguyen et al. (2017)	13	11	45.53 (13.87)	69.23%	795.15 (714.23) days	Treatment as usual (TAU)	11	10	41.90 (12.95)	63.64%	2093.36 (2192.62) days	Significant improvement in sleep quality and reduction in fatigue for CBT group compared to TAU. Secondary improvements were significant on the HADS.
Ponsford et al. (2015)	26	26	39.88 (14.24)	76.9%	3.58 (5.87) years	Waitlist control (WLC)	23	23	39.87 (12.88)	73.9%	2.61 (3.68) years	Significantly greater reduction in HADS scores for the CBT groups compared to WLC.
Potter et al. (2016)	26	25	40.1 (10.3)	58%	23% 6-12m 23%12-24m 54%>24m	Waitlist control (WLC)	20	20	43.1 (13.1)	50% M	35% 6-12m 15%12-24m 50% >24m	Significant increase in quality of life and reduction on anxiety for the CBT group compared to WLC.
Silverberg et al. (2013)	15	13	40.4 (13.5)	40%	23.13 (7.0) days	Treatment as usual (TAU)	13	11	37.5 (10.0)	38%	25.4 (9.1) days	Significantly fewer participants in the CBT group experienced PCS symptoms. Reduction anxiety scores on the HADS (no statistical analysis).
Tiersky et al. (2005)	14	11	47.55 (11.78)	54.5%	5.01 (5.46) years	Wait list control (WLC)	15	9	46.00 (9,35)	32.3%	22.2 (2) years	Significant reduction on the SCL 90-R anxiety subscale for the CBT group compared to WLC.

Effect of CBT at Reducing Anxiety Symptoms

A random-effects model allowed the meta-analysis to predict the overall SMC, based upon the distribution of true effect sizes (Viechtbauer, 2010). See Figure 2 for the forest plot illustrating the meta-analysis of the included 10 studies, for the anxiety outcome measure, following the completion of a CBT informed intervention. The pooled SMC was -0.26 (95% CI -0.41 to -0.11). This represents a small overall effect size of CBT in the reduction of anxiety symptoms following TBI.

The 95% confidence intervals of the overall effect size do not cross the zero threshold, which indicates that the results are statistically significant; however, it could be argued that the margin is close. Tests of heterogeneity were found to be non-significant (p=.09), indicating that the combined estimate is a meaningful description of the included studies.

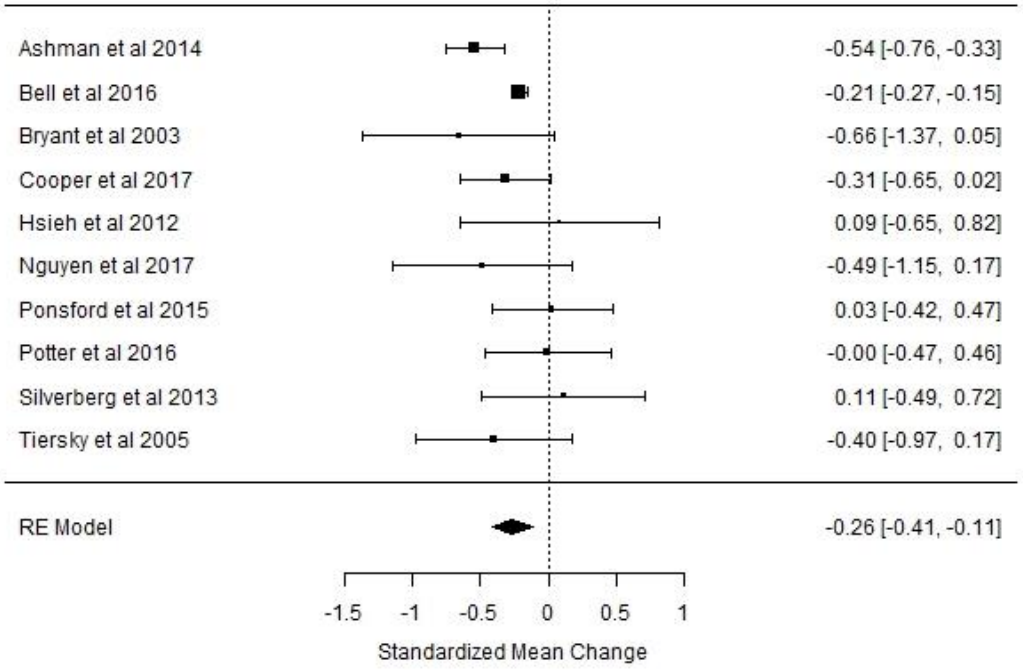

Figure 2. Forest Plot of the Effect size (ES) and 95% Confidence Intervals (CIs) in the 10 Included Studies.

A further conservative analysis was conducted, excluding the studies which did not clearly identify using an ITT analysis (Potter et al., 2016; Tiersky et al., 2005). This resulted in a SMC of -0.27 (95% CI -0.45 to -0.10).

The forest plot demonstrated that the greatest effect size was found by Bryant et al. (2003), which compared CBT to supportive counselling. This study had a very small sample size and large CIs, which cross the line of null effect, therefore indicating a lack of precision and a non-statistically significant result. Two of the studies reported statistically significant effect sizes; Ashman et al. (2014) and Bell et al. (2016). The CBT interventions utilised in these studies were delivered over the longest time periods (16 weeks and 24 weeks respectively). Bell et al. (2016) was the largest study in the meta-analysis which involved telephone interventions within a military sample. The 95% CIs of the remaining eight studies crossed the line of null effect, indicating that a null effect could have been a true effect. Many of the smaller studies had large CIs and were likely underpowered due to small samples.

Publication Bias

To assess for publication bias, a funnel plot of the included studies was created (see Figure 3). An asymmetrical funnel plot would indicate the presence of publication bias. Visual inspection of the funnel plot revealed no obvious evidence of publication bias, given the relatively symmetrical pattern around the SMC. There was evidence of a wide distribution of effect sizes amongst the smaller studies, indicating that smaller studies with small or non-significant results have been published.

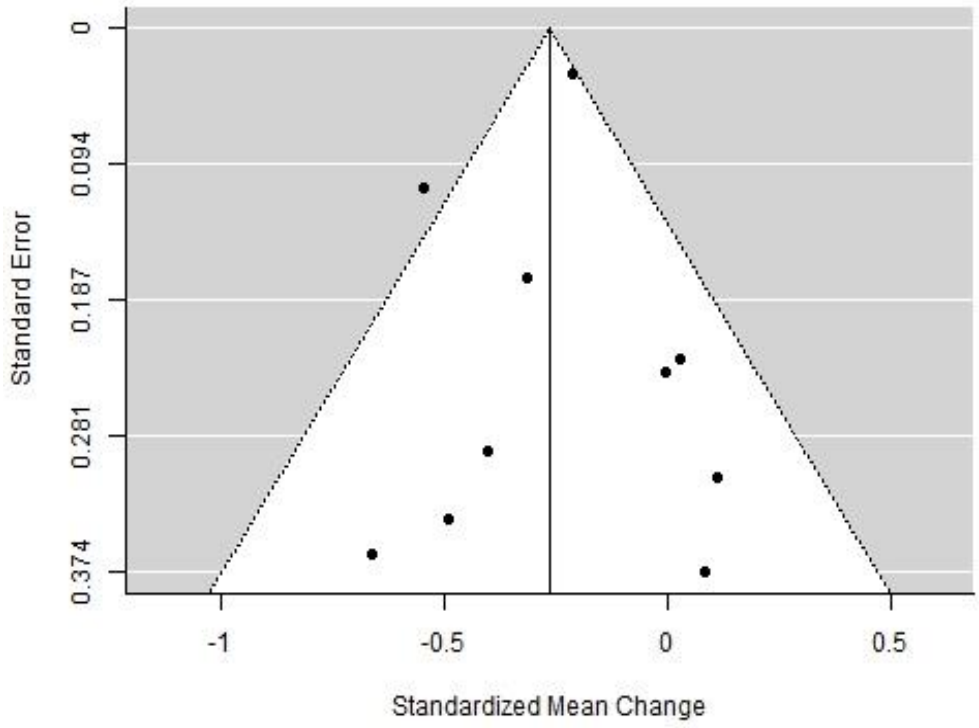

Figure 3. Funnel Plot to Assess for Publication Bias.

Discussion

The current meta-analysis aimed to synthesise the available controlled literature on the effectiveness of CBT for reducing anxiety symptoms following TBI and found a small, but significant effect size (SMC = -0.26). This suggests that following TBI, interventions involving CBT result in a small reduction in anxiety symptoms in comparison to control conditions, suggesting that CBT is the mechanism for change, not just contact with clinicians. The overall effect size found in this meta-analysis falls within all the confidence intervals of the included studies and the effect size of each study falls within the confidence intervals of each other. This supports the homogeneity of the sample and increases the reliability of the current meta-analysis.

The findings from the current meta-analysis are supported by a previous meta-analysis by Waldron, Casserly and O'Sullivan (2013) which was conducted within ABI populations. Waldron and colleagues reported effect sizes ranging from 0 to 0.42 when investigating the efficacy of CBT on reducing anxiety symptoms, with various focuses of the CBT intervention (e.g. social skills, coping etc). The average effect size was 0.17, which is similar to the small effect size reported in this meta-analysis. The overall effect size reported in this meta-analysis is smaller than the medium to large effect sizes that have been found in non-TBI clinical populations. This could suggest that CBT is not as effective at reducing symptoms of anxiety within the TBI population; possibly due to the presence of cognitive impairment acting as a barrier to treatment.

In comparison to pharmacological interventions, CBT has a negligible side effect profile (Schermuly-Haupt, Linden, & Rush, 2018) and was generally well tolerated across the studies, with 82% of participants who started CBT completing the intervention. The manualised nature of CBT meant that treatment fidelity was high, and it was feasible to administer widely across TBI populations. CBT is also considered to be a more cost-effective approach than pharmacological interventions alone, with costs of CBT costs offset by reduced access to healthcare (Myhr & Payne, 2006).

As with all meta-analyses, the overall effect size of the meta-analysis tends to be driven by the larger studies. In this meta-analysis, studies by Ashman et al. (2014) and Bell et al. (2016) are driving the effect size. Bell et al. (2016) was the largest study within this meta-analysis conducted on a sample of 356 military servicemen. Participants received 12 bi-weekly telephone calls, of either an education only intervention, or a CBT informed problem-solving therapy (PST). Post-treatment, the PST group significantly improved on the PCL-M compared to the control group (p=.04, treatment difference 2.89). Results however were not maintained at a 6 month follow up. The authors consider whether these effects were specific

to the PST intervention, or whether improved problem solving resulted in a generalised feeling of improved wellbeing. Additionally, potential qualitative differences within military samples need to be taken into consideration.

Similarly, Bryant et al. (2003) found that receiving five sessions of CBT within two weeks of injury, resulted in significantly fewer instances of PTSD than supportive counselling (SC; 8% vs 58%). Although this finding could be explained by rapid early spontaneous recovery, which occurs shortly after TBI (Nudo, 2013). Additionally, in comparison to the SC group, the CBT group reported a significant reduction in anxiety (p=.05); however, these effects did not persist at the six-month follow up. It would be important that future research includes robust follow up periods to determine the maintenance effect of CBT interventions.

Ponsford et al. (2016) reported a significant improvement in anxiety in their study. The current meta-analysis did not identify a significant effect. It must be noted however that for this meta-analysis, to maximise consistency, data was extracted immediately pre and post-intervention (at 3 and 12 weeks). The positive effect size reported by Ponsford et al. (2016) was found at 21 weeks, following a booster session of CBT; the effect of which was not considered within this meta-analysis.

Within the study by Ashman and colleagues (2016) a third of participants met the diagnostic criteria for an anxiety disorder at baseline, which reduced to 20% post-intervention; this difference was not found to be statistically significant. This meta-analysis only used the trait scale of the STAI and found a statistically significant difference between the CBT and SPT groups. This suggests that there was significant reduction on the trait scale of the STAI, but this did not translate into a significant reduction in diagnosable anxiety disorders.

The distinction between a statistically significant effect size and a clinically significant reduction in anxiety symptoms needs to also be considered. It is therefore important to question what an effect size of -0.26 would look like in terms of reduction of anxiety symptoms. Four out of the five studies that administered the HADS, did not report post-intervention scores that were below the clinical threshold (Hsieh et al., 2012; Ponsford et al., 2016; Potter et al., 2016; Silverberg et al., 2013). The mean post-intervention score from Nguyen et al. (2017) was below the clinical threshold, however it was not above clinical threshold at pre intervention. This suggests that although reductions in HADS scores were identified, scores did not reduce to below clinical thresholds, and it is not known whether symptom reductions were clinically observable.

Whelan-Goodinson, Ponsford and Schönberger (2009) report that within TBI populations, clinical thresholds of the HADS do not strongly correspond with clinical diagnoses of anxiety. The anxiety subscale had a sensitivity of 75% and a specificity of 69%. The authors recommend using a structured clinical interview, such as in the Diagnostic and Statistical Manual (DSM-V; American Psychiatric Association, 2013) to assess for anxiety post-TBI. Further research should therefore consider the validity of the anxiety measure utilised and use more comprehensive assessment measures.

It is worth noting that the current meta-analysis only looked at the reduction in anxiety symptoms using one anxiety outcome measure. Some of the included studies, where anxiety was not a primary outcome, did report significant changes in other areas. In the study by Silverberg et al. (2013) significantly fewer participants in the CBT group experienced symptoms of post-concussion syndrome (54% vs 91%). In the study by Nguyen at al. (2017) there was a significant improvement in sleep quality and reduction in fatigue for CBT group compared to TAU and Tiersky et al. (2005) reported reduced emotional distress for the CBT group. Hsieh et al. (2012) and Ponsford et al. (2016) both considered the effect of MI

compared to NDC prior to the CBT intervention. The findings by Hsieh et al. (2012) demonstrated that MI and CBT resulted in a significantly greater reduction in anxiety than NDC and CBT, however Ponsford et al. (2016) did not find a significant difference.

Limitations

There were several limitations to the current meta-analysis. It was not possible to control for the variation in the severity of TBI, the location of damage and the time since injury within the sample. There was also variation in the severity of anxiety symptoms of the sample included; with some studies only including participants with a diagnosed psychiatric disorder. This again results in confounding variables that could not be controlled for.

Additionally, due to the current lack of research into CBT interventions specifically targeting anxiety post-TBI, the current meta-analysis included a broad range of CBT interventions, which further increases the heterogeneity of the sample. In Waldron and colleagues' (2013) meta-analysis, when the CBT intervention was aimed specifically at anxiety, larger effect sizes were reported (average effect size of 1.04). The authors concluded that CBT is more effective when aimed at a specific difficulty, and these specific improvements do not necessarily generalise to have a significant therapeutic effect on anxiety. It could however be argued, that CBT addresses anxiety, regardless of the primary focus, for example by targeting catastrophising cognitions or acting upon safety behaviours. Despite predicted heterogeneity within the sample, tests of heterogeneity were not significant. Due to the small number of studies within this meta-analysis that included a follow up, it was not possible to conduct further meaningful analysis to consider the maintenance effect of CBT. It is important that future research considers the long-term effect of such interventions and whether improvements are maintained.

As with all meta-analyses, the risk of publication bias needs be taken into consideration. There may be a tendency to publish statistically significant findings and not non-significant results (Zakzanis, 2001); which was coined by Rosenthal (1979) as the "file-drawer problem". Visual inspection of the forest plot produced in this meta-analysis suggested that there were a number of small studies reporting small and non-significant effect sizes; reducing the possibility that publication bias was present. It is possible that within TBI populations there is less chance of publication bias, due to general difficulties recruiting within this population.

Additionally, the interpretation of individual effect sizes must be considered carefully, as multiple factors can influence a given effect size; particularly different types of control conditions. For example, studies that compared CBT to a wait list control condition may be more likely to report a statistically significant effect size, compared to studies that used an alternative or comparable intervention. Within the current meta-analysis however, the studies with a non-significant effect size utilised a variety of control groups, including both TAU/WLC and other forms of active intervention.

Conclusion

Anxiety is highly prevalent, debilitating and negatively impacts rehabilitation and recovery following TBI. This is the first meta-analysis to consider the effect of using CBT informed interventions to reduce anxiety in the TBI population, using evidence from RCTs. The results of this meta-analysis indicate that CBT results in a small but significant reduction in anxiety symptoms for individuals who have experienced a TBI.

This meta-analysis would support the use of CBT to treat anxiety symptoms following TBI, considering its easy to administer nature and negligible side effect profile, compared to

alternative pharmacological interventions. It is however important that the clinical significance in addition to the statistical significance of the intervention is considered. Future research with CBT specifically targeting anxiety in the TBI population needs to be conducted, in order to further determine its efficacy and allow increased homogeneity across studies. Additionally, in light of recent developments into alternative psychological interventions to treat anxiety post-TBI, including MBCT and ACT, further well-controlled research should continue investigating these alternatives to determine the most efficacious and feasible psychological intervention in this population.

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Chapter 2

Empirical Paper

Instructions for Authors – Neuropsychological Rehabilitation

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Neuropsychological Correlates of Social Isolation Following Acquired Brain Injury.

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Abstract

Background: Social isolation is a common sequalae following acquired brain injury. It is associated with poor rehabilitation outcomes and reduced quality of life, however its underling mechanisms remain unclear. The current study aimed to take an exploratory approach to investigate the potential association between cognitive functioning, self-awareness and social isolation following ABI.

Method: Twenty-seven participants were recruited from a community brain injury service. Participants completed self-report questionnaires of social isolation, objective measures of cognitive functioning (i.e. cognitive flexibility, disinhibition, working memory) and self-awareness. An objective comparison of self-awareness was provided by each participant's treating clinician.

Results: There were no significant associations between social isolation and measures of working memory or cognitive flexibility. Disinhibition and reduced self-awareness were associated with an increased reported number of family contacts, but not non-kin acquaintances. There was a trend towards over-estimation of difficulties being associated with increased emotional loneliness. Demographic factors, including rurality and marital status are also likely important.

Discussion: Increased disinhibition and reduced self-awareness, specifically underestimation of difficulties, were associated with increased family contact. Poor self-awareness and living in rural communities may protect against subjective experiences of social isolation. Limitations of the current study and implications for future research and clinical practice are discussed.

Keywords: Acquired Brain Injury, Social Isolation, Cognitive Functioning, Self-Awareness

Introduction

Acquired Brain Injury (ABI) is any injury to the brain that occurs after birth, including traumatic brain injury (TBI), cerebrovascular accident (CVA) tumour, infection and oxygen deprivation. ABI is considered one of the leading causes of disability worldwide (Rutland-Brown, Langolis, Thomas, & Xi, 2003; Langlois, Rutland-Brown, & Wald, 2006) with individuals often living with disability for many years following injury (Brooks, Shavelle, Strauss, Hammond, & Harrison-Felix, 2015). Many individuals experience significant improvements within the first twelve-months post-injury; however cognitive impairments, including deficits in memory (Shum, Sweeper, & Murray, 1996), executive functioning (Leon-Carrion et al., 1998), information processing (Dymowski, Owens, Ponsford, & Willmott, 2015) and self-awareness (Schacter, 1990; Sherer, Hart, & Nick, 2003; Bach & David, 2006) often persist long-term.

Poor social outcomes are well documented following ABI. Individuals are significantly less likely to participate in recreational and social activities (Brown, Gordon, & Spielman, 2003). They often encounter difficulties establishing and maintaining meaningful social relationships; resulting in the loss of pre-injury friendships, a significant decline in the size of social networks and a decrease in the quantity and quality of social interactions (Finset, Dyrnes, Krogstad, & Berstad, 1995; Hoofien, Gilboa, Vakil, & Donovick, 2001; Lefebvre, Cloutier, & Josee Levert, 2008; Andelic et al., 2010). These negative psychosocial outcomes are likely to persist throughout the lifetime if not addressed (Finch, Copley, Cornwell & Kelly, 2016).

It is therefore not surprising that social isolation is frequently reported during the chronic stages of ABI (Morton & Wehman, 1995; Olver, Ponsford, & Curran, 1996) and is considered the most profound life change following injury (Sander & Struchen, 2011). Social isolation is a multifaceted concept and can be described as a lack of contact between an

individual and society; characterised by absent social relationships. Hawthorne (2006) describes social isolation as a lack of significant relationships; to relate to, to trust and provide support. Social isolation can elicit feelings of loneliness, which is a comparatively more subjective concept. Loneliness describes one's perception of being alone and the negative emotional reaction elicited. Loneliness was described by Perlman and Peplau (1981) as the unpleasant experience that occurs when an individual's social network is deficient in some important way, either quantitatively or qualitatively.

The impact of social isolation is well documented and is not unique to the ABI population. Social isolation and associated feelings of loneliness have been found to be detrimental for both psychological and physical health and are associated with increased mortality (House, Landis, & Umberson, 1988; House, 2001; Holt-Lunstad, Smith, & Layton, 2010; Shankar, Rafnsson, & Steptoe, 2014). Following ABI, successful integration into the community is important for rehabilitation and life satisfaction; it has been positively associated with physical and psychological quality of life and inversely related to emotional distress (Burleigh, Farber, & Gillard, 1998; Williams, Rapport, Millis, & Hanks, 2014; Forslund, Roe, Sigurdardottir, & Andelic, 2013). A clear understanding of the factors that underpin social isolation and associated loneliness is therefore vital for maximising rehabilitation outcomes and ensuring good quality of life following ABI. Despite the importance of social relationships for physical and psychological wellbeing, Sander and Struchen (2011) noted that compared to productivity outcomes, research into predictors of social outcomes are disproportionately low.

Previous research has suggested a number of variables that contribute to social difficulties following ABI, however the evidence base remains inconclusive. Implicated factors include; cognitive impairments, anxiety, depression, embarrassment, poor social judgement, emotional recognition, pragmatic communication skills and personality changes

(Wood & Yurdakul, 1997, Shorland & Douglas, 2010; Struchen, Pappadis, Sander, Burrows, & Myszka, 2011; Bogart, Togher, Power, & Docking, 2012), however, their relationship with experiences of social isolation have not yet been considered.

Biopsychosocial models to account for psychosocial outcomes following ABI have been developed and include cognitive deficits as factors that directly contribute to post-injury behaviour (Lishman, 1972; Kendall & Terry, 1996; Gainotti, 1993), however the relationship between specific higher level cognitive functions and social outcomes remains inconclusive (Azouvi, Arnould, Dromer, & Vallat-Azouvi, 2017). Previous studies have investigated the impact of specific cognitive functions on psychosocial outcomes following ABI and discovered that working memory, disinhibition, processing speed and cognitive flexibility play a role (Vilkki et al., 1994; Bowman, 1996; Ownsworth & McKenna, 2004). Contrary to this, Spikman and colleagues (2012) concluded that impaired social performance was not related to general cognitive deficits.

During social interactions, the ability to select appropriate social behaviours and mental flexibility to adjust behaviour and attention in accordance with social context is required (Shany-Ur & Rankin, 2011). The ability to inhibit, possibly inappropriate responses and shift attention from the content of one's own thoughts, are often impaired following ABI, and are required for successful social interactions (Tate, 1999; Spikman et al., 2012). Research has indicated that cognitive flexibility is an important predictor of social outcomes after ABI (Vilkki et al., 1994). In terms of disinhibition, Pearce, Cartwright, Cocks and Whitworth (2016) investigated the relationship between disinhibition and social communication difficulties. They concluded that reduced inhibition speed was a stronger predictor of social outcomes, than failures in inhibition.

Working memory refers to the ability to temporarily retain information whilst also performing other cognitive tasks (Baddeley, 1983). It is an important factor for successful

social interactions and is a predictor of psychosocial outcome following ABI (Wood & Rutterford, 2006). May et al. (2017) investigated associations between post-injury behaviour and neuropsychological functioning and found that better working memory was associated with better community functioning. Other cognitive factors were unrelated to post-injury behaviour. A limitation of this study was that the assessment of social integration was based on the individual's subjective ratings which may lack validity, for example due to factors such as self-awareness.

To the authors' knowledge, there is no empirical research to date that has considered the relationship between cognitive functioning and individuals' experiences of social isolation following ABI. The current study will therefore consider the relationship between the cognitive functions proposed in the literature to be important for social outcomes; cognitive flexibility, working memory and disinhibition.

Factors other than cognition are also likely to contribute to social isolation after ABI. Self-awareness is the ability of an individual to recognise difficulties they experience as a result of their injury, typically resulting in an underestimation of difficulties (Crosson et al., 1989). Underestimation of difficulties has been found to have a negative impact upon on rehabilitation outcomes (Allen & Ruff, 1990; Prigantio, 1988; Najenson et al., 1975; Schachter, Gilsky, & McGlynn, 1990); whereas increased levels of self-awareness are predictive of successful community integration (Sherer et al., 1998; Ownsworth & Clare, 2006; Robertson, & Schmitter-Edgecombe, 2015). Following ABI individuals may not fully understand the nature of their difficulties and the impact they have upon their social relationships (Harvey & Miller 1998; Tadir & Stern 1985). Additionally, they may not be aware of social losses they have experienced (Coetzer, 2004) and the influence that this may have on their subjective experience of social isolation is not yet known.

Despite the frequency of social isolation following ABI and the potentially adverse consequences for rehabilitation, community integration and quality of life, the factors underpinning social isolation following ABI remains unclear. Further understanding of these factors could help to develop clinical approaches for the identification and rehabilitation of social isolation. To the authors' knowledge, the association between cognitive functioning, self-awareness and social isolation has not yet been empirically researched. The aim of the current exploratory study, therefore, was to consider the relationships between cognitive functioning, self-awareness and social isolation.

As the study was exploratory in nature, specific hypotheses were not generated, however in the interest of transparency, the following predictions were made; *1)* Cognitive functioning (i.e. cognitive flexibility, disinhibition and working memory) would be associated with social isolation following ABI; *2)* Self-awareness would be associated with social isolation following ABI.

Method

Participants

Twenty-seven participants with ABIs of varying aetiology and severity were recruited from a community brain injury rehabilitation service. All participants were aged between 26 and 73 and the time since injury ranged from one to 40 years. All participants had been referred to the brain injury service for a wide range of physical, cognitive, emotional and behavioural difficulties as a result of their ABI. Demographic characteristics of the sample are summarised in Table 1.

Table 1. Participant Demographics.

	All Participants (N=27)	TBI (*n*=13)	CVA (*n*=9)	Other (*n*=5)
Age (M, [SD])	51.26 (12.73)	49.85 (16.19)	53.56 (9.77)	50.80 (7.56)
Gender (*n*, % Male)	17 (63)	9 (69.2)	7 (77.8)	1 (20)
Years Since Injury (M, [SD])	9.05 (10.86)	14.96 (13.02)	3.70 (3.94)	3.35 (2.77)
Severity of ABI (*n, %)*				
Mild	4 (14.8)	1 (7.7)	2 (22.2)	1 (20.0)
Moderate	9 (33.3)	2 (15.4)	5 (55.6)	2 (40.0)
Severe	14 (51.9)	10 (76.9)	2 (22.2)	2 (40.0)
Employment Status (*n*, %)				
Employed	2 (7.4)	1 (7.7)	1 (11.1)	-
Unemployed	17 (66.7)	8 (61.5)	5 (55.6)	5 (100)
Retired	7 (25.9)	4 (30.8)	3 (33.3)	-
Marital Status (*n*, %)				
Married/Cohabiting	21 (77.8)	10 (76.9)	7 (77.8)	4 (80.0)
Single	3 (11.1)	1 (7.7)	1 (11.1)	1 (20.0)
Widowed/Separated	3 (11.1)	2 (15.4)	1 (11.1)	-
Rurality (no. people per hectare; M, [SD])	18.48 (19.15)	18.00 (20.25)	21.72 (20.09)	13.88 (17.23)

ABI was confirmed through clinical imaging data (e.g. Magnetic Resonance Imaging/ Computerised Tomography scans) or confirmation from a consultant neurologist. Retrospective review of medical notes was used to obtain information regarding the nature and severity of ABI. ABI severity was categorised as mild, moderate or severe using the Mayo Classification System (Malec et al., 2007) The type of ABI was split into three categories; TBI, CVA and other (e.g. brain tumour, infection etc.).

To account for any potential confounding variables, exclusion criteria were employed. Participants were excluded if their ABI was sustained less than 12 months prior to the study, they had current substance misuse difficulties, co-morbid psychiatric conditions or severe cognitive impairment that would impair their ability to participate in the research or give their informed consent. Due to the verbal requirements of some of the selected measures, non-verbal participants were also excluded from the study.

Measures

Demographic Data

The first author obtained demographic information from each participant, including; age, gender, time since injury, nature and severity of injury, employment status, marital status and area of residence.

Measures of Social Isolation

De Jong Gierveld Loneliness Scale-6 (DJGLS-6; De Jong Gierveld & Van Tillburg, 2006). The DJGLS-6 is a six-item self-report scale, which subjectively measures two different types of loneliness; emotional loneliness (i.e. when relationships are lacking intimacy) and social loneliness (i.e. when the number of relationships is less than desired). Higher scores indicate higher levels of loneliness. Cronbach's α coefficients for the total

scale were found to vary between 0.70 and 0.76 indicating good internal reliability. For the emotional loneliness scale, reliability coefficients varied between 0.67 and 0.74 and for social loneliness 0.70 to 0.73 (de Jong Gierveld & Tilburg, 2006).

Lubben Social Network Scale-6 (LSNS-6; Lubben, 1988; Lubben et al., 2006). The LSNS-6 is a brief, self-report measure designed to gauge social isolation by measuring social support. It could be considered a more objective measure of social isolation, considering the quantity of social relationships an individual has. It consists of six items, whereby participants report the number of relatives (kin subscale) or acquaintances (non-kin subscale) that they have regular contact with. Higher scores are indicative of more social contact. Internal consistency for the LSNS-6 has been found to be consistently good (Cronbach's α; 0.83). Internal consistency for the kin subscale has been found to fall between 0.84 and 0.89, and 0.80 to 0.82 on the non-kin subscale (Lubben et al., 2006).

Neuropsychological Measures

Hayling Sentence Completion Test (HSCT; Burgess & Shallice, 1997). The HSCT is part of the Hayling and Brixton test and is a measure of response inhibition. It consists of two sets of 15 sentences with the last word missing (e.g. The captain wanted to stay with the…). In section one; sensible completion, the examiner reads each sentence aloud and the participant completes the sentences with an appropriate word, yielding a simple measure of response initiation speed. In section two; unconnected completion, the participant must complete the sentences with an unrelated word, giving a measure of response suppression ability and time taken to respond. This requires the ability to inhibit an automatic response before generating an alternative. The time taken to provide responses was summed across the 15 sentences in each section. As in research by Burgess and Shallice (1996), to control for speech or initiation factors, time latencies were calculated subtracting Time A from Time B.

Bigger latencies indicated a longer time taken to supress automatic responses. All responses to Section B were recorded verbatim and assigned an error category in line with the test manual (Burgess & Shallice, 1997). Errors were assigned if the word completed the sentence sensibly or had a semantic connection to the sentence, indicating an inability to supress an automatic response. Error frequencies were totalled for each participant across all 15 trials. A greater error rate was indicative of increased inability to supress automatic responses. Test-retest reliability for the HSCT has been found to be good, at .76 (Burgess & Shallice, 1996).

Trail Making Task (TMT; Reitan, 1958). The TMT was selected as it is considered a traditional measure of cognitive flexibility (Lange et al., 2005). In Trail A, participants were required to connect 25 consecutive numerical targets as quickly as possible (e.g. 1,2,3…etc.). In part B, participants were required to connect targets alternating between numbers and letters (e.g. 1-A, 2-B, 3-C…etc.). The time difference between Trial A and Trial B was calculated in seconds, which provided a measure of cognitive flexibility, whilst controlling for baseline motor speed. Higher scores indicate poor cognitive flexibility. Research has indicated that the TMT has good reliability for part A (Cronbach's $\alpha = 0.75$), part B (Cronbach's $\alpha = 0.85$) and the difference between part A and B (Cronbach's $\alpha = 0.74$; Giovagnoli et al., 1996).

Digit Span (DS; Wechsler, 2008). The DS is a subtest from the Wechsler Adult Intelligence Scale (WAIS-IV; Wechsler, 2008) and is commonly used as a measure of auditory working memory. Participants were read aloud a sequence of numbers and then asked to recall the sequence. With each trial, the sequence length increased by one digit, from three to nine. Firstly, subjects were required to recall the digits in order (DS forwards) and then in reverse order (DS reversed). The participant's span was the maximum number of digits recalled without error, with higher scores indicating better working memory. The current study used the total of the DS forward and DS reversed. Test-retest reliability was

reported to be good for both DS forward and DS reversed; Cronbach's α =.81 and .65 respectively (Levine, Miller, Becker, Selnes, & Cohen, 2004; Waters & Caplan, 2003).

Measure of Awareness

Awareness Questionnaire (AQ; Sherer, Bergloff, Boake, High & Levin, 1998). The AQ is designed to assess the level of self-awareness, otherwise referred to as insight, that the participant has into their deficits following ABI. It consists of three rating forms; patient, carer/relative and clinician. Questions address a range of physical, cognitive and behavioural factors and raters are asked to consider the patient's current functioning in comparison to their pre-morbid ability. Ratings are made on a five-point scale from "much worse" to "much better". The patient and clinician rating forms were used in the current study, due to anticipated difficulties obtaining carer or relative ratings.

Impaired self-awareness is identified by calculating the discrepancy between patient and clinician ratings. Positive discrepancies indicate underestimation of difficulties and negative discrepancies indicate over-estimation (Prigatano & Altman, 1990; Cicerone, 1991). A discrepancy of 20 or higher, in either direction, is suggestive of clinical levels of impaired self-awareness (Sherer et al., 2003; Evans, Sherer, Nick, Nakase-Richardson, & Yablon, 2005). Reliability analysis indicated good internal consistency (Sherer et al., 1998; Carroll & Coetzer, 2011; Hellebrekers, Winkens, Kruiper, & Van Heugten, 2017).

Procedure

Ethical approval was obtained from the National Health Service Research Ethics Committee and the School of Psychology Ethics Committee at Bangor University, UK. Following ethical approval, clinicians at the community brain injury service identified and approached eligible participants on their caseload. Following an expression of interest, verbal consent was gained by the clinician for the principal author to contact potential participants via telephone. Potential participants were then contacted to discuss the research and arrange a convenient time for participation. All participants gave fully informed verbal and written consent. Testing was undertaken in one session of up to 90 minutes and took place in local NHS clinic rooms or at the participants' home if preferable. Travel costs for participants were reimbursed and a £10 shopping voucher was provided for participation. All participants received a full debrief following the testing session and the chance to ask further questions.

Statistical Analysis

The **s**tatistical software package IBM SPSS version 25 (IMB Corp, 2018) was used to perform all statistical analyses. Initially, Shapiro-Wilks tests of normality were conducted to assess whether clinical variables met the required assumptions for parametric tests to be performed. Variables that did not conform to the assumptions of normality were; DJGLS-6 Total; DJGLS emotional scale; DJGLS social scale; AQ client scale; TMT A; TMT B; TMT Latency; HSCT A; HSCT B; HSCT Latency; HSCT error; DS longest backwards. An attempt to transform the non-normal variables was made, using relevant bimodal, square and square root transformations as appropriate. The variables however remained non-normal; therefore, the non-transformed variables were used in the analyses.

Initially, preliminary analyses were conducted to determine whether there were any statistically significant differences between the CVA and TBI groups on measures of cognitive

functioning or social isolation. To account for violations in normality, independent samples *t*-tests were performed, using bootstrapping with 10,000 samples.

Spearman's rho correlational analyses were then performed to examine associations between cognitive functioning, self-awareness and social isolation. Additionally, a series of ad hoc comparisons were made between social isolation and general demographic and clinical injury-related variables.

Results

Preliminary Analyses

Independent sample *t*-tests revealed that there were no significant differences between the TBI (n=13) and CVA (n=9) groups across all measures of social isolation and cognitive impairment ($p \geq .38$). It was not deemed meaningful to run *t*-tests on the 'other' category as this only contained 5 participants. All participants were therefore combined into one sample (N=27). The descriptive and inferential statistics for all measures are outlined in Table 2.

Table 2. Descriptive Statistics of Measures.

N = 27	Minimum Score	Maximum Score	Mean (SD)	*t*-test of statistical difference between TBI and CVA		
				95% CI for mean difference	t	df
DJGLS-6 Total	0	6	3.30 (1.96)	-2.17, .79	-.85	20
Emotional Loneliness	0	3	1.81 (1.08)	-.91, .64	-.28	20
Social Loneliness	0	3	1.48 (1.28)	-1.60, .55	-.97	20
LSNS-6 Total	3	26	15.04 (5.68)	-3.19, 7.32	.70	20
Kin	0	14	7.96 (3.16)	-2.49, 2.43	-.02	20
Non-Kin	0	15	7.07 (4.28)	-1.42, 5.47	1.05	20
AQ						
AQ Patient Form	22	55	33.13 (8.04)	-6.97, 6.38	-.05	20
AQ Clinician Form	23	49	34.59 (6.70)	-5.64, 6.38	.23	20
AQ Difference	-14	17	-1.35 (6.79)	-3.25, 7.21	.61	20
TMT						
TMT A (secs)	22.18	125.35	50.32 (22.74)	-36.33, 4.58	-1.42	20
TMT B (secs)	50.12	302.42	124.38 (65.21)	-81.44, 26.81	-.98	20
TMT Latency (secs)	16.00	203.88	74.06 (51.53)	-54.13, 28.19	-.62	20
HSCT						
HSCT A (secs)	8.07	141.00	28.55 (26.55)	-51.40, 2.06	-1.56	20
HSCT B (secs)	14.91	243.17	64.16 (44.98)	-68.39, 20.30	-.85	20
HSCT Latency (secs)	-3.00	102.17	35.60 (28.67)	-21.65, 28.80	.30	20
HSCT Error	0	9	2.37 (2.56)	-.40, 3.34	1.43	20
DS Total	6	15	10.04 (2.74)	.23, 4.22	2.07	20
DS longest forwards	3	9	5.89 (1.76)	-.05, 2.59	1.82	20
DS longest reversed	3	6	4.15(1.06)	.206, 1.72	2.30	20

Note. DJGLS; De Jong Gierveld Loneliness Scale-6; LSNS-6; Lubbens Social Network Scale, 6; AQ; Awareness Questionnaire, TMT; Trail Making Task; HSCT; Hayling Sentence Completion Task; DS; Digit Span.

Main Analysis

Spearman's rho correlations were calculated to examine potential relationships between cognitive functioning, self-awareness and social isolation. As there were no significant differences between the TBI and CVA groups across measures of social isolation and cognitive impairment, the correlations were calculated for the whole sample (N=27). The

variables relating to cognitive functioning (TMT latency, HSCT latency, HSCT error and DS total) were correlated with measures of social isolation (DJGLS-6 emotional loneliness and social loneliness scales and LSNS-6 kin and non-kin scales) and self-awareness (AQ difference). The results of the correlational analysis are summarised in Table 3.

Table 3. Correlation Analysis of Measures of Cognitive Functioning and Social Isolation.

	DJGLS-6 Emotional	LSNS-6 Kin	LSNS-6 Non-Kin	TMT Latency	HSCT Latency	HSCT Error	Digit Span Total
DJGLS- 6 Social	.331† *p*=.092	-.384* *p*=.048	-.518** *p*=.006	-.100 *p*=.618	.074 *p*=.713	-1.45 *p*=.470	.050 *p*=.804
DJGLS-6 Emotional	-	-.119 *p*=.556	-.074 *p*=.715	-.190 *p*=.342	.145 *p*=.469	-.265 *p*=.182	.035 *p*=.863
LSNS-6 Kin	-.119 *p*=.556	-	.103 *p*=.610	.044 *p*=.829	-.364† *p*=.062	.421* *p*=.029	-.094 *p*=.640
LSNS-6 Non-Kin	.074 *p*=.715	.103 *p*=.610	-	.070 *p*=.728	-.142 *p*=.480	-.154 *p*=.444	.170 *p*=.396
AQ Difference	-.365† *p*=.060	.375* *p*=.50	-.003 *p*=.99	-.159 *p*=.436	-.460* *p*=.016	.291 *p*=.141	.227 *p*=.255

Note. †$p \leq .10$ *$p \leq .05$, **$p \leq .01$; DJGLS; De Jong Gierveld Loneliness Scale-6; LSNS-6; Lubbens Social Network Scale, 6; AQ; Awareness Questionnaire, TMT; Trail Making Task; HSCT; Hayling Sentence Completion Task; DS; Digit Span.

Unsurprisingly, the social loneliness scale of the DJGLS-6 was significantly correlated with the kin (p=.048) and non-kin scale (p=.006) of the LSNS-6. This indicates that those who subjectively reported high levels of social loneliness, did reported fewer social contacts, both with family and non-related acquaintances. This may suggest that it was not just a perceived sense of social isolation experienced by participants.

Cognitive Functioning

There were no statistically significant correlations found between the TMT or Digit Span and any measures of social isolation, subjective or objective ($p \geq .34$), indicating that cognitive flexibility and working memory were not significantly associated with reported social isolation. There was a statistically significant positive correlation between the HSCT error rate and the kin scale of the LSNS-6. (p=.029). This would suggest that more disinhibited individuals, reported more family contacts. This relationship was not present for the non-kin subscale, which resulted in a non-significant negative correlation. The negative correlation between the LSNS-6 kin scale and the HSCT latency was approaching significance (p=.062); tentatively indicating that those who took longer to suppress automatic responses, may have reported more family contacts. Again, this relationship was not significant for the LSNS-6 non-kin subscale.

Self-Awareness

Investigation of the discrepancies between the AQ patient and clinician ratings indicated that none of the participants scored in the clinical range for impaired self-awareness (Sherer et al., 2003; Evans et al., 2005). Two participants scored between 10 and 20 points higher than the clinician rating, suggestive of scores approaching the clinical level. Fifteen participants had negative AQ discrepancies indicating that they had potentially overestimated the impact of their difficulties.

The relationship between the DJGLS-6 emotional scale and AQ difference was approaching significance (p=.060). This was suggestive of a trend towards those with poor self-awareness, specifically underestimation of difficulties, reporting lower levels of emotional loneliness than those who overestimated their difficulties. Additionally, the relationship between self-awareness and the LSNS-6 kin scale was significant (p=.05)

indicating that underestimation of difficulties was associated with increased family contact. This relationship was not present for the non-kin subscale. There was also a statistically significant negative relationship with HSCT latency and AQ difference (p=.016). Indicating that those with poor insight into their difficulties were quicker to provide answers, possibly due to impulsivity. When considering the absolute discrepancy, disregarding the direction of the AQ difference, there were no significant relationships identified with any measure of social isolation ($p \geq .21$). This would indicate that it is not simply a discrepancy between the participants' rating and the clinicians' rating, but it is important to consider whether participants under or overestimated their difficulties.

Additional Analyses

A series of ad hoc comparisons were made between measures of social isolation and general demographic and clinical injury-related variables. Spearman's rho correlations revealed no significant correlations between social isolation and age or time since injury ($p\geq$ .49). There was a significant negative correlation between rurality and the DJGLS social loneliness scale (r_s=-.432, p=.025); indicating that the participants who lived in more rural areas reported lower levels of social loneliness.

A Mann-Whitney U test revealed no significant gender differences on measures of social isolation ($p\geq$ .78). Independent measures Kruskal-Wallis tests revealed that there were no significant differences between participants with different severities of brain injury (mild, moderate or severe) on measures of social isolation ($p\geq$ .29). The majority of the sample however, (n=23) had experienced moderate or severe brain injuries. Additionally, the role of marital status was examined. There was a significant difference between participants with different marital statuses and scores on the DGJLS-6 emotional scale (H=7.828, p=.020). Individuals who were single, or divorced/widowed, scored higher on emotional loneliness

than those who were married/cohabiting. It is important to note however, that the majority of the sample (*n=21)* were married or cohabiting, therefore there was limited variance in this variable.

Discussion

The aim of this exploratory study was to investigate potential relationships between cognitive functioning, self-awareness and social isolation following ABI. As the study was exploratory in nature, specific hypotheses were not tested, however general predictions were made based upon the existing literature investigating psychosocial outcomes that; *1)* cognitive flexibility, response inhibition and working memory and *2)* self-awareness would be associated with social isolation following ABI.

Limited support for the relationship between cognitive functioning and social isolation was found. Spearman's correlations demonstrated that there were no significant relationships between tests of mental flexibility or working memory and measures of social isolation. The current study did find that more disinhibited individuals (i.e. higher HSCT error rate) and possibly those who took longer to inhibit automatic responses (i.e. larger HSCT latency) reported to have more family contacts, but in contrast not more friends. This suggested that that more disinhibited individuals had more family contacts, possibly due to increased support needs. Caring for individuals with ABI can result in significant stress and burn out (Kreutzer, Marwitz & Kepler, 1992; Kreutzer, Gervasio & Camplair, 1994; Marsh, Kersel, Havill & Sleigh, 1998; Man, 2002; Tramonti et al., 2015). It may therefore be that extended family members become involved in order to reduce the burden of caregiving. The relationships with the non-kin scale, although not significant were negative. It is possible that family members have increased tolerance of impairments and behavioural changes, including disinhibited behaviour following ABI, in comparison to non-kin acquaintances. The HSCT

error provides a measure of failed inhibition, whereas the HSCT latency could be considered to examine processing speed (i.e. the time taken for an individual to supress automatic responses). These results would corroborate the finding of Pearce, Cartwright, Cocks and Whitworth (2016) who concluded that reduced inhibition speed was a stronger predictor of disinhibited communication behaviours, than failures in inhibition; however, our findings would indicate that failures in inhibition do play a role.

Increased disinhibition was associated with more family contact; however, this was not accompanied with decreased emotional loneliness. Emotional loneliness refers to the quality of social relationships as opposed to the quantity. Following ABI, there are often shifts in relationship roles; (Leathem, Heath & Woolley, 1996; Wood & Yurdakul; 1997; Bodley-Scott & Riley, 2015); for example, a spouse may have to take on the role of caregiver. Although these individuals are experiencing increased family contact, there may have been a shift in the nature of such relationships; resulting in a decreased quality.

Our findings suggest that with the exception of disinhibition, specific cognitive profiles were not associated with social isolation, subjective or objective. Our results lend support to the findings of Spikman et al. (2012) who concluded that poor performance on tests of social cognition were not due to general cognitive deficits including processing speed, working memory and executive functioning. It is worth noting that as the HSCT is only validated for use in English. Therefore, there may have been a bias towards those participants whose first language was English, potentially putting first language Welsh speakers at a disadvantage.

The second prediction was that self-awareness would be associated with social isolation following ABI. The current study found that reduced insight, specifically underestimation of difficulties, was associated with increased family contact. In addition, the relationship between insight and subjective reports of emotional loneliness was approaching

significance. This would tentatively suggest that those with preserved insight or those who overestimate their difficulties may be more vulnerable to experiencing loneliness. Psychological theories of self-awareness have suggested that reduced levels of self-awareness and an inability to recognise difficulties following ABI acts as a 'psychological defence mechanism' (Weinstein & Kahn, 1955; Gainotti, 1993; Prigatano, 1996). In line with such theories, it could be considered that poor insight may be protective against subjective experiences of social isolation. Future research incorporating longitudinal designs would allow for further insights into the relationship between self-awareness and social isolation. There were no significant associations identified when the absolute discrepancy of the AQ was considered; i.e. when the direction of the discrepancy was disregarded. This would indicate that it was not simply a discrepancy between clinician and patient AQ scores; but the direction of the discrepancy that was important. The protective nature of self-awareness may therefore only be present for those individuals who underestimate their difficulties.

Taken together, these results would suggest that individuals who demonstrate a greater level of impairment (i.e. increased disinhibition and reduced self-awareness, specifically underestimation of difficulties) necessitated more family contact. It is plausible that impairments in these domains could be considered more observable than other impairments and have the potential to cause more difficulties within social situations (e.g. embarrassment and shame). Increased family support may therefore reduce the impact of such social difficulties, outside the family unit who are possibly more tolerant.

The results of the current study would tentatively suggest that more disinhibited individuals and those with increased insight into their difficulties, may report higher levels of loneliness after ABI; potentially indicative of greater vulnerability to social isolation. Interestingly, preliminary analysis indicated that there were no significant differences between the severity of injury and the levels of disinhibition or self-awareness exhibited. This

would suggest that the severity of ABI was not associated with self-reported social isolation. It is thought that lesions to certain areas of the brain are associated with specific neuropsychological profiles; for example, damage to the right hemisphere may be associated with poor insight (Keenan, Nelson, O'Connor, & Pascual-Leone, 2001) and disinhibition with damage to the frontal lobes (Dimitrov et al., 2003). The relationship between specific lesions and social isolation was considered to be beyond the scope of the current exploratory study and may be an important area to consider in future research.

Previous research has considered that associations between cognitive functioning and social difficulties may be partly driven by other factors including injury severity and time since injury (May et al., 2017, Pearce et al., 2016; Spikman, 2012). Within the current study, the examination of demographic and injury factors found no such relationships. The only demographic factors which were found to be statistically significantly associated with social isolation were rurality and marital status. Increased rurality was associated with lower levels of subjective social loneliness. This finding could be accounted for by the possibility that more rural areas have a better sense of community, than larger, more urban areas. This is in line with the findings by Henning-Smith, Moscovice and Kozhimannil (2019) who reported that residents in more rural areas had more social relationships and were able to rely more on their family. It is also worth noting that rurality is a complex and multifaceted concept, with many interactions between various factors, including age and culture (Henning-Smith et al., 2019). In addition, the current study did not measure how long participants had lived at their current address, a factor which may have impacted upon their opportunities to develop relationships and therefore be related to their perception of social isolation (Anderson & Thayer, 2018). Future research would look to explore possible confounding relationships when considering rurality.

As expected, marriage/ cohabitation was associated with lower levels of emotional loneliness, however, causality could not be established, as to whether this was due to the direct effect of relationship breakdown or certain cognitive profiles. This is an area requiring further research. Only six participants in the current sample, however, were not married or cohabiting, therefore reducing the variation within this variable. When interpreting the results of the current study, the influence of rurality and marital status on social isolation must be taken into consideration.

Limitations

The current study was exploratory in nature and aimed to explore possible factors associated with social isolation following ABI; which to our knowledge has not been empirically researched to date. As these findings are preliminary, it is difficult to draw firm conclusions at this stage and relationships identified must be interpreted with caution. The current study was also limited by a small sample, resulting in decreased power. A power analyses (parameters ß=0.80, $\alpha = .05$) indicated that with a sample size of 27, the current study had 80% power to detect an effect size of .51, which is considered a large effect size. The modest sample size therefore led to a high risk of Type II errors in this study.

Additionally, the sample included ABIs of varied aetiology and severity which likely reduced external validity and increased the heterogeneity of the sample. Confounding variables may have been present, as it was not possible to assess pre-morbid experiences of social isolation and cognitive functioning. The use of self-report measures also likely introduced bias when measuring more objective measures of social isolation. As this study was cross-sectional and exploratory in nature, the identification of causal relationships, and the change of relationships across time, were not possible. Future research, including tightly controlled longitudinal studies, possibly including control groups, would allow for further

clarity into these relationships. Larger sample sizes would increase the power to detect smaller associations between variables. Additional power analyses (parameters: ß=0.80, α = 0.05) indicated that to detect a medium sized correlation of 0.3, a sample size of 84 would be required.

Despite potential limitations, the current study consisted of a genuine clinical sample, which was representative of individuals accessing NHS community brain injury rehabilitation services. To the authors' knowledge it is the first study to explore the relationships between cognitive functioning, self-awareness and social isolation following ABI.

Directions for Future Research

The current study found that disinhibition and self-awareness, particularly underestimation of difficulties, may be associated with experiences of social isolation. As this was an exploratory study, these findings are preliminary and could help to inform and direct future research. Future research may therefore look to replicate and expand on these associations. Hierarchical regressions could be conducted to consider the predictive relationships of cognitive factors and self-awareness with social isolation. The role that rurality plays within this relationship is also of interest. The current study was conducted in North Wales, which is a geographically large and a relatively rural area. Replication of this study within more urban areas, such as large cities, would allow for further insights into the role of rurality in social isolation in ABI populations.

Clinical Implications

The effective identification of social isolation and those who may be at increased risk, is vital for ensuring effective rehabilitation and improved quality of life post ABI. This is of particular importance within community brain injury rehabilitation services who provide

support for individuals during the chronic stages of ABI, when social isolation presents the biggest problem (Morton & Wehman, 1995; Olver, Ponsford, & Curran, 1996). The results of this research would support the necessity of using a biopsychosocial approach when considering social isolation. Awareness of certain social, demographic factors that may put individuals at risk of social isolation (i.e. living in less rural areas, single marital status) and effective monitoring of cognitive and psychological factors associated with social isolation (i.e. disinhibition, self-awareness) would allow for effective monitoring, identification and targeting of social interventions.

Conclusion

The current study aimed to explore the relationships between social isolation; cognitive functioning and self-awareness following ABI. It was predicted that specific cognitive functions (i.e. working memory, disinhibition and mental flexibility) and social awareness would be associated with social isolation. Contrary to previous literature into psychosocial outcomes, the results of this study indicate that, with the exception of disinhibition, cognitive functioning was not significantly associated with social isolation. There was a trend towards reduced self-awareness acting as a protection against self-reported emotional loneliness. Underestimation of difficulties and increased disinhibition were associated with an increased number of family contacts, but not non-kin acquaintances. Social isolation continues to be a common experience following ABI and has detrimental effects on rehabilitation outcomes and quality of life. Demographic factors, including rurality and marital status are likely also implicated. It is likely that the mechanisms behind social isolation are complex and multifaceted in nature and further clarification of the underlying mechanisms and risk factors for social isolation is vital to allow for the effective identification and intervention of social isolation following ABI.

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Chapter 3

Contributions to Theory and Clinical Practice

Abstract

The current thesis aimed to explore the psychosocial impact and outcomes following brain injury; and consisted of three topically related chapters. The first chapter contained a systematic literature review and meta-analysis that explored the efficacy of Cognitive Behaviour Therapy (CBT) for reducing anxiety symptoms following traumatic brain injury (TBI). A small, statistically significant effect for reducing anxiety symptoms was found.

The second chapter consisted of an exploratory empirical paper which aimed to investigate the relationships between cognitive functioning, self-awareness and social isolation following acquired brain injury (ABI). Results indicated that general cognitive functions were largely not associated with social isolation, however increased disinhibition and reduced self-awareness were associated with greater quantity of family contact, but not acquaintances. Poor self-awareness, specifically underestimation of difficulties, may be protective against emotional loneliness. The role of demographic and clinical factors may also be of importance.

This final chapter aimed to discuss the implications of both papers for psychological theory and clinical practice. In addition, a personal reflective commentary is provided.

Contributions to Theory, Research and Clinical Practice: Literature Review

Anxiety is the most commonly reported neuropsychiatric complaint following TBI (Gould, Ponsford, Johnston, & Schonberger, 2011) affecting up to 70% of individuals (Rao & Lykestos, 2000; Rao & Lykestos, 2002). The presence of anxiety can restrict an individual's access to, and engagement in rehabilitation services, resulting in poor rehabilitation outcomes, increased impairment and reduced quality of life (Fann, Katon, Uomoto, & Esselman, 1995; Whitnall, 2006); thus illustrating the importance of conducting such a review.

The development of anxiety post TBI is multifaceted; implicating a variety of factors; including physical, psychological, personality and environmental. Neurobiological damage as a result of TBI is likely implicated. Functional imaging studies have revealed that the development of anxiety was associated with damage to the temporo-limbic areas of the brain, specifically the amygdala, basal ganglia and frontal cortex (Rauch, Savage, Alpert, Fischman, & Jenike, 1997; Wise & Rundell, 1999). Although neurological pathology plays a key role in the development of anxiety, it is likely that other psychological and psychosocial factors, including pre-morbid personality, coping style and additional environmental variables also contribute to the development of anxiety following TBI (Williams, Evans, & Fleminger, 2003). Models of adjustment following TBI, consider such direct and indirect influences, in addition to a variety of mediating factors (Lishman 1973; Gainotti, 1993; Kendall & Terry; 1996), see Figure 1 for a visual representation.

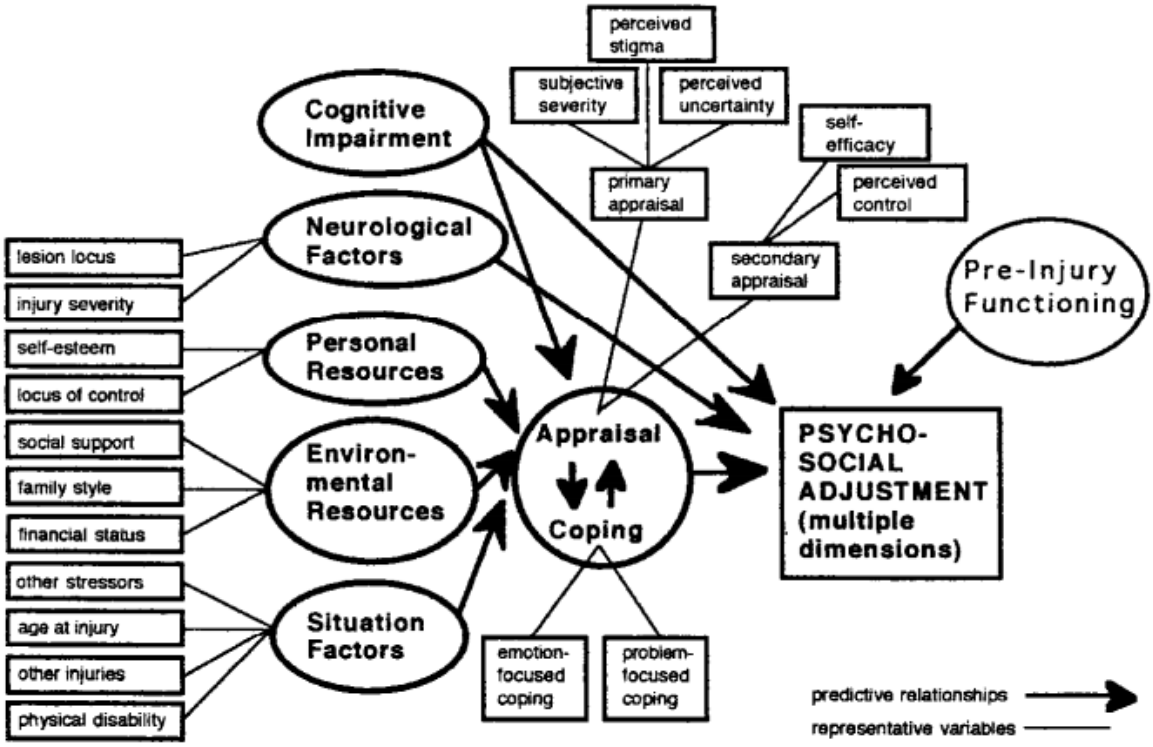

*Figure 1***.** Model of psychosocial adjustment following TBI (Kendall & Terry, 1996).

As the aetiology of anxiety after TBI is biopsychosocial in nature, it is not surprising that the exclusive use of pharmacological interventions has been found to be largely ineffective within this population (Perna, Bordini, & Newman, 2001; Warden et al., 2006). Effective treatments for reducing anxiety therefore must address these more psychological factors. CBT is one such intervention that attempts to do so. CBT is based on the premise that cognitions have an influence upon behaviour and emotions and posits that a change in one area will bring about reciprocal change in the others.

Experimentally controlled studies allow for the effectiveness of interventions to be determined and for causal relationships to be identified (Hagmayer, Sloman, Lagnado & Waldmann, 2007). Randomised controlled trials (RCTs), are considered to provide the best quality research evidence (Akobeng, 2005; Petrisor & Bhandari, 2007). A strength of the

current meta-analysis was that it used evidence exclusively from RCTs to examine efficacy of CBT to reduce anxiety symptoms following TBI.

The current meta-analysis found a small, but statistically significant reduction of anxiety symptoms was identified (effect size of -0.26). Whilst smaller than the effect of CBT in non-TBI clinical populations, the findings from the current meta-analysis do indicate that CBT interventions were somewhat effective at reducing symptom of anxiety following TBI.. Evidence has indicated that CBT has a negligible side effect profile, in comparison to pharmacological interventions (Schermuly-Haupt, Linden, & Rush, 2018). The manualised nature of CBT enhanced fidelity to the model and it can be easily delivered to all. In terms of clinical applications, this would provide support for the use of administering CBT interventions to reduce anxiety symptoms within TBI populations.

When analysing the findings of RCTs in order to consider the effectiveness of clinical interventions such as CBT, the distinction between a statistically significant and clinically significant effect size needs to be considered. A statistically significant effect size would indicate that the mean score of the treatment group was significantly different to the mean score of the control group, above and beyond what would be expected by chance. A clinically significant effect size however, would indicate that the intervention had a real and observable effect in clinical practice. For example, a clinically significant reduction in anxiety symptoms could be that an individual no longer meets the criteria for an anxiety disorder. It is important to note that not all statistically significant differences are clinically significant. When considering the current meta-analysis, it is important to question what an effect size of -0.26 would look like in clinical practice. Would this result in a reduction in anxiety symptoms that would be observable, or result in a meaningful improvement to an individual and their quality of life? Future research should look to consider the clinical significance of such interventions.

Only 10 studies met the inclusion criteria for the meta-analysis, and within this, only three used a CBT intervention which specifically targeted anxiety. It is important that more RCTs are conducted to investigate CBT to specifically to treat anxiety symptoms. Increasing the strength of the evidence base would provide stronger evidence for its clinical application. Due to the limited number of studies that met the inclusion criteria for the current meta-analysis, it has not been possible to conclude the most effective configuration of delivering CBT. There was however evidence to suggest that CBT delivered over longer time periods was more effective (e.g. 16 and 24 weeks). Future research may therefore look to consider the most effective method of CBT delivery, in terms of frequency of sessions, number of sessions, group or individual format etc. Additionally, within the current controlled evidence base, follow ups were limited. It is therefore important that future research considers the maintenance effects of CBT interventions at reducing anxiety symptoms.

Whilst the evidence base is comprised of scientific research, it is important to note that clinical practice is often influenced by a variety of other factors, including; clinical judgement and patient preference (American Psychological Association, 2002). The current meta-analysis provides evidence that CBT interventions were generally well tolerated by participants, as suggested by the relatively low drop-out rate across the studies. It is also important to note that the provision of specific psychological interventions is dependent upon the availability of resources, which, considering the current economic climate of the NHS, may be limited. Whilst the current meta-analysis did not set out to investigate the health economics of using CBT within the TBI population, evidence from the general clinical population indicates that, in comparison to pharmacological interventions, CBT is cost-effective in the long term (Myhr & Payne, 2006; Hollinghurst et al., 2015). Further research to examine the economic benefits of various interventions within the TBI population would help to offer clarity and inform effective service provision.

Contributions to Theory, Future Research and Clinical Practice: Empirical Paper

The current empirical paper aimed to take an exploratory approach to explore factors associated with social isolation following ABI. Over recent years, social isolation has received a lot of attention in the literature and the evidence base regarding its negative consequences has grown rapidly. Following ABI, successful social integration has been found to be positively associated with quality of life and inversely related to emotional distress (Burleigh, Farber, & Gillard, 1998; Williams, Rapport, Millis, & Hanks, 2014), therefore it is important that social isolation is identified and addressed within this population.

To date, research investigating the underlying factors related to social isolation within the ABI population had not been conducted. Predictions for the current empirical paper were therefore drawn from current literature regarding psychosocial outcomes following ABI. As the empirical paper was exploratory in nature, caution must be taken when interpreting the results. It is important that future research is conducted to replicate findings; using larger sample sizes and tightly controlled longitudinal studies to clarify these relationships. Further insight into the factors associated with social isolation would allow effective and timely identification and intervention.

Contrary to findings into psychosocial outcomes following ABI, the results of the empirical paper suggest that general cognitive functioning does not appear to play a significant role in the development of social isolation following ABI. This has important implications for clinical practice, as when considering those patients who may be at risk for social isolation, in depth, laborious cognitive assessments may not be necessary.

The potential relationship between self-awareness and social isolation has important implications for clinical practice. There is a large evidence-base supporting the notion that an individual's perception of their functioning (self-awareness) has greater influence on

emotional distress, including anxiety and depression, than their 'actual' level of functioning (Lezak & O'Brien, 1988; Godfrey, Partridge, Knight & Bishara, 1993; Malec, Machulda, & Moessner, 1997). For example, a study by Wallace and Bogner (2000) found that individuals with reduced levels of self-awareness into their difficulties were less likely to report symptoms of psychological distress, including depression and anxiety.

Psychological theories of self-awareness postulate that decreased self-awareness, specifically underestimation of difficulties acts as a 'psychological defence mechanism' (Gainotti, 1993; Prigatano, 1996; Weinstein & Kahn, 1955). Accordingly, research has demonstrated a negative relationship between self-awareness and depression; that is, the more self-awareness one has into their difficulties, the more depressed they are likely to be (Malec et al., 1997; Wallace & Bogner, 2000; Malec, Testa, Rush, Brown, & Moessner, 2007). Reduced self-awareness is common following ABI (Schacter, 1990; Sherer, Hart, & Nick, 2003) and tends to gradually improve over time (Ponsford, Sloan & Snow, 1995). In accordance with psychological theories described above, as self-awareness improves, individuals may be at increased risk of developing depression. Fleminger, Oliver, Williams and Evans (2003) argue that when individuals gain more awareness of their disability and the realisation of the reality of their limitations may trigger psychological responses, including depression.

The current empirical paper found preliminary support to suggest a relationship between self-awareness and reported social isolation. Specifically, that reduced awareness of one's difficulties may be associated with reduced self-reported emotional loneliness. This finding lends support to the above psychological theories proposing reduced self-awareness acts as a defence mechanism. Drawing upon the evidenced relationship with depression, it is plausible that as self-awareness improves, patients may become increasingly vulnerable to experiencing social isolation. This may be of importance for community brain injury services,

who provide long term support in the chronic stages of ABI. It may therefore be of importance to closely monitor patients' levels of self-awareness, as improvements may trigger feelings of loneliness. As reduced self-awareness has a detrimental effect on rehabilitation outcomes (Groswasser, Mendelson, Stem, Schechter, & Najenson, 1977; Allen & Ruff, 1990; Prigatano, 1988; Fleming & Strong, 1995) rehabilitation efforts are often focused upon improving self-awareness. It would be important for clinicians to be aware of difficulties which may arise as self-awareness improves; including depression and loneliness. Patients experiencing social isolation, for a variety of reasons, may be unable to independently seek help. It is therefore important that community services are actively monitoring and asking questions regarding social isolation. This would allow for effective identification of those at risk and allow for timely interventions to prevent difficulties arising.

Additionally, it is also worth considering the way in which self-awareness is measured, and the limitations of attempting to measure such abstract concepts. The Awareness Questionnaire (AQ; Sherer, Bergloff, Boake, High, & Levin, 1998) was used in the current study to measure self-awareness. The AQ consists of three rating forms; patient, significant other and clinician. Self-awareness is measured by calculating the discrepancy between the patients' rating of their functioning and their clinicians' rating; with larger discrepancies indicating more impaired self-awareness (Sherer et al., 2003; Evans, Sherer, Nick, Nakase-Richardson, & Yablon, 2005). For this to be an accurate measure of self-awareness, one must assume that the clinician's rating of their patient's current functioning is more accurate than the patient's rating of themselves. Most clinicians, however, will have only met the patient after their brain injury and rely upon information from the patient themselves, their relatives and/or interpreting results from neuropsychological testing. The validity of their ratings therefore come into question. Caution must therefore be taken when interpreting the AQ, bearing these limitations in mind. To improve the accuracy of measuring

self-awareness, the current study could have considered using the significant other rating form in addition to the patient and clinician form. Significant others, who have known the patient pre and post ABI, may be more likely to be provide accurate answers; and this would also allow a comparison with the clinician scale to be made for additional accuracy.

The current paper identified that the rurality of participants may have implications for reported levels of social isolation, specifically that those who lived in a more rural area reported feeling less lonely. This is in line with findings from research conducted in the general population (Henning-Smith, Moscovice, & Kozhmannil, 2019). It is however important to note compared to large urban cities, the most urban areas in North Wales, are comparatively rural.

In sum, the current thesis aimed to investigate psychosocial outcomes after brain injury. When considering the meta-analysis in context with the empirical paper, research has indicated that increased social support and community integration may protect against emotional distress, including depression and anxiety. Increased socialisation with family and friends has been found to correlate with reduced levels of anxiety (Hada et al., 2015). Previous research has indicated that a rich social world is protective against psychological distress. It is therefore important that clinicians ensure the social world of their patients is as fruitful as possible. Gaining a clear understanding of the factors which are associated with social isolation could be considered the first step.

Personal Reflection

Since securing my first assistant psychologist post in a brain injury rehabilitation unit, I have felt a strong affinity to neuropsychology. I have spent time reflecting upon why this is, as it is not something that has affected me personally. I have come to realise that it is perhaps because I am only a twist of fate away from acquiring a brain injury myself. Brain injury does

not discriminate; no one is exempt. It doesn't favour the uneducated or the working class and as a result, it always deserves the upmost respect. Working within the field of neuropsychology, the fragility of life becomes strikingly apparent and it was an easy decision for me to undertake my doctoral thesis within this field.

The process of completing this thesis was largely an enjoyable one; however, it was not without its challenges. One of the first major challenges that I encountered was getting to grips with the terminology and mechanics of neuropsychology. Through patience and perseverance, both my own and my colleagues', I gradually learned how to decode the many acronyms, diagnostic terms and neuroanatomical regions of the brain. This experience was crucial in helping me to develop my vocabulary and consequently, my confidence within this highly specialist field of clinical psychology.

Without a doubt, I found the recruitment process to be most frustrating part of conducting this research. Due to the geography of North Wales and the large catchment area of the brain injury service, significant periods of time were spent travelling across North Wales to meet with participants, and of course, it was rare that two participants who lived in the same area were available on the same day. Whilst driving, I would often find myself wondering how this 'wasted' time could have been better spent; however, the warm welcomes that I received upon arrival immediately dissipated any frustration I may have been experiencing. Overwhelmingly participants welcomed me into their homes, offered me tea and Bara brith and I felt privileged to have the opportunity and time to listen to each individual story.

The topic of my empirical paper meant that conversations often focussed upon participants' experiences of social isolation and loneliness. I was struck by the impact that brain injury had on an individual's social world and how common social isolation and associated feelings of loneliness were within this population. Many of the participants I spoke

to appeared to have large support networks, consisting of scores of family and friends, yet often, they still felt isolated and alone. Despite objectively appearing well supported, frequently they noted a qualitative change in their relationships, feeling misunderstood, both by themselves and others. These discussions often evoked strong emotional responses, both in myself and participants. I found myself experiencing great sadness when participants talked about broken relationships and how they felt like outsiders to the friendship groups they were once central to. I noticed feelings of responsibility for bringing distress when it had perhaps not been there before. Frequently, I experienced a desire to alleviate distress and a temptation to override my role as researcher and adopt a more familiar therapeutic role. Sessions often ran over the time I had allocated; however, I was more than happy to immerse myself in each participant's story, offering empathy and validation. I was able to reflect upon the therapeutic benefit that being supported to express difficulties, and having a safe space to discuss them, seemed to have for participants.

Despite their many differences, all of the participants had something in common; their altruistic nature and desire to 'give something back'. This was ultimately a testament to the North Wales Brain Injury Service and the exemplary care they felt they had received. I was humbled to be able to, if only in some small way, help them to give something back.

Finally, finishing this thesis marks the beginning of the end of my clinical training; a journey that has been plagued with feelings of incompetence and self-doubt. It is only now, that I am able to look back on what I have achieved and feel a great sense of pride. The overwhelming support that I have received, both personally and professionally has greatly helped me to develop confidence in my own ability. I have come to accept that 'imposter syndrome' will no doubt follow me as I embark on life as a qualified Clinical Psychologist, however I look forward to taking this next step in my career and endeavour to embrace every and any new challenge that comes my way.

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Appendices

I. Bangor University, School of Psychology Ethics Committee Approval

II. Research Ethics Committee Approval

III. Health Research Authority & Health and Care Research Wales Approval

IV. Participant Consent Form

V. Participant Information Sheet

VI. Awareness Questionnaire (AQ)

VII. Lubbens Social Network Scale-6 Item (LSNS-6)

VIII. De Jong Gierveld Loneliness Scale-6 Item (DJGLS-6)

IX. Trail Making Task A & B (TMT)

Appendix I: Bangor University, School of Psychology Ethics Committee Approval

From: ethics@bangor.ac.uk <ethics@bangor.ac.uk>
Sent: 28 September 2018 09:04
To: Alice Little
Subject: Ethical approval granted for 2018-16317 Neuropsychological correlates of Social Isolation following Acquired Brain Injury

Dear Alice,

2018-16317 Neuropsychological correlates of Social Isolation following Acquired Brain Injury

Your research proposal number 2018-16317
has been reviewed by the School of 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: Research Ethics Committee Approval

NHS
Health Research Authority
South West - Cornwall & Plymouth Research Ethics Committee
Level 3
Block B
Whitefriars
Lewins Mead
Bristol
BS1 2NT

Telephone: 0207 104 8028
Fax:

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England or Wales until you receive HRA/HCRW Approval

07 November 2018

Miss Alice Olivia Little
North Wales Clinical Psychology Programme
42 College Road, Bangor University
Bangor, Gwynedd
LL57 2DG

Dear Miss Little

Study title:	**Neuropsychological correlates of Social Isolation following Acquired Brain Injury**
REC reference:	**18/SW/0242**
Protocol number:	**16317**
IRAS project ID:	**247858**

Thank you for responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

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 opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact hra.studyregistration@nhs.net outlining the reasons for your request.

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

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

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System, at www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Professional Indemnity]	1	16 July 2018
GP/consultant information sheets or letters [Letter to GP]	1	04 October 2018
HRA Schedule of Events	1.0	07 November 2018
HRA Statement of Activities	1.0	07 November 2018
IRAS Application Form [IRAS_Form_08102018]		08 October 2018
Other [Newsletter summary of findings]	1	04 October 2018
Other [Employers' Liability]		02 July 2018
Other [Response letter to REC]		
Participant consent form [Consent Form]	2	03 July 2018
Participant information sheet (PIS) [Participant Information Sheet]	3	31 October 2018
Research protocol or project proposal [Research Protocol]	1	22 August 2018
Summary CV for Chief Investigator (CI) [CI CV]		06 October 2018
Summary CV for supervisor (student research) [R.C]		
Summary CV for supervisor (student research) [C.S]		
Summary CV for supervisor (student research) [R.R]		
Validated questionnaire [De Jong Gierveld Lonliness Scale]		
Validated questionnaire [Community Integration Questionnaire]		
Validated questionnaire [Lubben Social Network Scale]		
Validated questionnaire [Awareness Questionnaire (Patient Form)]		
Validated questionnaire [Awareness Questionnaire (Clinician Form)]		
Validated questionnaire [Hayling Sentence Completion Page 1]		
Validated questionnaire [Hayling Sentence Completion Page 2]		
Validated questionnaire [Digit span Instructions]		
Validated questionnaire [Trail Making Task Updated]		

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

18/SW/0242	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

pp. Canon Ian Ainsworth-Smith
Chair

Email:nrescommittee.southwest-cornwall-plymouth@nhs.net

Enclosures: "After ethical review – guidance for researchers" *[SL-AR2]*

Copy to: *Mr Huw Ellis*
Dr Rosella Roberts, Betsi Cadwaladr University Health Board
Research-permissions@wales.nhs.uk

Appendix III: Health Research Authority & Health and Care Research Wales Approval

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Miss Alice Olivia Little
North Wales Clinical Psychology Programme
42 College Road, Bangor University
Bangor, Gwynedd
LL57 2DG

Email: hra.approval@nhs.net
Research-permissions@wales.nhs.uk

08 November 2018

Dear Miss Little

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**Neuropsychological correlates of Social Isolation following Acquired Brain Injury**
IRAS project ID:	**247858**
Protocol number:	**16317**
REC reference:	**18/SW/0242**
Sponsor	**School of Psychology, Bangor University**

I am pleased to confirm that HRA and Health and Care Research Wales (HCRW) Approval has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

How should I continue to work with participating NHS organisations in England and Wales?
You should now provide a copy of this letter to all participating NHS organisations in England and Wales, as well as any documentation that has been updated as a result of the assessment.

Following the arranging of capacity and capability, participating NHS organisations should **formally confirm** their capacity and capability to undertake the study. How this will be confirmed is detailed in the "*summary of assessment*" section towards the end of this letter.

You should provide, if you have not already done so, detailed instructions to each organisation as to how you will notify them that research activities may commence at site following their confirmation of capacity and capability (e.g. provision by you of a 'green light' email, formal notification following a site initiation visit, activities may commence immediately following confirmation by participating organisation, etc.).

It is important that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details of the research management function for each organisation can be accessed here.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within the devolved administrations of Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) has been sent to the coordinating centre of each participating nation. You should work with the relevant national coordinating functions to ensure any nation specific checks are complete, and with each site so that they are able to give management permission for the study to begin.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?
The document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

I am a participating NHS organisation in England or Wales. What should I do once I receive this letter?
You should work with the applicant and sponsor to complete any outstanding arrangements so you are able to confirm capacity and capability in line with the information provided in this letter.

The sponsor contact for this application is as follows:

Name: Mr Huw Ellis
Tel: huw.ellis@bangor.ac.uk
Email: 01248383229

IRAS project ID	247858

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **247858**. Please quote this on all correspondence.

Yours sincerely

Gurmel Bhachu
Permissions Service Manager (acting)

Email: Research-permissions@wales.nhs.uk

Copy to: *Mr Huw Ellis*
Dr Rosella Roberts, Betsi Cadwaladr University Health Board

IRAS project ID	247858

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Professional Indemnity]	1	16 July 2018
GP/consultant information sheets or letters [Letter to GP]	1	04 October 2018
HRA Schedule of Events	1.0	07 November 2018
HRA Statement of Activities	1.0	07 November 2018
IRAS Application Form [IRAS_Form_08102018]		08 October 2018
Other [Response letter to REC]		
Other [Newsletter summary of findings]	1	04 October 2018
Other [Employers' Liability]		02 July 2018
Participant consent form [Consent Form]	2	03 July 2018
Participant information sheet (PIS)	4	07 November 2018
Research protocol or project proposal [Research Protocol]	1	22 August 2018
Summary CV for Chief Investigator (CI) [CI CV]		06 October 2018
Summary CV for supervisor (student research) [R.C]		
Summary CV for supervisor (student research) [C.S]		
Summary CV for supervisor (student research) [R.R]		
Validated questionnaire [Hayling Sentence Completion Page 1]		
Validated questionnaire [Hayling Sentence Completion Page 2]		
Validated questionnaire [Digit span Instructions]		
Validated questionnaire [Trail Making Task Updated]		
Validated questionnaire [De Jong Gierveld Lonliness Scale]		
Validated questionnaire [Community Integration Questinnaire]		
Validated questionnaire [Lubben Social Network Scale]		
Validated questionnaire [Awareness Questionnaire (Patient Form)]		
Validated questionnaire [Awareness Questionnaire (Clinician Form)]		

IRAS project ID	247858

Summary of assessment

The following information provides assurance to you, the sponsor and the NHS in England and Wales that the study, as assessed for HRA and HCRW Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England and Wales to assist in assessing, arranging and confirming capacity and capability.

Assessment criteria

Section	Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	No comments
2.1	Participant information/consent documents and consent process	Yes	No comments
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	A statement of activities has been submitted and the sponsor is not requesting and does not expect any other site agreement to be used.
4.2	Insurance/indemnity arrangements assessed	Yes	The study is sponsored by Bangor University. IRAS Form A76 states insurance is provided for the design and management of the research. A copy of the insurance certificate issued by U.M. Association Limited is in the document store. At time of this governance report, the insurance expires on 31Jul2019. NHS Indemnity will apply for the conduct of the study.
4.3	Financial arrangements assessed	Yes	R&D form A65 confirms: no application for external funding will be made

Section	Assessment Criteria	Compliant with Standards	Comments
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	No comments
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	No comments
5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Yes	REC provisional opinion letter dated 30 Oct 2018 REC favourable opinion letter dated 07 Nov 2018
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	No comments
6.3	Devices – MHRA notice of no objection received	Not Applicable	No comments
6.4	Other regulatory approvals and authorisations received	Not Applicable	No comments

Participating NHS Organisations in England and Wales

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.
The study has one site type – All activities research The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England and Wales in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. Where applicable, the local LCRN contact should also be copied into this correspondence. If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England and Wales which are not provided in IRAS or on the HRA or HCRW websites, the chief investigator, sponsor or principal investigator should notify the HRA immediately at hra.approval@nhs.net, or HCRW at Research-permissions@wales.nhs.uk. We will work with these organisations to achieve a consistent approach to information provision.

IRAS project ID	247858

Principal Investigator Suitability

This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and Wales, and the minimum expectations for education, training and experience that PIs should meet (where applicable).
PI required at site GCP training is not a generic training expectation, in line with the HRA/HCRW/MHRA statement on training expectations.

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken
Use of identifiable patient records held by an NHS organisation to identify potential participants without their prior consent should be undertaken by a member of the direct care team for the patient, so it would not normally be acceptable for this to be done by staff not employed by that organisation. The activities at the participating NHS organisation will be undertaken by local staff therefore it is expected that adequate contractual relationship with the host organisation are already in place. Where contractual arrangements are not already in place, network/external staff (or similar) undertaking research activities would be expected to obtain Honorary Research Contracts on the basis of a Research Passport (if university employed) or a Letter of Access on the basis of an NHS to NHS confirmation of pre-engagement checks letter (if NHS employed). Enhanced DBS checks (incl. appropriate barred list checks) and occupational health clearance would be appropriate.

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales to aid study set-up.
The applicant has indicated that they do not intend to apply for inclusion on the NIHR CRN Portfolio.

Participant travel expenses will be reimbursed when participants are travelling to and from NWBIS for the study, participants will also receive a £10 shopping voucher for their participation.

Appendix IV: Participant Consent Form

PRIFYSGOL BANGOR UNIVERSITY

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

RESEARCH INFORMED CONSENT FORM

Title of Study: Neuropsychological correlates of Social Isolation following Acquired Brain Injury

Principal Investigator: Alice Little
psp93b@bangor.ac.uk

Research Supervisor: Dr Rudi Coetzer
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 the Principal Researcher Alice Little may access my medical records to gain contact information and/or details of my brain injury. ☐

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

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

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

I consent to my lead clinician (the individual who is responsible for my care within the North Wales Brain Injury Service) being informed of my participation in this study. ☐

I freely agree to participate in this study. ☐

Signatures:

Name of Participant (block capitals)	**Date**	**Signature**
Chief Investigator (block capitals)	**Date**	**Signature**

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 Huw Ellis, School of Psychology, Adeilad Brigantia, Penrallt Road, Gwynedd LL57 2AS.
Email: huw.ellis@bangor.ac.uk, Tel: 01248 383229.

Appendix V: Participant Information Sheet

PRIFYSGOL BANGOR UNIVERSITY

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

PARTICIPATION INFORMATION SHEET

Title of Study: **Neuropsychological correlates of Social Isolation following Acquired Brain Injury**

Chief Investigator: Alice Little (Trainee Clinical Psychologist)

Research Supervisor: Dr Rudi Coetzer (Consultant Neuropsychologist)

You have been invited to take part in a research study investigating the factors that are related to social isolation and loneliness after an Acquired Brain Injury.

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 before deciding whether to take part. You can take your time to read this information and talk to your friends, family, and clinician at the North Wales Brain Injury Service (NWBIS) before you make any decisions. One of the researchers will go through the information with you and answer any questions you may have.

What is the purpose of the study?

Research has shown that it is common for people who have had an acquired brain injury (ABI) to experience loneliness and social isolation. This study is looking at whether social isolation is related to specific difficulties in cognition (thinking), for example problems with memory or switching attention between different things. It will also look at whether the awareness that people have into their difficulties is related to their experiences of feeling socially isolated or lonely.

It is hoped that this study may help to provide clinicians and patients with the knowledge and understanding to address crucial underlying factors that are associated with loneliness and social isolation following an Acquired Brain Injury and help rehabilitation.

Why have I been invited?

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

Do I have to take part?

No. It's completely up to you to decide if you would like to take part. Before you decide, we ask you to read this information leaflet carefully. If there is anything that is not clear, or if you would like more information, please ask the researcher or contact our research staff (contact details are provided at the end of this leaflet). If you decide not to take part, **you do not need to give a reason**, and the standard of care you receive will not be affected in any way.

At any time during the study you can choose to stop taking part without giving any reason and any data that you have provided will be destroyed. Again, this will not have any impact on your future care.

What will happen to me if I decide to take part?

If you decide to take part in this research, your clinician at NWBIS will contact one of the researchers with your preferred contact details and let them know that you are interested in taking part. The Chief Investigator (Alice Little) will then contact you and arrange a time to meet at your convenience. You will be invited to complete a Consent Form, to indicate that you are happy to take part and agree to the arrangements described. We also suggest you keep a copy of the form for your records.

During the research, you will be asked to complete four short questionnaires and a series of puzzles. Completing these tasks will take no longer than **90 minutes**. There will be regular intervals in which you can take a short break. **The researcher will only need to meet with you one on occasion to complete these tasks.**

If is okay with you, your clinician at NWBIS will be asked to fill in one of the same questionnaires, to compare the two. With your permission, information about your brain injury will be collected from your patient file at NWBIS and your medical notes.

If you attend NWBIS to take part in the study, your travel costs (including your return journey) will be reimbursed. If you would like to take part in the research, but are unable to come to NWBIS, the researcher can arrange to come and visit you at a suitable location of your choice (e.g. your local GP surgery) or, if you prefer, the researcher can visit you at home. You will also receive a £10 shopping voucher to thank you for your participation.

You can withdraw from the study at any time without giving a reason. This will not affect the standard of care that you receive. If you decide to withdraw from the study after starting it, any information that we have collected will be securely destroyed in line with Betsi Cadwaladr University Health Board (BCUHB) policy.

Will my treatment be affected?

No, your treatment will not be affected in any way. During and after the research, your treatment will continue as normal.

What are the possible benefits of taking part

We cannot promise that the study will have a direct benefit to you, personally, 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. This may ultimately help to better understand why people who experience ABI might become socially isolated or lonely and can help clinicians to support people who experience loneliness. You can receive a copy of the results and any report published, when the study is completed.

What are the possible disadvantages of taking part?

This study does not involve any direct risk, but there are some important things to think about.

You will have to spend some time (up to 90 minutes) completing some tasks and questionnaires; you might find this process tiring. It is important to know that you can take short breaks whenever you choose. You can also choose to stop the process completely, at any time, without having to explain why.

Some of the questions will relate to your rehabilitation and whether you feel lonely sometimes. If you feel distressed by the questions being asked you can choose to take a break and you can also highlight your distress with the Chief Investigator who will attempt to address your concerns. You can also choose to stop the process completely without having to explain why.

If your questionnaire data suggests that you are experiencing symptoms of emotional distress, we will ask for your consent to inform your GP and / or NWBIS of this. We will also suggest that you speak to your NWBIS clinician about any emotional difficulties you are experiencing.

Will my information be kept confidential?

Yes, any information collected about you during this research will be kept strictly confidential, either in a locked filing cabinet or password protected computer. It will not be available by anyone external to the research team. We will identify any information about you by a study number which is known only to the researchers. The information and results of the study will then be anonymous. Your data (questionnaire responses and task scores) will be

collected by the researcher and will not be in any way linked to your personal details (name etc.) and cannot be traced back to you. As with all research, the anonymous data will be written up and submitted to an academic journal.

The anonymised and collated data will be securely held in the North Wales Clinical Psychology Programme for up to five years in accordance with BCUHB, it will then be destroyed.

How will your data be protected?

BCUHB will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. BCUHB keep identifiable information about you for five years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. To safeguard your rights, we will use the minimum personally-identifiable information possible. If you withdraw from the study, we will keep the information about you that we have already obtained. You can find out more about how we use your information https://digital.nhs.uk/about-nhs-digital/our-work/keeping-patient-data-safe/gdpr

BCUHB will keep your name, NHS number, contact details and information about your rehabilitation confidential and will not pass this information to Bangor University. NWBIS will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from Bangor University and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Bangor University will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number, contact details or information about your rehabilitation. BCUHB will keep identifiable information about you from this study for 5 years after the study has finished.

Will anyone else know I'm doing this?

Your involvement in this study is completely confidential. However, if you say something that makes us think that you are in danger through an act of harm from others or yourself, or someone else is in danger, we would have to share what you tell us with your lead clinician and your clinical team (the individuals within the North Wales Brain Injury Service who are responsible for your care) for further discussion and possible action. This rarely happens but we would let you know if we needed to do this.

What happens when the study stops?

The whole study is likely to finish in July 2019. If you would like, you can be sent a summary of the findings when it is finished.

Who is funding the research?

The study is being performed as part of Alice Little's (Chief Investigator) Doctoral training to become a Clinical Psychologist, and is organised by the North Wales Clinical Psychology Programme, at Bangor University. The study is also organised and supervised through the NHS. The research is fully insured through Bangor University.

Important contact details:

If you have any questions about this research or you would like more information, please contact the researchers, whose contact details are available below:

Chief Investigator: Alice Little
Trainee Clinical Psychologist
North Wales Clinical Psychology Programme
Brigantia Building

Bangor University
Bangor, Gwynedd
LL57 2DG
psp93b@bangor.ac.uk
01248 388365

Research Supervisor: Dr Rudi Coetzer
Consultant Clinical Neuropsychologist and Head of Service at NWBIS
rudi.coezter@wales.nhs.uk
01492 807770

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 Huw Ellis, School of Psychology, Adeilad Brigantia, Penrallt Road, Gwynedd LL57 2AS, Email: huw.ellis@bangor.ac.uk, Tel: 01248 383229

Appendix VI: Awareness Questionnaire (AQ)

Awareness Questionnaire
Patient Form

Name:_____ Patient #:_____ Date:_____

1	2	3	4	5
much worse	a little worse	about the same	a little better	much better

____ 1. How good is your ability to live independently now as compared to before your injury?

____ 2. How good is your ability to manage your money now as compared to before your injury?

____ 3. How well do you get along with people now as compared to before your injury?

____ 4. How well can you do on tests that measure thinking and memory skills now as compared to before your injury?

____ 5. How well can you do the things you want to do in life now as compared to before your injury?

____ 6. How well are you able to see now as compared to before your injury?

____ 7. How well can you hear now as compared to before your injury?

____ 8. How well can you move your arms and legs now as compared to before your injury?

____ 9. How good is your coordination now as compared to before your injury?

____ 10. How good are you at keeping up with the time and date and where you are now as compared to before your injury?

____ 11. How well can you concentrate now as compared to before your injury?

____ 12. How well can you express your thoughts to others now as compared to before your injury?

____ 13. How good is your memory for recent events now as compared to before your injury?

1	2	3	4	5
much worse	a little worse	about the same	a little better	much better

____ 14. How good are you at planning things now as compared to before your injury?

____ 15. How well organized are you now as compared to before your injury?

____ 16. How well can you keep your feelings in control now as compared to before your injury?

____ 17. How well adjusted emotionally are you now as compared to before your injury?

Awareness Questionnaire
Clinician Form

Clinician Name:_____ Date:_____

Patient:_____ Patient #:_____

1	2	3	4	5
much worse	a little worse	about the same	a little better	much better

____ 1. How good is the patient's ability to live independently now as compared to before his/her injury?

____ 2. How good is the patient's ability to manage his/her money now as compared to before his/her injury?

____ 3. How well does the patient get along with people now as compared to before his/her injury?

____ 4. How well can the patient do on tests that measure thinking and memory skills now as compared to before his/her injury?

____ 5. How well can the patient do the things he/she wants to do in life now as compared to before his/her injury?

____ 6. How well is the patient able to see now as compared to before his/her injury?

____ 7. How well can the patient hear now as compared to before his/her injury?

____ 8. How well can the patient move his/her arms and legs now as compared to before his/her injury?

____ 9. How good is the patient's coordination now as compared to before his/her injury?

____ 10. How good is the patient at keeping up with the time and date and where he/she is now as compared to before his/her injury?

1	2	3	4	5
much worse	a little worse	about the same	a little better	much better

____ 11. How well can the patient concentrate now as compared to before his/her injury?

____ 12. How well can the patient express his/her thoughts to others now as compared to before his/her injury?

____ 13. How good is the patient's memory for recent events now as compared to before his/her injury?

____ 14. How good is the patient at planning things now as compared to before his/her injury?

____ 15. How well organized is the patient now as compared to before his/her injury?

____ 16. How well can the patient keep his/her feelings in control now as compared to before his/her injury?

____ 17. How well adjusted emotionally is the patient now as compared to before his/her injury?

1	2	3	4	5
completely	severely	moderately	minimally	not at all

_____18. To what extent is the patient's accurate self-awareness impaired by his/her brain injury?

Appendix VII: Lubben Social Network Scale-6 (LSNS-6)

LUBBEN SOCIAL NETWORK SCALE – 6 (LSNS-6)

FAMILY: *Considering the people to whom you are related by birth, marriage, adoption, etc…*

1. How many relatives do you see or hear from at least once a month?
   0 = *none* 1 = *one* 2 = *two* 3 = *three or four* 4 = *five thru eight* 5 = *nine or more*

2. How many relatives do you feel at ease with that you can talk about private matters?
   0 = *none* 1 = *one* 2 = *two* 3 = *three or four* 4 = *five thru eight* 5 = *nine or more*

3. How many relatives do you feel close to such that you could call on them for help?
   0 = *none* 1 = *one* 2 = *two* 3 = *three or four* 4 = *five thru eight* 5 = *nine or more*

FRIENDSHIPS: *Considering all of your friends including those who live in your neighborhood*

4. How many of your friends do you see or hear from at least once a month?
   0 = *none* 1 = *one* 2 = *two* 3 = *three or four* 4 = *five thru eight* 5 = *nine or more*

5. How many friends do you feel at ease with that you can talk about private matters?
   0 = *none* 1 = *one* 2 = *two* 3 = *three or four* 4 = *five thru eight* 5 = *nine or more*

6. How many friends do you feel close to such that you could call on them for help?
   0 = *none* 1 = *one* 2 = *two* 3 = *three or four* 4 = *five thru eight* 5 = *nine or more*

Appendix VIII: De Jong Gierveld Loneliness Scale-6 (DJGLS-6)

De Jong Gierveld Loneliness Scale (6 item)

Please indicate for each of the 6 statements, the extent to which they apply to your situation, the way you feel now. Please, tick the appropriate answer.

1. I experience a general sense of emptiness:

Yes More or less No

2. There are plenty of people I can rely on when I have problems:

Yes More or less No

3. There are many people I can trust completely:

Yes More or less No

4. I miss having people around me:

Yes More or less No

5. There are enough people I feel close to:

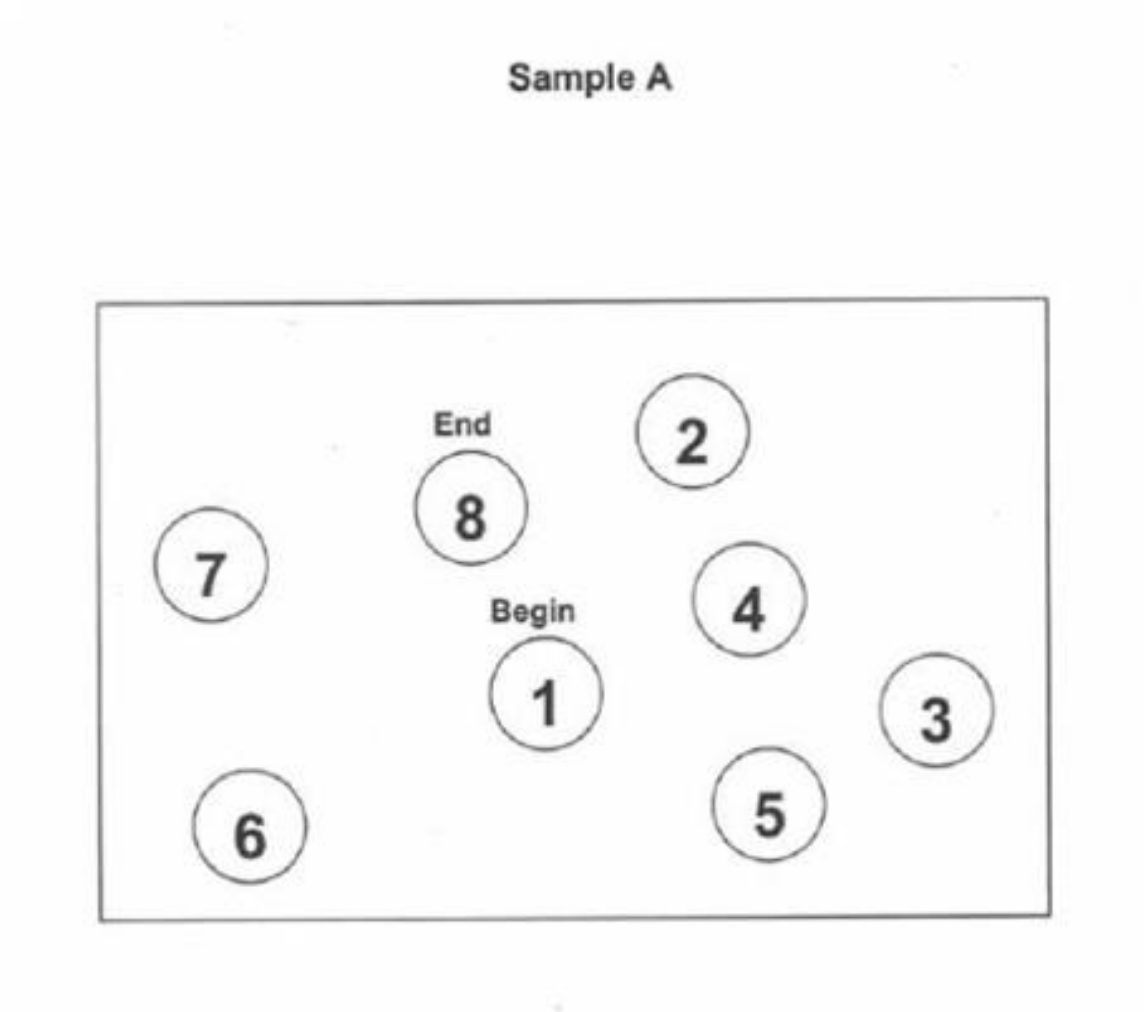
Yes More or less No

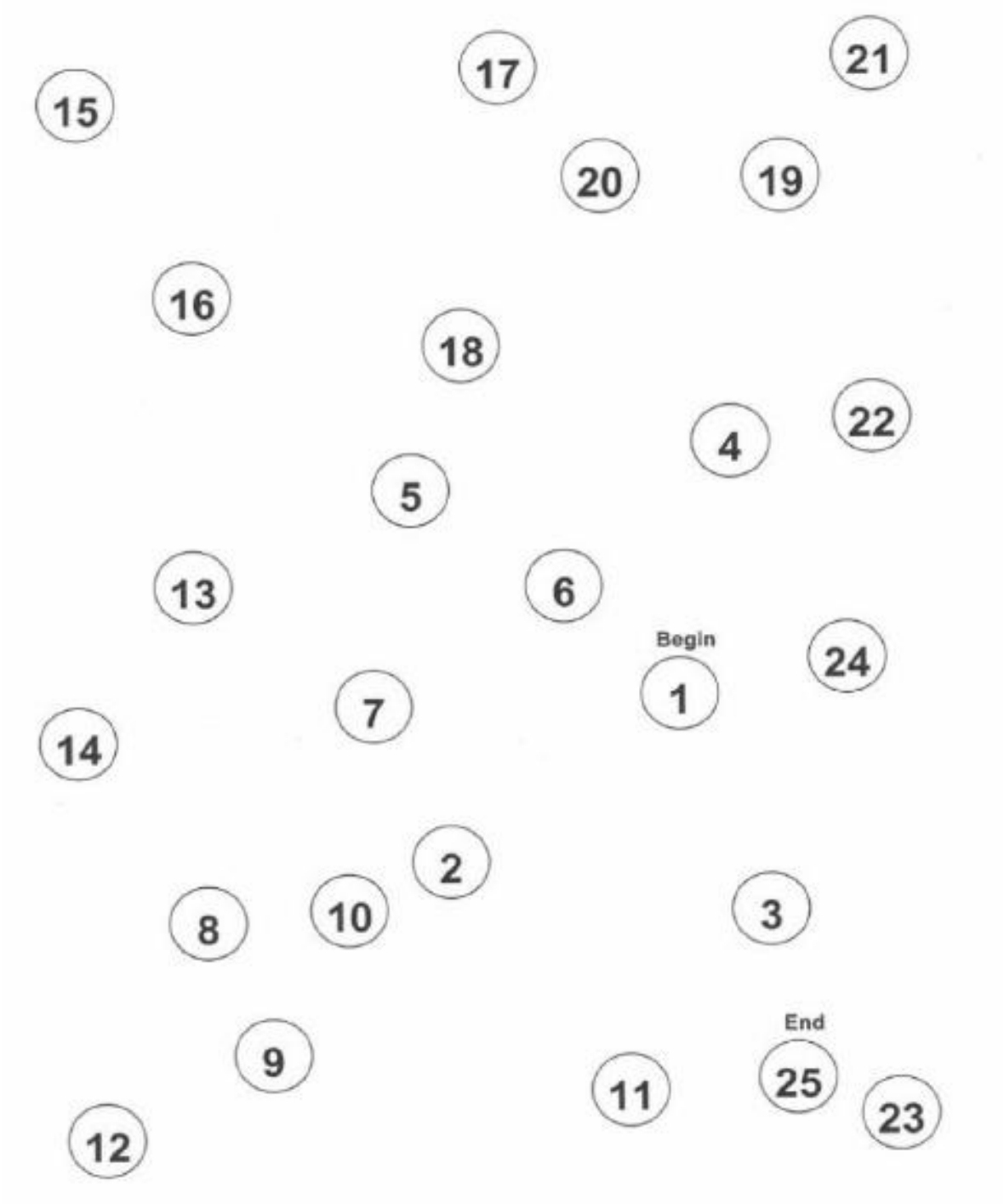
6. I often feel rejected:

Yes More or less No

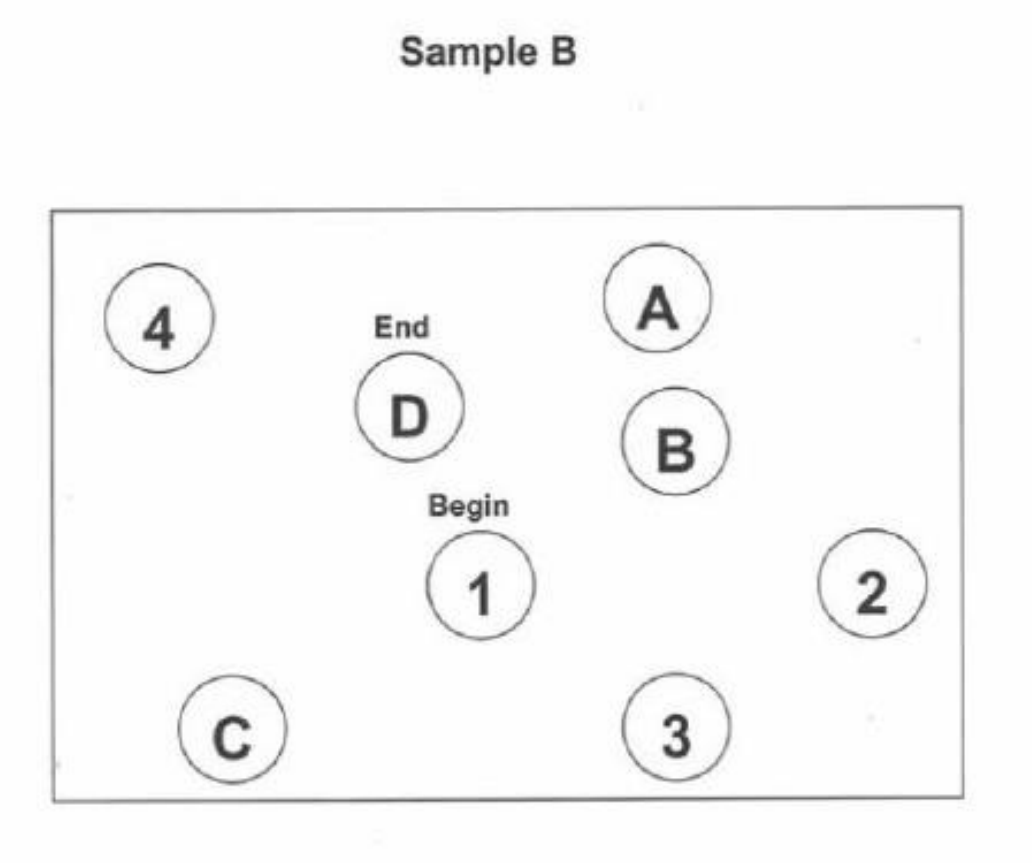
Appendix IX: Trail Making Task (TMT) A & B

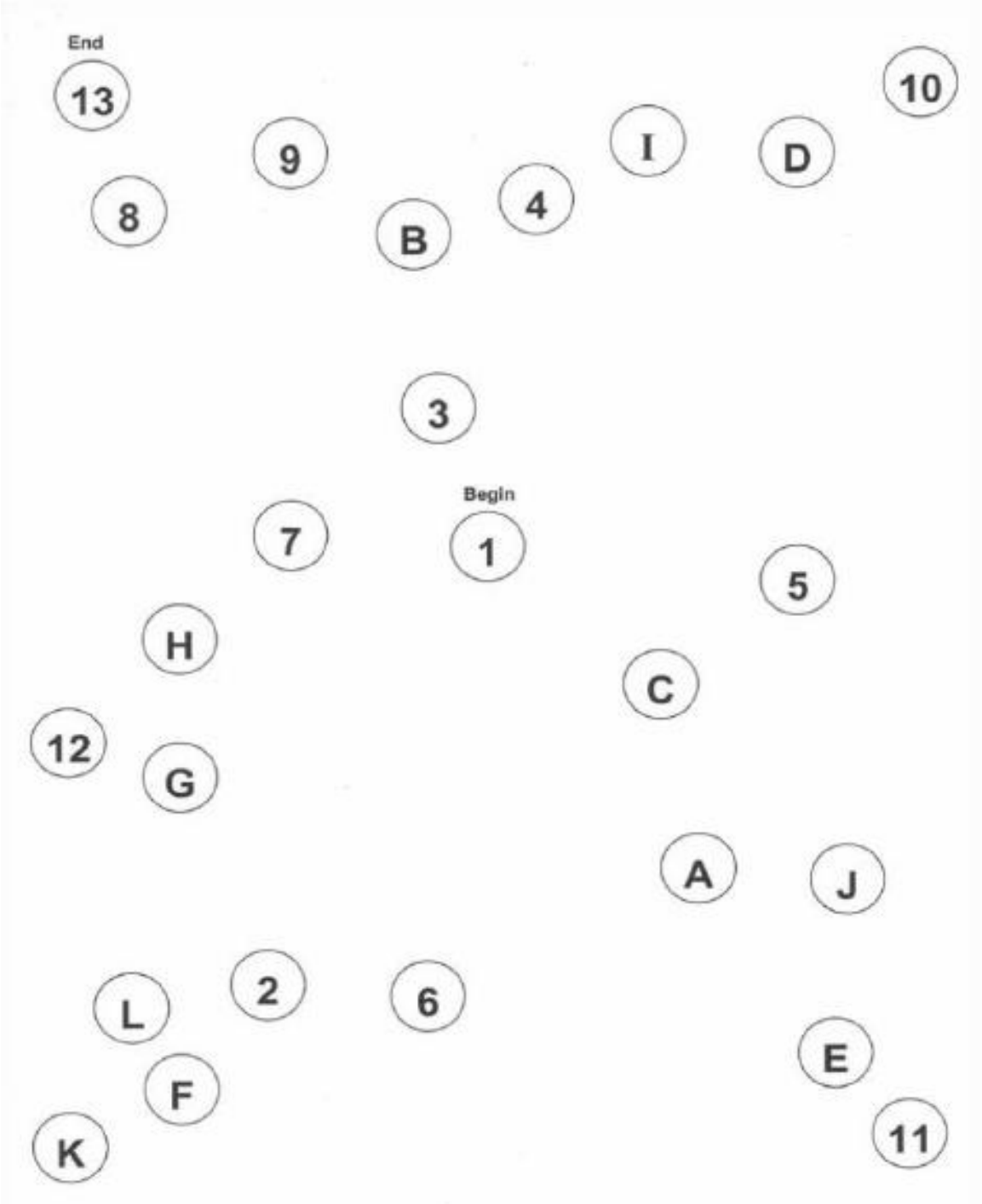
Trail Making Task A




17
21
15
20
19
16
18
22
4
5
13
6
Begin
24
1
7
14
2
10
3
8
End
9
11
25
23
12

Trail Making Task B




End
13
10
9
I
D
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B
3
Begin
7
1
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H
C
12
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A
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K

Word Count Statement

Thesis Abstract:	245
Chapter 1 – Meta-Analysis and Systematic Literature Review	
Abstract and keywords:	210
Main text (excluding figures, tables and references):	5,191
Reference list, tables and figures:	3,479
Chapter 2 – Empirical Paper	
Abstract and keywords:	211
Main text (excluding tables, figures and references):	5,578
Reference list, tables and figures:	2,955
Chapter 3 – Contributions to Theory, Research and Clinical Practice	
Abstract:	167
Main text (excluding tables, figures and references):	2,925
Reference list, tables and figures:	1,155
Appendices	
Total Word Count:	6, 217
Overall Thesis	
Total Word Count (excluding tables, figures, references and appendices):	14,298
Total Word Count of tables, figures, references and appendices:	13,806
Total Thesis Word Count: (including acknowledgements, table of contents, thesis abstract, tables, figures, reference lists and appendices):	29,147