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Self-esteem and Social Anxiety Following Brain Injury

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Word Count

Thesis Section	Text	Appendices (including references, figures and tables)	Total
Abstract	300	n/a	300
Literature Review	7981	10330	18311
Research Paper	7717	3826	11543
Critical Appraisal	3987	1138	5107
Ethics	4,658	10,006	14,664
Total	**24643**	**25600**	**49925**

Thesis Abstract

Empirical studies and theoretical models discussing psychological and psychosocial wellbeing following brain injury have increasingly suggested the importance of rehabilitation interventions which take into account the psychological resources of the individual, as opposed to focusing solely on cognitive or physical impairment.

The first paper systematically reviewed 27 quantitative studies to identify predictors or correlates of self-esteem following acquired brain injury (ABI) in adulthood. Various psychological variables are associated with low self-esteem, including greater changes in perceived identity and self-concept, poorer adjustment and higher levels of perceived loss. Higher self-esteem appears to be related to greater physical and functional impairment. The relationship between self-esteem and cognitive impairment is unclear. Low self-esteem is also strongly related to depression and poorer psychological outcomes following ABI.

The second paper describes a research project exploring social anxiety following traumatic brain injury (TBI). Despite the impact of TBI on physical, cognitive and social outcomes, no research to date has explored the role of psychological factors influencing the development of social anxiety. Hierarchical multiple regression was used to investigate demographic, clinical and psychological factors associated with social anxiety in a sample of 85 people who had experienced TBI. Psychological variables (self-esteem, locus of control, self-efficacy) provide a significant contribution to the amount of explained variance in social anxiety (above that explained by demographic and clinical variables). Moreover, perceived stigma independently predicted social anxiety. The findings support the importance of psychological variables in the development of social anxiety, and the significant role of stigma highlights the need for both individualised and societal interventions.

The third paper offers a critical appraisal of the research project, identifying key strengths and limitations in addition to discussing reflections on the process of conducting the

study. The results and implications of the study are discussed, with particular focus on social models of disability.

Declaration

This thesis represents work undertaken for the Doctorate in Clinical Psychology course at Lancaster University.

The work presented is the author's own (except where due reference is made) and has not been submitted for any other academic award.

William Curvis

15th May 2015

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First and foremost, I would like to thank everyone who participated in the research project for donating your time. This piece of research would not have been possible without your support and I hope that it serves a meaningful purpose. Special thanks also goes to the many professionals and volunteers I worked with across a range of NHS and third sector organisations during the recruitment phase. Without your support (and retweets), inviting people to take part in the study would have been impossible.

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I would also like to thank my friends and colleagues from our cohort. Sharing this experience with you all has been invaluable and I am honoured to work alongside each and every one of you.

Finally, I must thank my friends, my family and my girlfriend for their ongoing support and for putting up with me during the write-up process. I promise to find other topics of conversation from now on.

Will.

Contents

Section One: Literature Review

Factors Associated with Self-Esteem Following Acquired Brain Injury in Adults: A Systematic Review

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Prepared in accordance with instructions for authors for Neuropsychological Rehabilitation (Appendix 1-A)

Abstract

Self-esteem is potentially a key factor in psychological and psychosocial wellbeing following acquired brain injury (ABI). The current review aimed to systematically identify, synthesise and appraise all existing quantitative empirical studies on predictors or correlates of self-esteem following ABI in adulthood. In total, 27 papers met the inclusion criteria. A range of clinical factors were related to self-esteem after ABI, including the degree of physical and functional impairment. It is unclear if cognitive impairment is related to high or low self-esteem. Additionally, psychological variables such as coping styles, adjustment and perception of problems or rehabilitation are related to self-esteem following ABI. Depression is strongly associated with low self-esteem, alongside anxiety, psychological distress and quality of life. Limitations of the available research and recommendations for clinical practice and further research are discussed. In particular, there is a need to engage with contemporary theoretical understandings of self-esteem, integrated with and supported by developments in how self-esteem is conceptualised and measured over time in an ABI population. The findings of the review suggest that self-esteem is an important factor to consider following ABI, particularly in the context of developing individualised, formulation-driven rehabilitation interventions which take into account biological, social and psychological factors.

Keywords: Self-esteem, acquired brain-injury, rehabilitation, psychological.

Factors Associated with Self-Esteem Following Acquired Brain Injury in Adults: A Systematic Review

Acquired brain injury (ABI) is a broad term encompassing a range of acute focal and diffuse injuries including trauma (e.g., head injury or surgical intervention), vascular accident (e.g., stroke or subarachnoid haemorrhage), anoxia or other metabolic imbalance (e.g., hypoglycaemia), infection or inflammation (e.g., meningitis or encephalitis; Royal College of Physicians & British Society of Rehabilitation Medicine, 2003). People who have experienced an ABI often report reduced quality of life, with high rates of unemployment (Yasuda, Wehman, Targett, Cifu, & West, 2001), social isolation (Doig, Fleming & Tooth, 2001; Yates, 2003; Oddy & Humphrey, 1980) and relationship problems (Hibbard, Gordon, Flanagan, Haddad, & Labinsky, 2000).

The relationship between physical and psychological factors influencing recovery and rehabilitation has been increasingly acknowledged. For example, Gracey, Evans and Malley (2009) propose a model for ABI rehabilitation which incorporates research relating to maladaptive coping responses and discrepancies between the subjective views of the pre-injury and post-injury self. People who have experienced an ABI face an uncertain future as they come to terms with the physical, cognitive, psychological and psychosocial consequences of the injury, alongside the unpredictable nature of rehabilitation and society's response to those injuries (Fleminger & Ponsford, 2005; Simpson & Thomas, 2014).

Research suggests that psychological problems such as anxiety and depression are common following ABI (Broomfield, Quinn, Abdul-Rahim, Walters, & Evans, 2014; Bryant et al., 2010; Hackett & Pickles, 2014; Hiott & Labbate, 2002). Given the heterogeneous nature of ABI, it is unlikely that this is a sole consequence of physical damage to the brain (Fleminger, Oliver, Williams, & Evans, 2003). Psychological problems post-ABI can affect cognition, mood and motivation, further impeding engagement with rehabilitation (Khan-

Bourne & Brown, 2003). In the UK a broad, multidisciplinary approach to stroke rehabilitation is advocated by the National Institute for Health and Care Excellence (NICE, 2013) for people accessing services within the National Health Service (NHS). As psychological interventions such as cognitive-behavioural therapy (CBT) can be effective for anxiety and depression post-ABI (Stalder-Lüthy et al., 2013; Waldron, Casserly, & O'Sullivan, 2013), a better understanding of who is at increased risk of developing such problems could facilitate a bio-psychosocial approach to neuropsychological rehabilitation post-ABI (Wilson & Gracey, 2009).

Furthermore, while neurological factors have been shown to influence outcomes post-ABI, variation in psychosocial adjustment and rehabilitation cannot be adequately explained by these factors alone (Khan-Bourne & Brown, 2003; Tate & Broe, 1999). Kendall and Terry (1996) provide a model for the prediction of psychosocial adjustment post-ABI which incorporates the role of direct (neurological and neuropsychological impairment) and indirect (situational and environmental) antecedent factors, alongside mediating psychological variables such as personal resources, which influence appraisal and coping styles (Kendall & Terry, 1996). While the model proposed by Gracey et al. (2009) considers the process of rehabilitation after ABI, Kendall and Terry (1996) focus on the individual and environmental factors which interact to predict psychosocial outcome. The model suggests that a key personal resource contributing to psychosocial functioning after ABI is self-esteem.

Self-esteem has been defined as an individual's global, subjective and emotional evaluation of their perceived worth as a person (Rosenberg, 1965). However, despite much research, limited consistency is evident in how self-esteem is conceptualised and defined (Guindon, 2002; Robson, 1988). Indeed, Guindon (2002) calls for consistency and theoretical underpinnings in how researchers conceptualise self-esteem and proposes the following definition:

> The attitudinal, evaluative component of the self; the affective judgments placed on the self-concept consisting of feelings of worth and acceptance, which are developed and maintained as a consequence of awareness of competence, sense of achievement, and feedback from the external world. (p. 207)

Distinctions have been made between self-esteem and other related concepts such as self-concept (appraisals made about multiple dimensions of the self) or self-confidence (anticipation of successfully overcoming challenges or obstacles). However, these concepts differ from self-esteem as they do not incorporate a global, emotional evaluation of the self (Brown, 1993; Szymanski & O'Donohue, 1995).

Furthermore, due to conflicting patterns in empirical studies, self-esteem is increasingly seen as being more complex than the single low to high continuum originally proposed by Rosenberg (1965). It has been suggested that low and high self-esteem are separate constructs (Zeigler-Hill, 2006). In addition, the concept of "high" self-esteem has also been discussed as dichotomous by Kernis (2003), who compared secure high self-esteem with fragile high self-esteem. Fragile self-esteem is more in need of protection from threats and is associated with higher levels of distress and psychological problems (see Zeigler-Hill, 2011, for a review).

Moreover, Zeigler-Hill (2011) also discusses the discrepancy between implicit and explicit self-esteem as a marker for fragility. Explicit self-esteem is defined as the construction of conscious appraisals and feelings of self-worth and self-liking (Dijksterhuis, Albers & Bongers, 2009). Conversely, implicit self-esteem has been conceptualised as reflecting non-conscious and automatic global self-evaluations that people are unable or unwilling to report (Buhrmester, Blanton, & Swann, 2011; Zeigler-Hill, 2006). In addition, contingent self-esteem (i.e., the belief that self-worth is dependent on doing certain things or being a particular type of person) and self-esteem instability (i.e., fluctuations in self-worth

evaluations) are suggested as additional indicators of fragile self-esteem (Zeigler-Hill, 2011). These conceptualisations may be useful in explaining the role of self-esteem in rehabilitation and wellbeing following ABI. For example, if a person has fragile self-esteem they may be less able to engage in rehabilitation fully if they are inclined to protect limited self-esteem resources.

The debates around the construct have also led to further distinctions being drawn between global, state and selective self-esteem. Rosenberg (1965), in an early conceptualisation of the construct, considered self-esteem to be a global and uni-dimensional construct, reflecting an overall evaluative self-estimate of one's value and attitudes about the self. Global self-esteem is perceived to be relatively stable (Leary & Baumeister, 2004). Conversely, the term state self-esteem has been used to refer to more temporary evaluations of self-worth. By definition, these appraisals are more transitory and variable as they are affected by threats (e.g., a divorce) or boosts (e.g., a promotion) to one's perception of self-worth (Brown, 2006). Selective self-esteem is conceptualised as evaluations or appraisals of one's own value in a particular domain, area or situation (Leary & Baumeister, 2004). While global self-esteem is generally considered as less amenable to change than selective or state self-esteem, Guindon's (2002) assertion that global self-esteem is comprised of selective, variable elements may mean that, while general attitudes towards the self may be relatively stable, changes in those evaluations can be affected by life events or situational factors (Buhrmester et al., 2011).

Whether self-esteem is conceptualised as a state or a global personality trait, the potential for changeability may be increased by challenges such as those faced by people who have experienced a sudden or catastrophic life event such as ABI. While prospective research examining self-esteem before and after ABI is not available, people who have experienced ABI report significantly lower self-esteem than people who have not (Kelly, Ponsford, &

Couchman, 2013; Downing, Stolwyk, & Ponsford, 2013; Vickery, Sepehri, & Evans, 2008a). Additionally, retrospective reports from people who have experienced an ABI show that their current self-esteem is rated as lower than before their injury (Cooper-Evans, Alderman, Knight, & Oddy, 2008; Keppel & Crowe, 2000).

Qualitative research conducted with people who have experienced an ABI (Morris et al., 2005) also highlights how people often feel self-conscious about the physical and cognitive impact of their injuries. The impact of an ABI may have significant consequences for self-esteem if a person is less able to do the things they used to, particularly if self-appraials are contingent on goals or standards being attained. Furthermore, self-esteem instability is characterised by enhanced sensitivity to external events and high concerns around self-image, which may be compromised by the consequences of an ABI, particularly if someone is less able to receive the same social feedback on which they once relied.

Links between low self-esteem and psychological difficulties such as anxiety and depression in the general population are well established (Zeigler-Hill, 2011; Orth & Robins, 2013). People who have low self-esteem following ABI may be less able to utilise coping strategies and manage the physical, cognitive, psychological and psychosocial consequences of the injury if they are less able to focus on competence over limitations, or to maintain a sense of self-worth over feelings of hopelessness (Kendall & Terry, 1996). People with high self-esteem are more likely to attempt to increase their feelings of self-worth, whereas people with low or fragile self-esteem may be more unconciously concerned with protecting the limited self-esteem resources they have, therefore becoming more reluctant to risk failure or rejection (Zeigler-Hill, 2011). This defensive approach could impede rehabilitation following ABI.

A growing amount of research has suggested that self-esteem is both affected by ABI and associated with subsequent emotional adjustment and functional outcomes. A more

developed understanding of how self-esteem is affected by the physical, cognitive, psychological and psychosocial sequelae of ABI may help clinicians identify people at risk of developing psychological problems and conceptualise how the changes associated with an ABI are experienced by survivors, facilitating motivation and ability to engage with neuropsychological rehabilitation. Additionally, exploring whether self-esteem is associated with or predictive of psychological and functional outcomes will guide clinical practice by contributing to a more comprehensive understanding of the factors which influence neuropsychological rehabilitation. Consequently, a systematic literature review is useful at the present time to synthesise the available research findings around the factors found to be associated with self-esteem after ABI.

As research in this area has been limited by the variability in definitions of self-esteem and the integration of different constructs, this literature review will focus exclusively on self-esteem and not related constructs (e.g., self-concept, self-confidence). As this conceptualisation suggests that global self-esteem is developed during childhood and adolescence, this review will concentrate on adults who have experienced an ABI. Additionally, ABI is a broad term encompassing a range of neurological problems. This review will use the definition of ABI provided above, focusing on acute insults to the brain as opposed to degenerative or progressive neurological conditions. In summary, this review aims to review and appraise systematically the available quantitative research examining predictors or correlates of self-esteem following ABI in adulthood.

Method

Search Strategy

A systematic approach was used to identify and examine all research relevant to the research question. Seven electronic databases were searched for articles published in peer-reviewed journals: EMBASE, PsycInfo, Medline, Allied and Complementary Medicine

(AMED), Cumulative Index to Nursing and Allied Health Literature (CINAHL), Web of Science and ProQuest (International Bibliography of the Social Sciences). The following terms were combined using AND/OR Boolean operators to identify relevant research articles: brain injur*; head injur*; ABI; TBI; concussion; head trauma; brain damage; stroke; cerebrovascular; self-esteem; self-image; self-concept; self-worth[1]. Further details are provided in Appendix 1-B. No additional key-words were used by included papers, suggesting that the search strategy employed should have captured all relevant research articles. No limitations were placed on publication date.

Reference lists of included papers were hand-searched for potentially relevant articles. Key journals (Journal of Head Trauma Rehabilitation; Brain Injury; Stroke; Journal of Stroke and Cerebrovascular Diseases; International Journal of Stroke) were individually searched for articles relating to self-esteem. The literature search was conducted in October 2014 and, where possible, the search terms were saved and an e-mail alert was activated to highlight any studies published after this time. The search was repeated on 28th November 2014, identifying one newly published paper relevant to the review question (Shida, Sugawara, Goto & Sekito, 2014).

Inclusion and Exclusion Criteria

This review focused on the relationship between factors in people who had experienced ABI and self-esteem. All quantitative studies exploring factors which related to self-esteem in people who have sustained an ABI were considered for inclusion in the review, including cross-sectional and longitudinal studies. Only studies which focused primarily on adults (i.e., the majority of the participants were aged over 18) were included in the review. To explore factors relating to self-esteem post-ABI, studies were considered for inclusion if

[1] As discussed above, self-image, self-concept and self-worth are generally considered distinct theoretical constructs. However, the terms were included in the search strategy to ensure all relevant articles examining self-esteem were identified as these descriptive terms can contain some overlap

they measured self-esteem in people who have sustained an ABI, alongside at least one other variable. No restrictions were placed on how injuries were diagnosed or validated, or the amount of time since injury before the measures were taken. The review only included studies which employed standardised measures of self-esteem validated for use with an ABI population, with no restrictions on who completed the measure (e.g., self-report, clinician, carer). Studies were included if they utilised a measure of self-esteem, regardless of whether this was as an outcome or predictor variable. No restrictrictions were placed on publication date. Only papers which were written in English were eligible for inclusion.

Studies were excluded if they did not incorporate measures specifically designed to measure self-esteem. Studies which focused on people with diseases of the central nervous system with a recurrent, degenerative or progressive course (e.g., multiple sclerosis, dementia) were excluded from the review. Articles were excluded if they aggregated data with results from another population (e.g., a different health condition). Studies exploring the experiences of family members or caregivers were not included. Studies were required to report explicitly their measures and methodology. Qualitative studies were not included. While it is recognised that publication bias can result in skewed conclusions, the decision was taken to exclude studies where the full manuscript was not published in a peer-reviewed journal (e.g., conference presentations and dissertations) for practical access issues and to provide a baseline level of quality assurance.

Search Results

The electronic search identified 3862 records (further details are provided in Appendix 1-B). An initial screening of titles and abstracts identified 70 potentially relevant studies once duplicates were removed. Manual searches of relevant journals identified no additional papers. Reference lists of relevant papers subsequently identified 18 additional potentially relevant articles. A total of 88 full-text articles were accessed and considered

against the inclusion and exclusion criteria, with 27 subsequently included in the systematic review. An overview of this process is depicted in Figure 1.

[INSERT FIGURE 1 HERE]

Data Synthesis and Quality Assessment

Data relevant to the review's aims were extracted from each study. This included general study characteristics and details of participants, alongside factors associated with self-esteem following ABI and details of any statistical relationships reported. Due to the heterogeneity of the studies included and the variables measured, statistical synthesis via meta-analysis was considered inappropriate (Deeks, Higgins & Altman, 2008). All retrieved articles were critically appraised in terms of their methodological strengths and limitations. Criteria based on those developed for cohort, case-control and cross-sectional studies (Strengthening the Reporting of Observational Studies in Epidemiology [STROBE], 2011) were used to appraise each study on the basis of its population, methods, analyses, results and generalisability (Figure 2). Using a similar approach to a recent literature review around psychological and psychosocial factors associated with traumatic brain injury (Gill, Mullin & Simpson, 2014), these criteria were developed and expanded. This allowed for consideration of methodological issues specific to ABI studies using correlational and regression designs, in addition to the generalised reporting guidelines provided by STROBE.

[INSERT FIGURE 2 HERE]

Each study was scored against the individual criteria displayed in Figure 2, with a positive score indicating that the article provides sufficient information to meet the criteria and negative scores indicating either that information was either absent or considered inadequate. Total scores were calculated for each study and the quality of each was categorised as *low* (0 to 4)*, medium* (5 to 10) or *high* (11 to 16) to facilitate appraisal when

considering the overall results of all studies. No studies were excluded on the basis of the critical appraisal of their methodological quality as all had met the inclusion criteria.

Results

Characteristics of Included Studies

The main characteristics of each study included in the review are summarised in Table 1.

[INSERT TABLE 1 HERE]

Participants

The total number of participants who had experienced an ABI across the 27 included studies was 2655, excluding those duplicated in samples which were shared across the following studies: Downing, Stolwyk, and Ponsford (2013) and Ponsford, Downing and Stolwyk (2013); Anson and Ponsford (2006a) and Anson and Ponsford (2006b); Vickery, Evans, Lee, Sepehri, & Jabeen (2009a) and Vickery, Evans, Sepehri, Jabeen, & Gayden (2009b). Although the same samples were used in these papers, they were included as they used different analysis techniques to answer different research questions. In total 301 non-clinical participants were employed as controls across five studies (Downing et al., 2013; Howes, Edwards, & Benton, 2005a; 2005b; Ponsford, Kelly, & Couchman, 2014; Vickery, Sepehri, & Evans, 2008).

Sample sizes ranged from 13 (Howes, Edwards, & Benton, 2005a) to 986 (Ponsford et al., 2013). The mean age of ABI participants (excluding duplicates) across the included studies was 54.21 years, ranging from 14 (Keppel & Crowe, 2000)[2] to 96 (Teoh, Sims, & Milgrom, 2009). Across the included studies, 40.85% of ABI participants (excluding

[2] Two studies (Keppel & Crowe, 2000; Ponsford et al., 2013) included participants under the age of 18. As the majority of participants used in both studies were over 18, the studies were included in the review.

duplicates) were female. Studies were conducted in Australia (n = 8), United Kingdom (n = 8), United States (n = 8), China (n = 2) and Japan (n = 1).

Average time since injury ranged from 6.5 days (Chang & Mackenzie, 1998) to 11.17 years (Carroll & Coetzer, 2011). The main method of verifying ABI was by directly recruiting participants from ABI services or charities (n = 26), with one study recruiting discharged patients via a hospital database and confirming eligibility with a general practitioner (Teoh, Sims, & Milgrom, 2009). Eight of the included studies considered length of post-traumatic amnesia (PTA) or Glasgow Coma Scale (GCS) scores as a means of validating ABI and assessing severity. Five studies also used information from computerised tomography (CT) or magnetic resonance imaging (MRI) scans.

Methodological Characteristics

In total, 17 of the 27 included studies utilised a cross-sectional design. Longitudinal designs following individuals post-ABI were employed by eight of the studies, with the remaining two studies in the review assessing self-esteem pre- and post-intervention. In total 15 studies conducted regression analyses, 11 studies reported bivariate correlations, 4 reported between-group comparisons with controls and 3 made within-group comparisons.

Measures

All included studies adopted self-report measures of self-esteem. The most commonly used measure in the studies was the Rosenberg Self-Esteem Scale (RSES, Rosenberg, 1965; n = 17), with other studies including the State Self-Esteem Scale (SSES, Heatherton & Polivy, 1991; n = 6), Visual Analogue Self-Esteem Scale (VASES, Brumfitt & Sheeran, 1999; n = 5) and Coopersmith Self-Esteem Inventory (CSEI, Coopersmith, 1981; n = 1). Only two studies (Fung, Lui, & Chau, 2006; Vickery et al., 2008) used two different measures of self-esteem, with the majority employing a single assessment of the construct. One study (Cooper-Evans et al., 2008) made use of retrospective ratings of self-esteem.

Key Findings

Demographic variables. Of the seven studies which explored the relationship between age and self-esteem, Vickery et al. (2009b) found that younger participants had significantly higher self-esteem while Shida et al. (2014) found that participants older than 75 reported higher self-esteem. Five studies found no significant association between age and self-esteem (Thomas & Lincoln, 2008; Vickery, 2006; Vickery et al., 2008b; Vickery et al., 2008c; Vickery et al., 2009c). Vickery et al. (2009b) and Vickery et al. (2009a[3]) found that males showed higher self-esteem, while six other articles reported no significant association with gender (Keppel & Crowe, 2000; Thomas & Lincoln, 2008; Vickery, 2006; Vickery et al., 2008b; Vickery et al., 2008c; Vickery et al., 2009c). Vickery et al. (2009a) found that self-esteem improved less with increasing age.

Four studies explored the relationship between self-esteem and education. Vickery et al. (2009b) reported that self-esteem was significantly associated with higher levels of education. However, in a separate sample Vickery et al. (2008b) reported that lower education was associated with higher levels of self-esteem instability in the SSES Appearance subscale. Furthermore, Vickery (2006) found no significant correlation between education level and self-esteem as measured by the VASES. Only two studies explored the relationship between race and self-esteem after ABI. Vickery (2006) found no significant relationship between race and self-esteem as measured by the VASES, although Vickery et al. (2008b) reported that African-American participants had significantly higher self-esteem as measured by the SSES. Thomas and Lincoln (2008) and Fung et al. (2006) explored the relationship between self-esteem and marital status, finding no significant association.

Injury variables. Vickery et al. (2009b) and Vickery et al. (2009c) found that having history of stroke was associated with significantly lower self-esteem, however four studies

[3] As highlighted above, this study used the same sample as another included in the review.

found no significant association with having had a previous ABI (Thomas & Lincoln, 2008; Vickery, 2006; Vickery et al., 2008b; Vickery et al., 2008c). No significant relationships were found between self-esteem and injury severity, as measured by PTA (Anson & Ponsford, 2006a; 2006b[3]) or coma duration (Fung et al., 2006). Age at injury was not found to be significantly related to self-esteem in three studies (Anson & Ponsford, 2006a; Anson & Ponsford, 2006b[3]; Fung et al., 2006). Shida et al. (2014) found that participants who had experienced their ABI more than four years ago had higher self-esteem, though no justification was given for why this length of time was chosen. Four other articles explored the relationship between self-esteem and time since injury, all reporting no significant association (Anson & Ponsford, 2006a; Anson & Ponsford, 2006b[3]; Keppel & Crowe, 2000; Riley et al., 2010).

Three of the seven articles exploring the relationship of self-esteem with laterality (i.e., whether the ABI occurred within the right or left hemisphere of the brain) found significant associations. Three studies found that participants with right hemisphere ABIs reported significantly lower self-esteem scores on VASES (Vickery, 2006; Vickery et al., 2008c; Vickery et al., 2009a[3]; Vickery et al., 2009b). Vickery et al. (2009c) found that self-esteem correlated significantly with laterality of stroke but did not report the direction of this relationship. Conversely, four articles found no significant relationship between location of brain injury and self-esteem as measured by RSES, (Keppel & Crowe, 2000; Thomas & Lincoln, 2008), VASES (Vickery et al., 2008a) and SSES (Vickery et al., 2008b).

Physical health. A significant positive relationship was found between self-esteem and physical condition in a female sample (Howes et al., 2005a), though the same authors found no significant association with extent of physical disability in a male sample (Howes et al., 2005b). Vickery et al. (2009c) found that number of comorbid physical health problems

was significantly associated with lower self-esteem. Similarly, Shida et al. (2014) found that self-esteem was negatively associated with sleep problems, pain and paralysis.

Cognitive functioning. General cognitive functioning and self-esteem were found to be significantly positively correlated (Cooper-Evans et al., 2008; Vickery et al., 2008b; Vickery et al., 2009a; Vickery et al., 2009c), with Vickery et al. (2008b) also finding that cognitive functioning was positively correlated with stability of self-esteem. However, Howes et al. (2005a) found that, in a sample of women who had experienced ABI, higher cognitive functioning was associated with lower self-esteem. Howes et al. (2005b) reported no significant correlation between self-esteem and general cognitive functioning while Cooper-Evans et al. (2008) found no significant relationship with magnitude of cognitive impairment. Pre-morbid intellectual functioning was found to be positively significantly associated with self-esteem in one study (Anson & Ponsford, 2006a), though with the same sample Anson and Ponsford (2006b[3]) found that it did not correlate significantly with percentage change on self-esteem following a coping skills group intervention.

Mixed findings were reported by studies investigating specific domains of cognitive abilities. No significant relationships were observed between self-esteem and memory (McGuire & Greenwood, 1990; Anson & Ponsford, 2006a; Anson & Ponsford, 2006b[3]; Vickery, 2006) or attention (Vickery, 2006). Cooper-Evans et al. (2008) found a significant relationship between executive functioning and self-esteem, suggesting that greater impairment was associated with higher self-esteem. However, three studies report no significant relationship between self-esteem and executive functioning (Anson & Ponsford, 2006a; Anson & Ponsford, 2006b[3]; Vickery, 2006). Poorer self-awareness was found to be significantly associated with higher self-esteem in one study (Carroll & Coetzer, 2011), while Cooper-Evans et al. (2008) reported that people with poorer awareness of executive

functioning impairments had significantly higher levels of self-esteem. However, two studies (utilising one sample) found no significant relationship (Anson & Ponsford, 2006a; 2006b[3]).

Thomas and Lincoln (2008) found that expressive and receptive language impairment was associated with lower self-esteem, though Vickery (2006) found no significant relationship. Additionally, Bakheit et al. (2004) found no significant relationship between self-esteem and aphasia severity. In the only study to assess visuo-perceptual integrity, Vickery (2006) found that higher impairment was significantly related to lower levels of self-esteem.

Functional independence. Self-esteem was found to be significantly positively associated with and predictive of functional independence (Chang & Mackenzie, 1998; Fung et al., 2006; Howes et al., 2005a; Shida et al., 2014; Teoh et al., 2009; Thomas & Lincoln, 2008; Vickery et al., 2008c; Vickery et al., 2009a). Vickery et al. (2009c) reported that lower self-esteem interacted with more functional independence to predict higher levels of depression on self-care, mobility and cognitive domains of functional independence. Self-esteem was also found to be significantly lower in people living in a nursing or rehabilitation home (Thomas & Lincoln, 2008), and negatively associated with length of rehabilitation stay (Vickery et al., 2009c).

Self-esteem was positively associated with perceived recovery (Vickery et al., 2009b) and satisfaction with rehabilitation (Fung et al., 2006; Shida et al., 2014). Vickery et al. (2009a) suggested that those with higher self-care, mobility skills and perceived recovery upon admission showed greater improvement in self-esteem over time. Additionally, low self-esteem was found to be related to higher subjective stress associated with being hospitalised (Vickery et al., 2009b).

Psychological factors. McGuire and Greenwood (1990) reported a significant relationship between self-esteem and the degree of perceived burden. Greater changes in

perceived identity (Carroll & Coetzer, 2011) and self-concept (Carroll & Coetzer, 2011; Ponsford et al., 2014) before and after ABI were associated with lower self-esteem. Additionally higher levels of perceived loss and poorer adjustment, the two areas of grief measured by the Brain Injury Grief Inventory (Coetzer, Vaughan & Ruddle, 2003), were both significantly related to lower self-esteem (Carroll & Coetzer, 2011).

Negative appraisal of coping resources and coping styles characterized by avoidance, worry, wishful thinking, self-blame, and using drugs and alcohol were associated with lower levels of self-esteem (Riley et al., 2010; Anson & Ponsford, 2006b). Additionally, participants who tended to overgeneralise negative outcomes were more likely to have lower self-esteem (Vickery et al., 2009b).

Sexuality and relationships. Higher self-esteem after ABI was found to be significantly associated with higher levels of sexual functioning and relationship quality, in addition to broader social functioning (Downing et al., 2013[3]; Ponsford et al., 2013; Howes et al., 2005a). Additionally, body image (a significant factor in predicting relationship functioning) was found to be positively correlated with self-esteem (Keppel & Crowe, 2000).

Emotional wellbeing. Low self-esteem after ABI was found to be significantly associated with lower general mood ratings and psychological wellbeing, in addition to higher levels of emotional distress (Howes et al., 2005b; Downing et al., 2013[3]; Ponsford et al., 2013; Shida et al., 2014; Vickery, 2006; Vickery et al., 2009b). Higher self-esteem was also found to be significantly associated with higher levels of anxiety in three studies (Cooper-Evans et al., 2008; Howes et al., 2005b; Vickery, 2006), though two papers reported no significant relationship between self-esteem and anxiety (Anson & Ponsford, 2006b; Ponsford et al., 2014). Teoh et al. (2009) also report a significant relationship between quality of life and self-esteem. Self-esteem was a significant predictor of overall psychosocial functioning in one study (Tate & Broe, 1999).

In total, 16 studies reported a significant relationship between low self-esteem and higher levels of depression after ABI (Anson & Ponsford, 2006a; Carroll & Coetzer, 2011; Cooper-Evans et al., 2008; Fung et al., 2006; Garske & Thomas, 1992; Howes et al., 2005a; 2005b; Ponsford et al., 2013; Vickery, 2006; Vickery et al., 2008a; Vickery et al., 2008b; Vickery et al., 2008c; Vickery et al., 2009a[3]; Vickery et al., 2009b; Vickery et al., 2009c). Teoh et al. (2009) highlighted a significant difference between depressed and non-depressed participants on self-esteem. Low self-esteem was found to significantly predict higher levels of depression (Vickery et al., 2008b). Vickery et al. (2009b) report that having a history of depression was significantly associated with low self-esteem.

Vickery et al. (2009c) report significant main effects of self-esteem level on depressive symptoms, which were qualified by interactions between self-esteem and self-care and cognitive scores, and self-esteem stability and mobility. These remained significant after controlling for onset-admission interval, laterality of stroke and number of comorbidities. Vickery et al. (2009a) reported that higher mood was associated with higher initial scores of self-esteem, but mood did not significantly moderate the change in self-esteem during the course of acute stroke rehabilitation.

Quality Appraisal

The quality assessments of the included studies can be found in Table 2. All studies were rated as high, scoring eleven or above and indicating strong quality in terms of populations, methods, analyses, results and generalisability.

[INSERT TABLE 2 HERE]

All studies included in the review described the setting and how participants were recruited. All but one of the included studies provided appropriate details on demographic and clinical characteristics of participants. However four studies did not report inclusion and exclusion criteria, while only three studies provided details on how sample sizes were

determined. Of the twelve studies who collected data from participants at more than one time point, nine report on attrition.

All but one study provide details on the outcomes of statistical analyses reported, however only three report a priori power calculations. None of the included articles reported post hoc power calculations. Only four of the eleven studies which conducted multiple correlational analyses discussed corrections made. By failing to correct the effect size for the number of comparisons made, these studies may be at increased risk of Type I errors (i.e., reporting a significant relationship between two variables when one does not truly exist).

Discussion

The review highlights a broad range of pre-ABI and post-ABI factors which relate to self-esteem. The available research suggests that self-esteem is lower in people who have experienced an ABI, though only a small number of included studies examined this using control groups containing either people with other chronic health conditions or no health condition. The review highlights conflicting findings around the relationship between self-esteem post-ABI and a range of demographic factors (e.g., age, gender) and injury variables (e.g., history of stroke, laterality, injury severity), making it difficult to draw definitive conclusions regarding how these factors relate to self-esteem.

There is some evidence to support a relationship between self-esteem and cognitive functioning. However relatively few studies examine these factors directly, with many finding no significant relationship. Results are also mixed with regards to whether higher self-esteem is related to higher or lower levels of impairment. This is particularly evident in relation to executive functioning and awareness of cognitive problems, with three studies suggesting that greater impairment is related to higher self-esteem but two studies reporting no significant relationship. Low self-esteem appears to be moderately related to low

functional independence (in terms of physical ability and activities of daily living), with nine studies offering support for this relationship.

Self-esteem also appears to be strongly related to psychological outcomes, with low self-esteem found to be associated with lower quality of life and general psychological wellbeing. Three studies found that low self-esteem correlated with higher levels of anxiety, though two found no relationship. Depression was the most frequently investigated variable amongst the included studies and it is clear from the available results that self-esteem is significantly related to and predictive of higher levels of depression following ABI, with most studies reporting large effect sizes ($r > 0.5$) on a range of measures.

The review also highlights that a broad range of psychological variables may be associated with self-esteem, with all studies which examined psychological factors in relation to self-esteem reporting statistically significant relationships. Low self-esteem was found to correlate with greater changes in perceived identity and self-concept, in addition to poorer adjustment and higher levels of perceived loss. Use of negative coping styles, alongside negative appraisal of coping resources and outcomes, was found to be associated with lower self-esteem across three studies. Perceptions of impairment and burden, alongside satisfaction with rehabilitation, appear to be strongly associated with self-esteem.

The significance of psychological factors is consistent with increasing theoretical and empirical consensus that emotional wellbeing and psychosocial functioning are affected by a range of variables following ABI, with psychological factors playing a role above and beyond clinical and demographic variables (e.g., Khan-Bourne & Brown, 2003; Tate & Broe, 1999). In their model for rehabilitation processes following ABI, Gracey et al. (2009) highlight the importance of psychological factors by advocating the growth of adaptive, realistic self-representations, alongside consolidation of identity development through reducing discrepancy between pre-injury and post-injury representations of the self. They

discuss the impact of coping style on adjustment, particularly in terms of cognitive, emotional and behavioural responses following a significant traumatic event (Gracey et al., 2009).

Furthermore, given that low self-esteem is associated with anxiety and depression in the general population (Zeigler-Hill, 2011; Orth & Robins, 2013), and psychological problems are common following ABI (Broomfield et al., 2014; Bryant et al., 2010), the findings of the present review support the notion that self-esteem appears to be a key personal resource to consider following ABI, particularly in the development of psychological problems such as depression and anxiety. This is also in keeping with Kendall and Terry's (1996) model which suggests that self-esteem influences appraisal and coping style, therefore resulting in higher self-esteem contributes to more positive psychosocial and psychological outcomes following ABI.

However, the findings of the review must be considered in the context of several key limitations across the included studies, which may explain why such conflicting findings were observed. Although all studies were rated as being of high quality (in terms of population, methods, analysis, results and generalisability), few provided information regarding a priori or post hoc power calculations or adjustments made for multiple comparisons (e.g., Bonferroni corrections). Despite many studies in the review having relatively small or modest sample sizes, most used *p* values to determine significant results instead of discussing effect sizes which allow for more meaningful interpretation of the relative magnitude of the findings (Sullivan & Feinn, 2012). A reliance on correlational methods, which do not provide directional or predictive information, limits the usefulness of many studies in understanding relationships between self-esteem and associated variables. Additionally most studies failed to take into account the heterogeneous nature of ABI, often integrating people with a range of very different diagnoses into one sample.

Most notably, there is a general failure across the included studies to critically engage with how self-esteem is conceptualised or measured. As self-esteem was assessed as both a predictor and outcome variable across the included studies, it remains unclear whether lowered self-esteem is a consequence of ABI, if self-esteem has any predictive value in identifying problems post-ABI, or if self-esteem should be targeted in rehabilitation to improve outcomes. All of the included studies conceptualised self-esteem as a dichotomous (i.e., high or low), uni-dimensional construct. Decisions to assess global self-esteem were not made explicit by authors of any included studies. Even amongst the six studies which explored state self-esteem, no critical engagement with the theoretical literature around self-esteem was evident. Additionally, no studies examined implicit self-esteem. Though it is recognised that research into implicit self-esteem remains in its infancy (Dijksterhuis, Albers & Bongers, 2009), there is potential utility in identifying discrepancies between implicit and explicit self-esteem in highlighting fragility (Zeigler-Hill, 2011). Conceptualising and measuring self-esteem in a narrow way which does not embrace the complexity of current theoretical and empirical understanding limits the value of research into how self-esteem is affected by ABI and the role it might play in psychological wellbeing and rehabilitation.

Furthermore, a wide range of factors relating to self-esteem are examined. Most are only explored by a relatively small number of studies, making it difficult to draw strong conclusions about how specific variables relate to self-esteem following ABI. The varied and conflicted findings of the review reflect a lack of theoretical consistency, with disparate individual studies testing uncoordinated hypotheses which are not underpinned by a clear understanding of self-esteem and how it relates to ABI. There is a clear need for a solid theoretical model, linking current perspectives on self-esteem to the challenges of ABI in terms of mood, cognitive and physical impairment and social functioning. This is particularly

pertinent in relation to psychological factors, which may go some way to explaining the conflicting findings observed in relation to other demographic and clinical variables.

Additionally, the risk of publication bias must be considered, in that studies which do not find statistically significant results are less likely to be submitted or accepted for publication. This is particularly pertinent in relation to the findings around psychological variables, where the conclusions are reliant on a small number of studies all with statistically significant findings. Similarly, the review was limited to articles published in English and, considering that three of the included studies were from countries where English is not a first language, relevant articles written in other languages may not have been identified. Furthermore, the broad definition of ABI as applied in this review may limit the integration of the results and the subsequent application of the findings to practice. Broadening the scope of the review to examine the role of self-esteem in relation to other long-term health conditions would be useful in developing understanding of factors specific to ABI. Conversely, focusing on a particular diagnosis (e.g., stroke, traumatic brain injury) may help to consider issues which are specific to the experience of different types of brain injury.

The current review highlights several directions future research should take. It appears that self-esteem is potentially an important variable to consider following ABI, particularly in relation to outcomes such as psychological wellbeing. However, further research is required to clarify exactly how self-esteem relates to factors relevant to rehabilitation and wellbeing, with further studies needed which are designed to test hypothesised relationships between those variables suggested by contemporary theoretical developments. By carefully justifying the choice of hypothesised variables, theoretical and empirical understanding of the role of self-esteem following ABI will be improved.

Furthermore, drawing on contemporary models of self-esteem may require new or revised assessment tools, sensitive to fragile self-esteem within an ABI population. For

example, the interaction between fragile self-esteem and cognitive awareness would be a useful direction for future research, given that many people are left with impairments in executive functioning following ABI and commonly lack insight into the nature of their difficulties or are less able to self-monitor when doing a task. Additionally, no research to date has employed methods to assess implicit self-esteem in ABI population. While potentially complicated due to the impact of physical disability or cognitive impairment on assessment of reaction times, this could be extremely useful in the development of the field.

Further research is also required to guide the development of psychological and psychosocial interventions which incorporate self-esteem as a factor contributing to our understanding of underlying difficulties and change processes of rehabilitation. This is in keeping with advocates of bio-psychosocial approaches to rehabilitation, which draw on multiple models to guide effective interventions (Gracey et al., 2009; Wilson & Gracey, 2009). A stronger evidence base around the effectiveness of psychological interventions following ABI will help improve guidance for professionals working in these settings. For example in the UK, guidance for stroke rehabilitation (NICE, 2013) highlights the need for NHS services to provide emotional support, however the guidance only links to the recommendations made for managing depression in people with long-term physical health conditions, with no specific recommendations around how this should be done within an ABI population. Further research is required to support the development of internationally relevant guidelines for professionals and services which integrate a focus on psychological outcomes.

However, future research must be supported by more complex research methods, which go beyond correlational techniques to allow for assessment of directional relationships between variables to determine if self-esteem can predict or be predicted by other factors. Many of the included studies used designs and analysis techniques which did not allow for

examination of the process of non-linear change in self-esteem over time following ABI, or how such variations might correlate with or contribute to changes in outcomes. For example, improvement in a person's medical condition may lead to bi-directional change with better engagement in rehabilitation leading to self-esteem and better physical, emotional and psychosocial outcomes.

Advanced techniques such as multi-level modelling, as employed by Vickery et al. (2009a), are potentially useful in this respect as individual change and its correlates can be examined, as opposed to relying on average, group-level change as examined by difference scores (e.g., the difference between self-esteem at rehabilitation admission and discharge). A more developed understanding of how demographic, situational, psychological and injury factors might contribute to or correlate with trajectories of self-esteem change following ABI would enable services to incorporate individual differences into ABI rehabilitation (Jackson, 2010). Additionally, qualitative research which builds on the small amount of existing work (e.g., Morris et al., 2005) to specifically explore perspectives of self-esteem change following ABI, perhaps including both people who have experienced ABI and their carers, partners or families, would be useful in building on existing knowledge in this area.

Recent commentaries have also highlighted the need to incorporate social models of disability to challenge the notion that the severity of an individual's problems are the sole cause for disability and distress, with greater attention on economic, cultural and environmental barriers (Simpson & Thomas, 2014). Similarly, Kendall and Terry's (1996) model highlights the importance of situational factors in psychosocial wellbeing following ABI. Few studies in the review examined the impact of environmental variables and this is an important direction for future research if such factors can be targeted for intervention.

The findings also have implications for professionals such as clinical psychologists who work with people who have experienced ABI. As discussed, the results of this review

indicate it is difficult to define specifically how self-esteem is affected by ABI, or how self-esteem is predictive of further problems. However, there does seem to be potential value in considering self-esteem in assessment, formulation and intervention throughout the rehabilitation process following ABI. Though further examination is required, the available research suggests that self-esteem is lower following ABI. It is possible that low self-esteem could be a consequence of the challenges and psychosocial changes associated with ABI, thereby increasing the risk of emotional problems and highlighting the potential predictive utility of self-esteem in identifying people who may be less able to engage in rehabilitation effectively. Whether considered as an outcome affected by ABI or as a factor which might predict emotional and functional problems, self-esteem is associated with a range of variables relevant to ABI rehabilitation and may be a useful aspect of a person's presentation to consider.

Additionally, self-esteem may be an important mediating variable to consider as people adjust to loss (Nochi, 1998). Low self-esteem may put people at greater risk of overcoming negative psychosocial outcomes if they are less able to focus on competence or manage the demands and consequences of the ABI due to a lack of adaptive coping strategies which help them move through stages of adjustment (Kendall & Terry, 1996; Moore & Stambrook, 1995). While further research is required, self-esteem may be a useful factor for clinical psychologists to consider as the complex factors surrounding ABI are integrated into effective rehabilitation programmes which support psychological wellbeing.

Furthermore, while the disparate results across the included studies may be clarified through additional research, this may also reflect the complexity and heterogeneity of ABI. The varied results of the included studies could be suggestive of a need to build individualised programmes of care, taking a holistic approach to rehabilitation given the complex relationships between neurological and psychological factors. Additionally, there is

strong evidence to suggest that higher levels of physical health problems and lower levels of functional independence are associated with and predictive of lower self-esteem following ABI. This highlights the importance of rehabilitation which focuses on meaningful activities of daily living in addition to physical ability, with practitioners providing support which enhances people's self-esteem in addition to their physical skills.

While this is relevant to any professional working in ABI rehabilitation, it is particularly pertinent for clinical psychologists who work in these settings given their propensity to engage in direct and indirect work around improving psychological wellbeing of the people accessing services. Formulation is a core skill for clinical psychologists (British Psychological Society, 2011; American Psychological Association, 2006) and self-esteem may be a useful factor to consider in this process. However, there is a clear need for clinical psychologists to engage critically with the theoretical and empirical complexity around the construct of self-esteem. Simplified discourses around the conceptualisation of self-esteem remain prevalent in both the available research and commonly used therapeutic approaches to improving self-esteem (e.g., Fennell, 2009). Clinical psychologists must be aware of the issues surrounding the definition and measurement of self-esteem and implement formulations and interventions which are supported by theory and research, critically applied to meet the needs of people who have experienced ABI.

Engaging with this complexity will empower clinical psychologists to integrate self-esteem as a useful component of an individualised formulation, which may highlight potential problems or guide intervention. For example, a person with fragile self-esteem, which is maintained by defensive strategies and contingent on particular goals or standards being attained (Kernis, 2003), may present well initially. However they may become less engaged in rehabilitation over time, particularly if they are less willing or able to risk failure or recover from setbacks given their inclination to protect limited self-esteem resources by

distancing themselves from their failures (Zeigler-Hill, 2011). Furthermore, unusually high levels of self-esteem may reflect poor insight into cognitive difficulties post-ABI. An inverse relationship between cognitive awareness and depression following ABI is common (Fleminger et al., 2003) and self-esteem may be an important part of this process if it is negatively affected as awareness improves, and a person comes to recognise the impact of the ABI on their capabilities.

Conclusion

The current review aimed to identify, synthesise and appraise the available quantitative research to identify predictors or correlates of self-esteem following ABI in adulthood. In total, 27 papers were included in the review and considered good quality. Despite limitations in how the included studies conceptualised and measured self-esteem, a reliance on research designs which did not allow for analysis of complex relationships and a lack of a strong theoretical grounding underpinning the choice of hypothesised variables, a range of factors were identified as being related to self-esteem after ABI. These include psychological variables, in addition to the degree of physical, functional and cognitive impairment. Self-esteem also appears to be strongly related to psychological outcomes following ABI. Further research is required to examine the role of self-esteem in rehabilitation and psychological wellbeing following ABI, however this must be integrated with and supported by developments in how self-esteem is conceptualised and measured over time in an ABI population. A more developed understanding of self-esteem post-ABI will inform the development of individualised rehabilitation interventions which take into account biological, social and psychological factors to support the physical, social and psychological wellbeing of people who have experienced ABI.

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Table 1.
Main Characteristics of Included Studies.

Study	Design and Analysis	Sample and Setting	N (% female)	Mean age (SD); age range	Method of verifying ABI; mean time since injury (SD)	Self-esteem measure	Number of assessments	Summary of results relating to factors associated with self-esteem
Anson & Ponsford (2006a)	Cross-sectional, correlation.	People who experienced TBI, recruited through outpatient rehabilitation centre, Australia. Uses same sample as Anson & Ponsford (2006b)*.	33 (18%)	38 (12); X	Recruited through ABI service; PTA, GCS used to assess severity; 517 days (568)	RSES	1	Self-esteem was significantly associated with depression (r = .66, p < .001). Self-esteem was significantly positively correlated with adaptive coping (r = .56, p < .01) and negatively correlated with non-productive coping (r = -.49, p < .01) on CSA. Premorbid intellectual function (NART) was significantly correlated with self-esteem (r = .50, p < .01). Age at injury, self-awareness (PCRS, SADI), injury severity (PTA), executive function (BADS Six Elements) and memory (RAVLT) were not significantly associated with self-esteem. Time since injury was moderately correlated but not statistically significant (r = -.32).
Anson & Ponsford (2006b)	Multiple regression, within-subjects	People who experienced TBI, recruited	33 (18%)	38 (12); 20 – 81	Recruited through ABI service; PTA, GCS used	RSES	2 (pre- and post-intervention)	No independent variables (age at injury, time since injury, PTA duration, self-awareness [PCRS discrepancy, SADI total

	evaluation of group intervention.	through outpatient rehabilitation centre, Australia. Uses same sample as Anson & Ponsford (2006a)*			to assess severity; 517 days (568)			score], premorbid intellectual function [NART], executive function [BADS Six Elements], baseline anxiety/depression [HADS]) correlated significantly with self-esteem or predicted a significant proportion of the variance in the regression model. Corrections reported - Family-wise error rate of 0.05.
Bakheit, Barrett, & Wood (2004)	Longitudinal, correlation.	People who experienced stroke recruited from hospital, UK.	40 (55%)	69.8 (X); 38 - 91	Recruited from ABI service; all but one participant investigated with CT scan; X (X)	VASES	3 (within two weeks of stroke, three months and six months)	No significant correlation was found between self-esteem and aphasia severity (measured by WAB) at baseline, three months or six months.
Carroll & Coetzer (2011)	Cross-sectional, correlation.	People who experienced TBI recruited from community brain injury rehabilitation service, UK.	29 (28%)	46.3 (12.9); 22 - 64	Recruited through ABI service; GCS used to assess severity; 11.17 years (11.4)	RSES	1	Self-esteem was significantly associated with perceived identity change as assessed by discrepancies between current and retrospective ratings on HISDS (r = -.365, p < .05), depression (HADS; r = -.669, p < .01) and loss (BIGI; r = -.585, p < .01). High self-esteem was significantly correlated with better adjustment (BIGI; r = .562, p < .01) in addition to poorer awareness as measured by discrepancies between AQ ratings by self

								and clinician (r = .350, p < .01) and self and significant other (r = .401, p < .01).
Chang & Mackenzie (1998)	Longitudinal, multiple regression.	People who experienced stroke recruited from rehabilitation hospital (baseline) and community (follow-up), China.	152 (44%)	69.44 (9.33); 24 - 93	Recruited through ABI service; 6.5 days (2.75)	SSES	3 (baseline within 48 hours of admission, two weeks and three months after admission)	State self-esteem was found to significantly correlate with functional ability (BI) at baseline (r = .33, p < .001) and two weeks (r = .40, p < .001). Self-esteem after two weeks was found to significantly predict functional ability at 3 months (β = .20, p < .001), though baseline self-esteem did not. Statistics on the overall performance on the model were not reported.
Cooper-Evans, Alderman, Knight, & Oddy (2008)	Cross-sectional, correlation.	People who experienced ABI recruited from rehabilitation centre, UK.	22 (23%)	43 (11.82); 20 - 61	Recruited through ABI service; PTA, GCS used to assess severity; 122.05 months (102.74)	RSES	3 (1 retrospective and 2 current ratings of self-esteem used)	Self-esteem was significantly correlated with HADS depression (r = .65, p < .01) and anxiety (r = .71, p < .01). No clear relationship (r = .26, p > .05) was found between self-esteem and magnitude of cognitive impairment as measured by difference between pre-morbid IQ (WTAR) and current full-scale IQ (WAIS-III). However, self-esteem was significantly positively correlated with full-scale IQ (r = .43, p < .05) and negatively correlated with BADS scores of executive functioning (r = -.48, p < .05). Additionally, those with higher

								self-esteem had less awareness of executive functioning impairments as assessed by the difference between self-ratings and carer ratings on DEX (r = -.48, p < .05).
Downing, Stolwyk, & Ponsford (2013)	Cross-sectional, control comparison.	People who experienced TBI recruited from outpatient rehabilitation centre, Australia. Participants included in sample for Ponsford et al (2013)*	TBI: 865 (29.7%) Control: 142 (33.8%) Total: 1007	TBI: 34.7 (12.6); X Control: 32.97 (14.56); X	Recruited through ABI service; PTA, GCS used to assess severity; CT scans available for 832 participants; X (X)	RSES	1	Participants reporting increased total sexuality scores on the BIQS had higher self-esteem (t = 9.70, p < .001) compared to participants whose scores stayed the same or decreased. Similarly, participants with increased scores on the BIQS subscales of sexual functioning (t = 5.69, p < .001), relationship quality (t = 11.82, p < .001) and mood (t = 4.62, p < .001) had higher self-esteem. Alpha level of .001 was used to correct for number of comparisons.
Fung, Lui, & Chau (2006)	Cross-sectional, correlation.	People who experienced stroke recruited from hospitals, China.	73 (38%)	76.14 (7.15); X	Recruited through ABI service; 3 weeks (X)	SSES; RSES.	1	Depression (Chinese CES-D) was correlated with global self-esteem (r = -.59, p < .01) and state self-esteem (r = -.78, p < .01). Functional ability (BI) was significantly correlated with global self-esteem (r = .49, p < .05) and state self-esteem (r = .62, p < .05).
Garske & Thomas (1992)	Cross-sectional, correlation.	People who experienced	47 (32%)	27 (6.1), 19 - 40	Recruited through ABI service; 49.9	RSES	1	A significant correlation (r = -.740, p < .001) was found between low self-esteem and

		closed head injury recruited from rehabilitation centre, USA.			months (22.2)			higher depression (BDI) and lower satisfaction with rehabilitation needs (HSS, r = .706, p < .001). Analysis of variance found no significant relationships between self-esteem and injury severity (coma duration) or age at time of injury.
Howes, Edwards, & Benton (2005a)	Cross-sectional, between-subjects and correlation.	Females who experienced stroke/TBI recruited from charity or CP, UK.	ABI: 13 (100%) Matched controls: 13 (100%) Total: 26	ABI: 40.46 (13.09); X Control: 39.08 (14.29); X	Referred by ABI charity or CP; GCS, PTA used to assess severity; 5.52 years (5.39)	RSES	1	Self-esteem was significantly correlated with MMSE cognitive functioning (r = -.63, p < .05), mobility (r = -.64, p < .05 and social functioning (r = -.65, p < .05). Significant correlations were found between self-esteem and health (r = .61, p < .05) and physical condition (r = .75, p < .01). Self-esteem was significantly correlated with HADS depression (r = .58, p < .05). Women with ABI had lower self-esteem and higher depression than the control group.
Howes, Edwards, & Benton (2005b)	Cross-sectional, between-subjects and correlation.	Males who experienced stroke/TBI recruited from charity or CP,	TBI: 15 (0%) Stroke:	TBI: 33.93 (9.28); X Stroke: 40.50 (15.01); X	Referred by ABI charity or CP; TBI - 7.02 years (7.52); Stroke - 6.89 years (6.29)	RSES	1	Satisfaction with body, cognitive ability and physical disability did not significantly correlate with self-esteem in the ABI group. Self-esteem was significantly correlated with HADS scores on anxiety (r = .43, p < .05)

		UK.	10 (0%) Matched controls: 25 (0%) Total: 50	TBI control: 33 (12.63); X Stroke control: 40.18 (17.46); X				and depression (r = .54, p < .05) in the ABI group, in addition to the psychological well-being subscale on the bicro-39 (r = -.66, p < .001). ABI groups had significantly lower self-esteem scores than the control groups, though anxiety and depression correlated with self-esteem in both ABI and control participants.
Keppel & Crowe (2000)	Cross-sectional, multiple regression.	People who experienced stroke recruited from ward and rehabilitation outpatient clinic, Australia.	33 (60.6%)	36.73 (12.79); 14 - 57	Recruited through ABI service; MRI/CT scans used to confirm location of stroke; 7.03 months (7.60)	RSES	1 (retrospective and current ratings of self-esteem used)	No significant correlations were found between self-esteem and gender, time since stroke or type of stroke. Post-stroke self-esteem was correlated with post-stroke ratings of body image on BC-SC (r = .53, p < .001). Body image was the most significant predictor of self-esteem, accounting for 28% (R^2 = .28, p not reported) of the variance in the regression model, F (1,31) = 12.03, p < .05. Hemispheric lesion location (left/right/both) accounted for a further 4% (R^2 = .04, p not reported) of the variance in self-esteem.
McGuire &	Within-subjects,	People who	18	30.5 (X); X	Recruited through	RSES	2	A significant correlation was found between

Greenwood (1990)	pre-and post-intervention focused on memory impairment.	experienced ABI recruited from rehabilitation unit, UK.	(33.3%)		ABI service; X (X)			self-esteem and perceived burden (PBS) both before and after intervention (r = -.57, p < .001). A positive but non-significant correlation was found between changes in memory and changes in self-esteem pre- and post-intervention (r = .31, p = .30). No significant differences in self-esteem were observed between inpatients and outpatients.
Ponsford, Downing, & Stolwyk (2013)	Cross-sectional, random effects regression.	People who experienced TBI recruited from rehabilitation centre, Australia. Participants from Downing et al (2013) included in sample. *	986 (31.4%)	40.07 (16.53); 15 - 92	Recruited through ABI service; PTA, GCS used to assess severity; X (X)	RSES	Maximum of 2	A strong correlation was found between HADS depression and self-esteem (r = -.77, p < .001). Moderate but non-significant correlations were reported between ADL and self-esteem (r values not reported). In the regression model, low self-esteem was a predictor of scores on BIQS subscales of sexuality, sexual functioning, relationship quality and mood (all significant at p < .001).
Ponsford, Kelly, & Couchman (2014)	Cross-sectional, between-group comparison, correlation.	People who experienced ABI recruited through rehabilitation centre,	ABI: 41 (29.3%) Control: 41 (29.3%)	ABI: 39.7 (14.53), 18 - 73 Control: 38.71 (14.45); 18 - 71	Recruited through ABI service; 5 years (5.78)	RSES	1	Correlations were observed between self-esteem and HADS anxiety (r = -.29) and depression (r = -.26), though these were not statistically significant. Significant correlations were found between self-esteem and self-concept (TSCS)

		Australia. Total: 82						subscales: total self-concept (r = .49, p < .01); family self-concept (r = .48, p < .01); academic/work self-concept (r = .45, p < .01). Moderate but non-significant correlations were observed between self-esteem and personal self-concept (r = .40), social self-concept (r = .34) and physical self-concept (r = .30). All correlations were lower in the control group. Reported significance levels adjusted for number of corrections (Type I error rate of 0.05 / p, where p is number of dependent variables).
Riley, Dennis, & Powell (2010)	Cross-sectional, correlation and multiple regression.	People who experienced TBI, recruited from community brain injury charity, UK.	42 (21.4%)	43 (12); 24 - 69	Recruited through ABI service; 13 years (13.5)	RSES	1	Self-esteem was significantly correlated with avoidance on ATAQ A/T (r = .512, p < .001) and appraisal of coping resources on CRQ (r = -.796, p < .001) but not time post-injury. Self-esteem was not a significant predictor of the variance in avoidance, though the overall regression model incorporating CRQ, injury type and time post-injury was significant, F (4, 36) = 6.838, Adjusted R^2 = .369, p < .001.

Shida, Sugawara, Goto & Sekito (2014)	Cross-sectional, between-groups comparisons, stepwise multiple regression.	People who experienced stroke accessing hospital as outpatients, Japan.	65 (36.9%)	70.9 (11.1); 39 - 93	Recruited through ABI service; 10.7 years (8.3)	RSES	1	Self-esteem scores were significantly higher in participants who were older than 74 compared to those younger (t = -2.239, p = .029), and in those who experienced their ABI four or more years ago compared to more recently (t = -2.159, p = .035). Self-esteem was also significantly lower in participants who were restricted by pain or paralysis (t = -3.717, p < .001), had unpleasant feelings (t = -2.578, p = .012) or were dissatisfied with sleep (t = -2.661, p = .010). Significantly higher self-esteem was observed in participants who required movement assistance (t = -4.340, p < .001) and movement monitoring (t = -2.997, p = .004). However, participants were significantly more likely to have high self-esteem if they were effective communicators (t = -2.409, p = .017) and independent in toileting (t = -3.634, p = .001), grooming (t = -4.856, p < .001), bathing (t = -6.577, p < .001), eating (t = -2.409, p = .019) and dressing (t = -4.234, p < .001). Self-esteem was significantly higher in participants who

								had a role at home (t = -3.924, p < .001), were in employment (t = -2.339, p = .019), went out frequently for reasons other than work (t = -2.021, p = .048), attended ceremonial occasions (t = -2.784, p = .007) and voted in elections (t = -3.762, p < .001). Participants who had support from friends (t = -2.223, p = .030), were needed by family members (t = -3.203, p = .002) and were satisfied with the home environment (t = -2.036, p = .046) had significantly higher self-esteem scores. Self-esteem scores were significantly predicted by the stepwise multiple regression model (F = 24.19, R^2 = .769, adjusted R^2 = .738 p < .001). Independent bathing was the most significant predictor (β = .405, p < .001), followed by environmental attitudes such as being needed by family members (β = .389, p < .001), independent grooming (β = .292, p < .001) and sleep satisfaction (β = .237, p = .017)
Tate & Broe (1999)	Cross-sectional, regression.	People who experienced TBI recruited from	70 (25.7%)	X (X); X	Recruited through ABI service; PTA used to assess	CSEI	1	Level of self-esteem emerged as a significant predictor of psychological adjustment (β = -.10, p = .013) in the overall

		rehabilitation centre, Australia.			severity; 6 years (X)			logistic regression model (x^2 = 43.64, df = 9, p < .001) using a dichotomized measure (good/restricted psychosocial outcome) as the outcome variable.
Teoh, Sims, & Milgrom (2009)	Longitudinal, multiple regression.	People who experienced stroke living in community, Australia.	135 (32%)	67.5 (14.3); 25 - 96	Recruited through hospital database, eligibility confirmed with general practitioner; 11.7 months (4.9)	RSES	3 (baseline, ten weeks, six months	Hierarchical regression analysis found that self-esteem significantly predicted quality of life (AQoL) at ten weeks (β = .20, p = .04), satisfaction with life (SWLS) at baseline (β = .21, p = .25), ten weeks (β = .27, p = .002) and six months (β = .41, p < .001). Self-esteem was also a significant predictor of stroke impact (SIS) at baseline (β = .23, p = .012). Statistics on the overall performance on the model were not reported. ANCOVA analysis highlighted a significant difference between depressed and non-depressed participants on self-esteem (effect size = .28, p < .001).
Thomas & Lincoln (2008)	Longitudinal, multiple regression.	People who experienced stroke recruited from hospital, UK.	100 (49%)	70.15 (9.38); X	Recruited through ABI service; 30.87 months (8.29)	VASES	3 (baseline, one month and six month post-stroke)	VASES scores at one month and six months were not significantly related to gender, age, marital status, employment status, previous depression, previous stroke, side of lesion or stroke classification at baseline. Self-esteem was significantly correlated with

ADL at one month on the BI ($r = .37$, $p < .001$) and six months on the NEADL ($r = .38$, $p < .001$). Receptive language impairments (SST) and VASES scores were significantly correlated at one month ($r = .33$, $p < .001$) and six months ($r = .34$, $p < .001$). Expressive language impairments (SST) and VASES scores were significantly correlated at one month ($r = .37$, $p < .001$) and six months ($r = .49$, $p < .001$).

Paired samples *t*-test found no significant difference between VASES scores at one month and six months after stroke ($p = .063$). Living arrangements six months post-stroke were significantly related to VASES scores, $F(3, 88) = 2.79$, $p = .045$, with post-hoc tests demonstrating that those living in a nursing or residential home showed lower self-esteem than those living alone ($p = .05$).

Overall regression models exploring ADL and language impairment as predictors of self-esteem were significant at one month, $F(2, 97) = 14.83$, $R^2 = .24$, $p < .001$ and six months, $F(2, 89$, $R^2 = .31$, $p < .001$, with baseline receptive and expressive language

								impairment and ADL scores (BI and NEADL) significant predictors of self-esteem at six months post-stroke. Receptive language impairment was not a significant predictor in the final regression model. Living arrangements at time of stroke, having a previous stroke and side of lesion did not predict VASES scores at six months, although experiencing a total anterior circulation infarction significantly predicted lower VASES scores than other types of stroke.
Vickery (2006)	Cross-sectional, correlation.	People who experienced stroke recruited from inpatient rehabilitation unit, USA.	156 (55%)	65.8 (X); 18 - 92	Recruited through ABI service; 20 days (X)	VASES	1	No significant correlations were found between VASES ratings and age, education, gender, race. No significant differences in self-esteem scores were found between patients with first-time stroke and those with history of prior stroke, or between patients with high or low visual acuity. Patients with a right hemisphere stroke had lower mean self-esteem ratings compared to the left hemisphere group, t (146) = -2.42, p = .02. The measure of visuoperceptual integrity was the only subscale of the BADS to significantly correlate with self-esteem (r =

								.26, $p < .001$), with measures of memory, language functioning, attention or abstract reasoning not reaching significance. No significant differences were found between patients with severe or mild language impairment or visuoperceptual deficits. Self-esteem was significantly correlated with mood disturbance (VAMS; $r = -.66$, $p < .001$), depression (GDS; $r = -.65$, $p < .001$) and anxiety (AMAS; $r = -.52$, $p < .001$). Participants with low self-esteem (VASES total < 32) reported significantly greater levels of depression (GDS), t (46) = -2.92, $p = .005$, and emotional disturbance (VAMS), t (46) = -.5.31, $p < .001$.
Vickery, Sepehri, & Evans (2008a)	Cross-sectional, between-group and within-group analysis, regression.	People who experienced stroke recruited from inpatient rehabilitation unit, USA.	ABI: 80 (52%) Control: 80 (56%) Total: 160	ABI: 62 (13); 24 - 85 Control: 62 (13); 22 - 87	Recruited through ABI service; 14 days (13)	VASES; RSES.	1	No significant group differences on either self-esteem measure were found between patients with right and left hemisphere strokes. Depression (GDS) was found to be significantly correlated with RSES ($r = -.75$, $p < .05$) and VASES ($r = -.77$, $p < .05$) in the stroke group. Bonferroni corrections reported. Exploratory regression analysis indicated that depression (GDS) accounted for a

								significant amount of variance in self-esteem scores, with dependent variables of RSES (β = -.439, p < .001) and VASES (β = -.492, p < .001). Ratings on each self-esteem measure also accounted for significant variance in the other, even after controlling for the effect of ratings of depressive mood. These patterns were present for both stroke and control patients, though the amount of variance was less in the control group.
Vickery, Sepehri, Evans & Lee (2008b)	Longitudinal, regression.	People who experienced stroke recruited from inpatient rehabilitation unit, USA.	79 (47%)	67.6 (14); 34 - 91	Recruited through ABI service; neuro-imaging reports consulted; 11.1 days (9.6)	SSES	8 (twice a day for 4 consecutive days)	No significant relationships were found between self-esteem and age, gender, history of prior stroke, time since stroke or laterality of recent stroke. Lower education was associated with higher levels of self-esteem instability (higher deviation across scores) in the SSES appearance subscale (r = -.26, p = .02). Additionally, African American participants tended to indicate higher scores on the SSES appearance subscale (r = .36, p < .001). A significant correlation was found between MMSE scores and self-esteem stability (r = .31, p = .007) and the three SSES subscales (Performance: r = -.34, p = .003; Social: r = -.40, p < .001; Appearance:

								r = -.29, p = .012). Depression (GDS) was significantly associated with total SSES (r = -.53, p < .001) and all three subscales (Performance: r = -.53, p = .003; Social: r = -.41, p < .001; Appearance: r = -.52, p = .012). Depression was also significantly correlated with SSES stability (r = .26, p < .05). Regression analysis highlighted that self-esteem level significantly predicted depression scores (R^2 = .29, β = -.250, p < .001). A significant interaction of self-esteem level and stability emerged in the second block of the regression model (R^2 = .33, β = -.019, p < .05).
Vickery, Sherer, Evans, Gontkovsky & Lee (2008c)	Cross-sectional, regression.	People who experienced stroke recruited from inpatient rehabilitation unit, USA.	176 (55%)	68.1 (13.3); 24 - 92	Recruited through ABI service; neuro-imaging reports consulted; X (X)	VASES	1	Significant relationships were found between self-esteem and GDS depression (r = -.72, p < .001), laterality (r = .18, p < .05), length of stay in rehabilitation (r = -.18, p < .05) and FIM subscales of self-care (admission: r = .23, p < .005; discharge: r = .27, p < .001) and mobility (admission: r = .18, p < .05; discharge: r = .29, p < .001). Self=esteem was significantly correlated

with efficiency of improvement (the difference between the admission and discharge scores, divided by the number of days in the rehabilitation unit) for the mobility subscale ($r = .22$, $p < .005$) but not self-care. Age, gender, onset-admission interval, comorbidities and presence of previous strokes were not significantly associated with self-esteem.

In the regression model, self-esteem was significantly associated with self-care domain score ($\beta = .165$, $p = .014$) whereas depression was not. A significant interaction was found between self-esteem and depression ($\beta = -.117$, $p = .021$), suggesting that poorer self-care efficiency was associated with lower self-esteem only among those reporting fewer depressive symptoms. Self-esteem was also predictive of discharge mobility ($\beta = .186$, $p = .007$) and mobility efficiency (increase in scores per day; $\beta = .319$, $p = .002$). Efficiency was again qualified by an interaction between self-esteem and depression ($\beta = -.190$, $p = .019$).

Vickery, Evans, Lee, Sepehri, & Jabeen (2009a)	Multilevel modelling	People who experienced stroke recruited from inpatient rehabilitation unit, USA. Taken from sample utilised in another article (Vickery, Evans, Sepehri, Jabeen, & Gayden, 2009b)	120 (57%)	68.7 (10.9); 41 - 87	Recruited through ABI service; 9.9 days (9.2)	SSES	10 (baseline within first three days of admission, every three days subsequently)	Modelling SSES scores as a function of time resulted in an intercept of 69.504 ($p <$ □.001) and a change estimate (i.e., slope) of 1.663 ($p < .001$), indicating that self-reported self-esteem significantly increased during rehabilitation. Initial SSES scores were significantly correlated with subsequent change ($r =$ □.25, $p < .01$), suggesting that participants with lower initial scores tended to have a steeper rate of change during rehabilitation and greater increases in self-reported self-esteem across time. Between-individual moderators: Lower initial self-esteem values (intercepts, β_0) were significantly associated with female gender ($\beta_0 = -7.691$, $p = .002$, $\beta_1 = .113$), left hemisphere stroke ($\beta_0 = -6.360$, $p = .002$, $\beta_1 = -.147$), history of stroke ($\beta_0 = -6.777$, $p = .012$, $\beta_1 = .493$) and lower admission FIM self-care ($\beta_0 = .356$, $p = .048$, $\beta_1 = .074$) and lower admission cognitive scores ($\beta_0 = .661$, $p < .001$, $\beta_1 = .053$), however the change rate of self-

esteem (β_1) was not significantly different among levels or categories of these variables. Age and pre-morbid depression did not significantly affect intercepts.

A significant Time X Age interaction (p = .027), indicated that self-esteem improved less with increasing age. Additionally, significant interactions between Time X Admission FIM self-care (p = .049) and Time X Admission FIM mobility (p = .017) suggested that those with higher self-care and mobility skills upon admission had steeper self-esteem growth curves (i.e. showing greater improvement in self-esteem over time).

Within-individual moderators: Higher mood was associated with higher initial scores of self-esteem ($p < .001$) and the change rates of mood and self-esteem were significantly correlated (r = -.34, $p < .001$), though mood did not significantly moderate the change in self-esteem. Individuals with lower initial ratings of perceived recovery reported greater rate of change in self-esteem over time (p = .030), as lower initial perceived

								recovery scores were associated with lower initial self- esteem ratings (r = .48, p < .001).
Vickery, Evans, Sepehri, Jabeen, & Gayden (2009b)	Longitudinal, multiple regression.	People who experienced stroke recruited from inpatient rehabilitation unit, USA**	120 (57%)	68.7 (10.9); 41 - 87	Recruited through ABI service; 9.9 days (9.2)	SSES	10 (baseline within first three days of admission, every three days subsequently)	Self-esteem level was significantly associated with younger age (r = .22, p = .02), education (r = .32, p < .001), male gender (r = -.29, p < .001), right hemisphere stroke (r = -.35, p < .001), and no history of prior stroke (r = -.25, p = .007). Higher self-esteem stability (lower SSES score standard deviation) was associated with older age (r = -.21, p = .02) and higher education (r = -.27, p = .003). A non-significant relationship was observed with premorbid history of depression (r = -.17, p = .07). Self-esteem was significantly associated with depression (GDS) on admission (r = -.64, p < .001) and discharge (r = -.72, p < .001), in addition to baseline impairment distress (IDS; r = -.66, p < .001), perceived recovery (PRS; r = .61, p < .001), subjective stress associated with hassles experienced by rehabilitation experienced (r = -.54, p < .001) and individuals' tendency to overgeneralise a bad outcome or experience as having negative implications for self-

								worth (OGS; $r = .64$, $p < .001$). Self-esteem stability was not significantly correlated with any of these variables. Four regression analyses were conducted to explore how depression (GDS) scores at discharge related to self-esteem, self-esteem stability and one other variable; stress from hospital-based hassle, overgeneralisation, impairment-related distress or perceived recovery. Two-way interactions between self-esteem, self-esteem stability and each variable did not emerge as significant predictors of depression at discharge. However, significant ($p < .05$) three-way interactions were observed between self-esteem, self-esteem stability and each variable.
Vickery, Sepheri, Evans & Jabeen (2009c)	Longitudinal, multiple regression.	People who experienced stroke recruited from inpatient rehabilitation unit, USA **	120 (57%)	68.7 (10.9); 41 - 87	Recruited through ABI service; 9.9 days (9.2)	SSES	10 (baseline within first three days of admission, every three days subsequently)	Significant positive correlations were observed between self-esteem and functional independence (FIM) self-care ($r = .21$, $p < .05$), mobility ($r = .21$, $p < .05$) and cognitive scores ($r = .37$, $p < .001$). Low self-esteem was significantly correlated with higher depression at discharge (GDS; $r = -.72$, $p < .001$), number of comorbidities ($r =$

-.36, $p < .001$) and laterality of stroke ($r = -.36$, $p < .001$). Self-esteem stability (within-person standard deviation of SSES scores) was not significantly correlated with any variable.

Regression analyses explored how depression (GDS) scores at discharge related to self-esteem, self-esteem stability and each FIM subscale; self-care, mobility and cognitive scores. There were significant main effects of self-esteem level on depressive symptoms for each FIM subscale ($R^2 = .52$, $\beta = -.71$, $p < .001$). These were qualified by interactions between self-esteem and self-care ($R^2 = .55$, $\beta = .16$, $p < .05$) and cognitive scores ($R^2 = .57$, $\beta = .21$, $p < .05$), and self-esteem stability and mobility ($R^2 = .55$, $\beta = -.17$, $p < .05$). These remained significant after controlling for onset-admission interval, laterality of stroke and number of comorbidities. Three-way interactions between self-esteem, self-esteem stability and each subscales did not emerge as significant predictors of depression at discharge.

Note: Articles are presented in alphabetical order. ABI = Acquired brain injury; ADL = Activities of daily living; AMAS = Adult Manifest Anxiety Scale (Reynolds, Richmond and Lowe, 2003); ANCOVA = Analysis of covariance;
ANOVA = Analysis of variance; AQ = Awareness Questionnaire (Sherer, Bergloff, Levin, High, Oden & Nick, 1998); AQoL = Assessment of Quality of Life (Hawthorne, Richardson & Osborne, 1999); BADS = Behavioural Assessment of Dysexecutive Syndrome (Wilson, Alderman, Burgess, Emslie & Evan (1996); BDI = Beck Depression Inventory (Beck & Steer, 1987); BI = Barthel Index (Collin, Wade, Davies & Horne, 1988); Bicro-39 = Brain Injury Community Rehabilitation Outcome Scales (Powell, Beckers & Greenwood, 1998); BIGI = Brain Injury Grief Inventory (Coetzer, Vaughan & Ruddle, 2003); CES-D = Centre for Epidemiological Studies Depression Scale (Radloff, 1977); CP = Clinical psychology/psychologist; CSA = Coping Scale for Adults (Frydenberg & Lewis, 1996); CSEI = Coopersmith Self-Esteem Inventory (Coopersmith, 1981); CT = Computerised tomography; DEX = Dysexecutive Questionnaires (part of BADS battery); FIM = Functional Independence Measure (Wright, 2000); GDS; Geriatric Depression Scale (Yesavage et al., 1983); HADS = Hospital Anxiety and Depression Scale (Zigmond & Snaith, 1983); HISDS = Head Injury Semantic Differential Scale (Tyerman & Humphrey, 1984); HSS = Human Service Scale (Kravetz, Florian & Wright, 1985); IDS = Impairment Distress Scale (Vickery et al., 2009b); MMSE = Mini Mental State Exam (Folstein, Folstein & McHugh, 1975); MRI = Magnetic resonance imaging; N = Number of participants; Overgeneralization Scale (Carver, La Voie, Kuhl, & Ganellen, 1988); PBS = Perceived Burden Scale (Livingston, Brooks and Bond, 1985); PCRS = Patient Competency Rating Scale (Prigatano, Fordyce & Zeiner, 1986); PRS = Perceived Recovery Scale (Vickery et al., 2009b); PTA = Post-traumatic Amnesia; RAVLT = Rey Auditory Verbal Learning Test (Rey, 1941); RSES = Rosenberg Self-Esteem Scale (Rosenberg, 1965); SADI = Self-Awareness of Deficits Interview (Fleming, Strong & Ashton, 1996); NART = National Adult Reading Test (Nelson, 1982); SD = Standard deviation; SIS = Stroke Impact Scale (Duncan, Wallace, Lai, Johnson, Embretson & Laster, 1999); SSES = State Self-Esteem Scale (Heatherton & Polivy, 1991); SST = Sheffield Screening Test (Blake, McKinney, Treece, Lee & Lincoln, 2002); SWLS = Satisfaction With Life Scale (Diener, Emmons, Larsen & Griffin, 1985); TBI = Traumatic brain injury; TCSC = Tennessee Self-Concept Scale (Fitts & Warren, 1996); VAMS = Visual Analogue Mood Scales (Stern, 1997); VASES = Visual Analogue Self-Esteem Scale (Brumfitt & Sheeran, 1999); WAB = Western Aphasia Battery (Kertesz, 1982); WAIS-III = Wechsler Adult Intelligence Scale – Third Edition (Wechsler, 1999); WTAR = Wechsler Test of Adult Reading (Wechsler, 2001); X = Not reported.

* Contacted lead author to confirm that these articles shared participants with other included studies.
** Contacted lead author to confirm that these articles use two different samples despite similarities.

	Anson & Ponsford (2006a)	Anson & Ponsford (2006b)	Bekheit et al. (2004)	Carroll & Coetzer (2011)	Chang & Mackenzie (1998)	Cooper-Evans et al. (2008)	Downing et al. (2013)
Population							
1. Description of the setting, alongside details of how participants were recruited and data were collected (including number of assessments).	+	+	+	+	+	+	+
2. Confirmation that participant has experienced ABI, either through clinician report, recruitment approach (e.g. via hospital) or participant self-report.	+	+	+	+	+	+	+
3. Inclusion and exclusion criteria clearly defined.	-	+	+	+	+	+	+
Methods							
4. Design of study allows for assessement of factors that are associated with self-esteem.	+	+	+	+	+	+	+
5. Use of standardised measure of self-esteem validated in ABI population.	+	+	+	+	+	+	+
6. All additional variables (e.g. demographic, predictors, outcomes) clearly defined with details of methods of assessment provided.	+	+	+	+	+	+	+
7. Details provided on how the study sample size was determined.	-	-	-	-	-	-	-
8. Details provided on attrition and those who were eligible but did not participate or complete the study.	-	-	+	+	+	+	+
Analysis							
9. A priori power calculation provided.	-	-	-	-	-	-	-
10. Details provided on statistical methods used.	+	+	+	+	+	+	+

Results							
11. Details provided on demographic and clinical characteristics of study participants (i.e. age, gender, time since ABI, inpatient/outpatient status, type of ABI).	+	+	+	+	+	+	+
12. Details provided on any boundaries used when continuous variables were categorised (e.g. injury severity).	+	+	+	+	+	+	+
13. Provides adequate details on outcomes of all statistical analyes reported, including level of significance.	+	+	+	+	+	+	+
14. Provides details of statistical corrections applied to significance levels (e.g. Bonferroni).	-	+	-	-	-	-	+
Generalisability							
15. Key results (in relation to self-esteem) summarised with reference to study objectives.	+	-	+	+	+	+	+
16. Conclusions drawn (in relation to self-esteem) give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies and other relevant evidence.	+	-	+	+	+	+	+
17. Discussion of limitations of study in relation to its generalisability to wider clinical practice, taking into account any potential bias or imprecision.	+	+	-	+	-	+	+
Total Score	**12**	**12**	**13**	**14**	**13**	**14**	**15**

	Fung et al. (2006)	Garske & Thomas (1992)	Howes et al. (2005a)	Howes et al. (2005b)	Keppel & Crowe (2000)	McGuire & Greenwood (1990)	Ponsford et al. (2013)
Population							
1. Description of the setting, alongside details of how participants were recruited and data were collected (including number of assessments).	+	+	+	+	+	+	+
2. Confirmation that participant has experienced ABI, either through clinician report, recruitment approach (e.g. via hospital) or participant self-report.	+	+	+	+	+	+	+
3. Inclusion and exclusion criteria clearly defined.	+	-	+	+	+	-	-
Methods							
4. Design of study allows for assessement of factors that are associated with self-esteem.	+	+	+	+	+	+	+
5. Use of standardised measure of self-esteem validated in ABI population.	+	+	+	+	+	+	+
6. All additional variables (e.g. demographic, predictors, outcomes) clearly defined with details of methods of assessment provided.	+	+	+	+	+	+	+
7. Details provided on how the study sample size was determined.	-	-	-	-	-	-	-
8. Details provided on attrition and those who were eligible but did not participate or complete the study.	-	+	-	-	+	-	+
Analysis							
9. A priori power calculation provided.	-	-	-	-	-	-	-
10. Details provided on statistical methods used.	+	+	+	+	+	+	+

Results							
11. Details provided on demographic and clinical characteristics of study participants (i.e. age, gender, time since ABI, inpatient/outpatient status, type of ABI).	+	+	+	+	+	-	+
12. Details provided on any boundaries used when continuous variables were categorised (e.g. injury severity).	+	+	+	+	+	+	+
13. Provides adequate details on outcomes of all statistical analyes reported, including level of significance.	+	+	+	+	+	+	-
14. Provides details of statistical corrections applied to significance levels (e.g. Bonferroni).	-	-	-	-	-	-	-
Generalisability							
15. Key results (in relation to self-esteem) summarised with reference to study objectives.	+	+	+	+	+	+	+
16. Conclusions drawn (in relation to self-esteem) give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies and other relevant evidence.	+	+	+	+	+	+	+
17. Discussion of limitations of study in relation to its generalisability to wider clinical practice, taking into account any potential bias or imprecision.	+	-	+	-	+	+	-
Total Score	**13**	**12**	**13**	**12**	**14**	**11**	**11**

	Ponsford et al. (2014)	Riley et al. (2010)	Shida et al. (2014)	Tate & Broe (1999)	Teoh et al. (2009)	Thomas & Lincoln (2008)	Vickery (2006)
Population							
1. Description of the setting, alongside details of how participants were recruited and data were collected (including number of assessments).	+	+	+	+	+	+	+
2. Confirmation that participant has experienced ABI, either through clinician report, recruitment approach (e.g. via hospital) or participant self-report.	+	+	+	+	+	+	+
3. Inclusion and exclusion criteria clearly defined.	+	+	+	+	+	+	+
Methods							
4. Design of study allows for assessement of factors that are associated with self-esteem.	+	+	+	+	+	+	+
5. Use of standardised measure of self-esteem validated in ABI population.	+	+	+	+	+	+	+
6. All additional variables (e.g. demographic, predictors, outcomes) clearly defined with details of methods of assessment provided.	+	+	+	+	+	+	+
7. Details provided on how the study sample size was determined.	-	-	-	-	-	-	-
8. Details provided on attrition and those who were eligible but did not participate or complete the study.	-	-	-	+	-	+	-
Analysis							
9. A priori power calculation provided.	-	-	-	-	-	-	-
10. Details provided on statistical methods used.	+	+	+	+	+	+	+

Results							
11. Details provided on demographic and clinical characteristics of study participants (i.e. age, gender, time since ABI, inpatient/outpatient status, type of ABI).	+	+	+	+	+	+	+
12. Details provided on any boundaries used when continuous variables were categorised (e.g. injury severity).	+	+	+	+	+	+	+
13. Provides adequate details on outcomes of all statistical analyes reported, including level of significance.	+	+	+	+	+	+	+
14. Provides details of statistical corrections applied to significance levels (e.g. Bonferroni).	+	-	-	-	-	-	-
Generalisability							
15. Key results (in relation to self-esteem) summarised with reference to study objectives.	+	+	+	+	+	+	+
16. Conclusions drawn (in relation to self-esteem) give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies and other relevant evidence.	+	+	+	+	+	+	+
17. Discussion of limitations of study in relation to its generalisability to wider clinical practice, taking into account any potential bias or imprecision.	+	+	+	-	+	+	+
Total Score	**14**	**13**	**13**	**13**	**13**	**14**	**13**

	Vickery et al. (2008a)	Vickery et al. (2008b)	Vickery et al. (2008c)	Vickery et al. (2009a)	Vickery et al. (2009b)	Vickery et al. (2009c)
Population						
1. Description of the setting, alongside details of how participants were recruited and data were collected (including number of assessments).	+	+	+	+	+	+
2. Confirmation that participant has experienced ABI, either through clinician report, recruitment approach (e.g. via hospital) or participant self-report.	+	+	+	+	+	+
3. Inclusion and exclusion criteria clearly defined.	+	+	+	+	+	+
Methods						
4. Design of study allows for assessement of factors that are associated with self-esteem.	+	+	+	+	+	+
5. Use of standardised measure of self-esteem validated in ABI population.	+	+	+	+	+	+
6. All additional variables (e.g. demographic, predictors, outcomes) clearly defined with details of methods of assessment provided.	+	+	+	+	+	+
7. Details provided on how the study sample size was determined.	-	+	-	-	+	+
8. Details provided on attrition and those who were eligible but did not participate or complete the study.	-	+	-	+	+	+
Analysis						
9. A priori power calculation provided.	-	+	-	-	+	+
10. Details provided on statistical methods used.	+	+	+	+	+	+

Results						
11. Details provided on demographic and clinical characteristics of study participants (i.e. age, gender, time since ABI, inpatient/outpatient status, type of ABI).	+	+	+	+	+	+
12. Details provided on any boundaries used when continuous variables were categorised (e.g. injury severity).	+	+	+	+	+	+
13. Provides adequate details on outcomes of all statistical analyes reported, including level of significance.	+	+	+	+	+	+
14. Provides details of statistical corrections applied to significance levels (e.g. Bonferroni).	+	-	-	-	-	-
Generalisability						
15. Key results (in relation to self-esteem) summarised with reference to study objectives.	+	+	+	+	+	+
16. Conclusions drawn (in relation to self-esteem) give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies and other relevant evidence.	+	+	+	+	+	+
17. Discussion of limitations of study in relation to its generalisability to wider clinical practice, taking into account any potential bias or imprecision.	+	+	-	+	+	+
Total Score	**14**	**15**	**11**	**13**	**15**	**15**

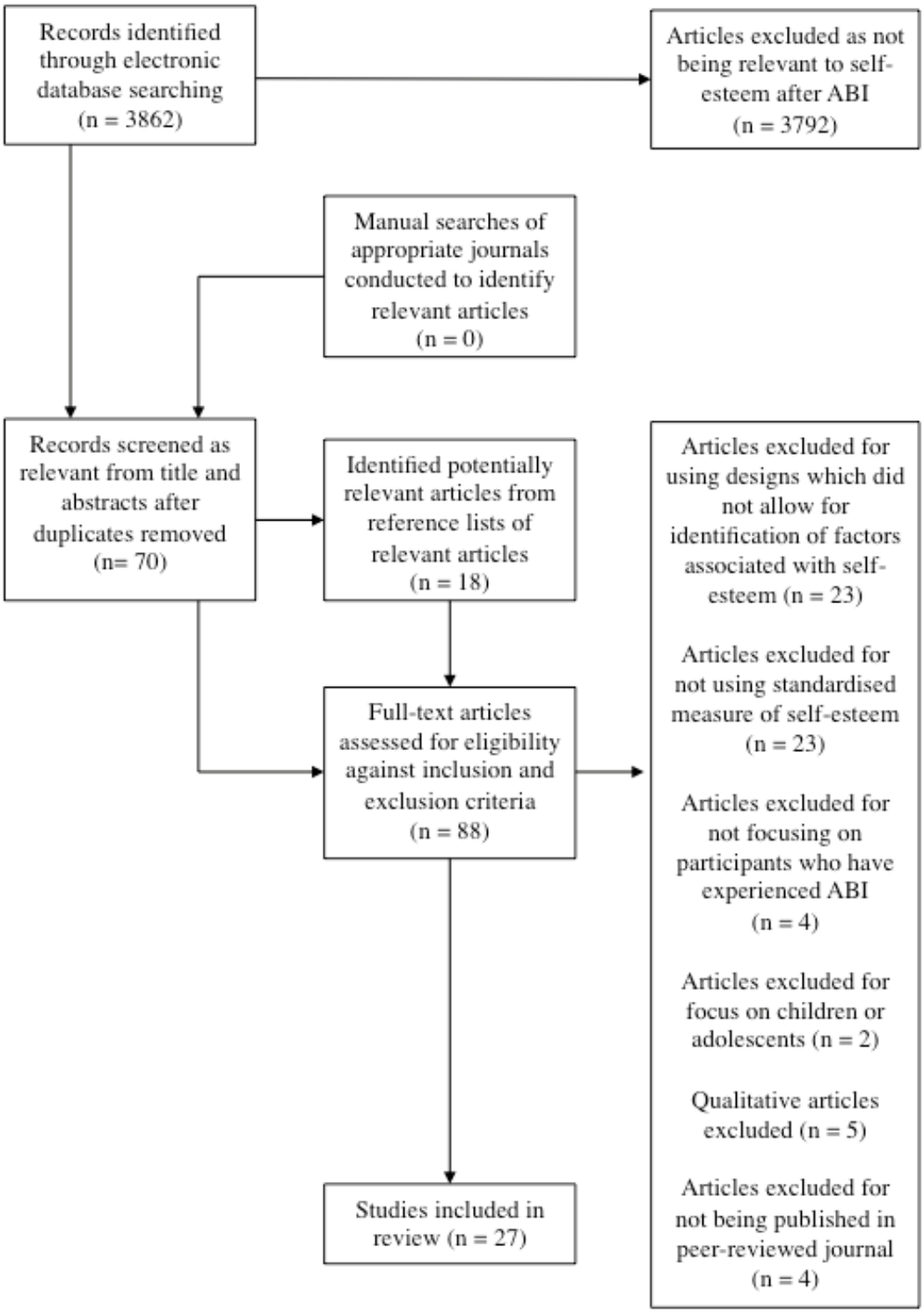


Figure 1. Flowchart displaying the process of identifying articles for inclusion in the review.

Quality Criteria

Population

1. Description of the setting, alongside details of how participants were recruited and data were collected (including number of assessments).
2. Confirmation that participant has experienced ABI, either through clinician report, recruitment approach (e.g. via hospital) or participant self-report.
3. Inclusion and exclusion criteria clearly defined.

Methods

4. Design of study allows for assessement of factors that are associated with self-esteem.
5. Use of standardised measure of self-esteem validated in ABI population.
6. All additional variables (e.g. demographic, predictors, outcomes) clearly defined with details of methods of assessment provided.
7. Details provided on how the study sample size was determined.
8. Details provided on attrition and those who were eligible but did not participate or complete the study.

Analysis

9. A priori power calculation provided.
10. Details provided on statistical methods used.

Results

11. Details provided on demographic and clinical characteristics of study participants (i.e. age, gender, time since ABI, inpatient/outpatient status, type of ABI).
12. Details provided on any boundaries used when continuous variables were categorised (e.g. injury severity).

Figure 2. Criteria used to assess the quality of studies included in the review.

13. Provides adequate details on outcomes of all statistical analyes reported, including level of significance.
14. Provides details of corrections applied (e.g. Bonferroni).

Generalisability

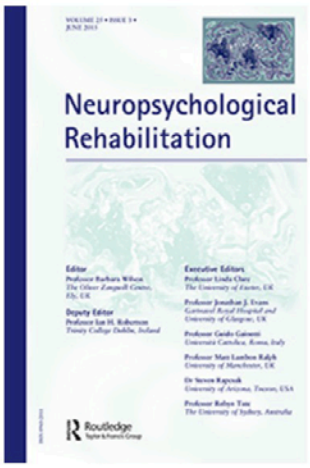
15. Key results (in relation to self-esteem) summarised with reference to study objectives.
16. Conclusions drawn (in relation to self-esteem) give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies and other relevant evidence.
17. Discussion of limitations of study in relation to its generalisability to wider clinical practice, taking into account any potential bias or imprecision.

Appendices

Appendix 1-A: Neuropsychological Rehabilitation Instructions for Authors

Appendix 1-B: Search Strategy and Results

Appendix 1-A: Neuropsychological Rehabilitation Instructions for Authors



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Appendix 1-B: Search Strategy and Results

Search terms and Boolean operators employed:

"brain injur*" or "head injur*" or ABI or TBI or concussion or "head trauma" or "brain damage" or stroke or "cerebrovascular"

AND

"self-esteem" or "self esteem" or "self-image" or "self-concept" or "self-worth"

Database	**Number of records identified**	**Number of records screened as relevant**
Embase	1699	39
PsycInfo	876	28
Medline	659	15
Allied and Complementary Medicine (AMED)	149	8
Cumulative Index to Nursing and Allied Health Literature (CINAHL)	422	6
Web of Science	49	3
ProQuest (International Bibliography of the Social Sciences)	8	1
Total	**3862**	

Section Two: Research Paper

Social Anxiety Following Traumatic Brain Injury: An Exploration of Associated Factors

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Trainee Clinical Psychologist

Doctorate in Clinical Psychology

Lancaster University, Lancaster, UK

Abstract word count: 185

Word count (excluding abstract, references, appendices & tables): 7, 717

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Prepared in accordance with instructions for authors for Neuropsychological Rehabilitation (see Appendix 1-A)

Abstract

Social anxiety (SA) following traumatic brain injury (TBI) has the potential to significantly affect an individual's general psychological wellbeing and social functioning, however little research has explored factors associated with its development. The present study used hierarchical multiple regression to investigate the demographic, clinical and psychological factors associated with SA following TBI. A sample of 85 people who have experienced TBI were recruited through social media websites and brain injury services across the North-West of England. The overall model was significant, explaining 52-54.3% of the variance in SA (across five imputations of missing data). The addition of psychological variables (self-esteem, locus of control, self-efficacy) made a significant contribution to the overall model, accounting for an additional 12.2-13% of variance in SA above that explained by demographic and clinical variables. Perceived stigma was the only significant independent predictor of SA ($B = .274$, $p = .005$). The findings suggest that psychological variables are important in the development of SA following TBI and must be considered alongside clinical factors. Furthermore, the significant role of stigma highlights the need for intervention at both an individualised and societal level.

Keywords: traumatic brain injury, social anxiety, stigma, psychological

Social Anxiety Following Traumatic Brain Injury: An Exploration of Associated Factors

Traumatic brain injury (TBI), generally defined as a non-degenerative insult to the brain caused by an external mechanical force (e.g., from a road traffic accident or a fall), can lead to temporary or permanent impairment of brain function, affecting cognitive and physical abilities (World Health Organisation [WHO], 2006; Menon, Schwab, Wright, & Maas, 2010). Head injuries are the most common cause of death and impairment in people under 40 (National Institute for Health and Care Excellence [NICE], 2014; WHO, 2006). Around 1.4 million people attend accident and emergency departments in England and Wales every year following a TBI, with 200,000 of these injuries severe enough to warrant admission to hospital (NICE, 2014). Estimates from the United States suggest that 1–2% of the population (around five million people) live with impairments following TBI (Kelly & Becker, 2001). Cross-cultural prevalence data are provided by Brockfield, Perini and Rapee (2014).

People who have experienced a TBI are at increased risk of developing psychological difficulties such as depression and anxiety (Bryant et al., 2010; Moore, Terryberry-Spohr & Hope, 2006). Recognising psychological problems after TBI can be challenging, given the complex interactions between the neurological and emotional sequelae of TBI and the difficulties in identifying symptoms of psychological problems in the context of other factors (e.g., cognitive impairment, physical disability) associated with TBI (Scheutzow & Wiercisiewski, 1999). As psychological problems following TBI may affect wellbeing and inhibit recovery (Morton & Wehman, 1995), it is imperative to improve understanding and management of these difficulties during assessment and rehabilitation (Williams, Evans & Fleminger, 2003).

Furthermore, it is vital to understand the social context in which TBI rehabilitation occurs. Social functioning is commonly affected by TBI and this can have a significant

impact on life satisfaction (Pierce & Hanks, 2006; Truelle, Fayol, Montreuil, & Chevignard, 2010). Qualitative research highlights the importance of social activity in making sense of oneself following TBI (Yeates, Gracey, & Mcgrath, 2008). However, declines in leisure activities, social contact, independence, functional status and employment opportunities are often reported following TBI (Antonak, Livneh, & Antonak, 1993; Temkin, Corrigan, Dikmen, & Machamer, 2009). Severity of injury fails to account fully for differences in psychosocial functioning post-TBI (Antonak et al., 1993).

Following TBI people may feel embarrassed or self-conscious in social situations given the frequency of physical consequences (e.g., disability, hemiparesis, skull depressions, scarring, tremors, motor/speech problems) and often unseen cognitive problems with word finding, attention, memory, executive functioning and processing speed (Hiott & Labbate, 2002; Moore et al., 2006; Wright & Telford, 1996). Social interaction can be negatively impacted following TBI if a person is less able to follow or engage in conversation (Morris et al., 2005). Consequently, problems following TBI may result in people becoming particularly anxious in social situations (Moore et al., 2006; Wright & Telford, 1996).

Social anxiety (SA) is characterised by a marked fear of situations in which a person might face scrutiny from others and subsequent avoidance of common triggers (e.g., social interactions, meeting new people, public speaking) which can result in significant distress and impairments in functioning (NICE, 2013; American Psychiatric Association [APA], 2013). In the UK, NICE (2013) suggest that 12% of people in the general population meet the criteria for SA, with similar rates observed in the United States (Kessler, Berglund, Demler, Jin, Merikangas & Walters, 2005), Europe (McDowell et al., 2013) and Australia (Crome, Grove, Baillie, Sunderland, Teesson & Slade, 2014).

Anxiety (Rao & Lyketsos, 2002) and declines in psychosocial functioning (Antonak et al., 1993) following TBI are well documented. However, the available research examining

SA following TBI is limited and of poor quality. A prospective cohort study of people who had experienced traumatic injuries found that 6.1% of people with mild-TBI met criteria for SA three months post-injury, rising to 9% after 12 months (Bryant et al., 2010). These rates were higher than in participants who experienced other kinds of traumatic injuries not affecting the brain. The differences were not statistically significant, however the authors also report that people who experienced TBI were over twice as likely to develop SA after twelve months (Bryant et al., 2010). Conversely, Newton and Johnson (1985) found that SA was lower in participants with a TBI compared to those without. However on closer examination, the TBI group comprised only eleven participants who exhibited a broad range of scores on a measure of SA. The authors concluded that although the mean score was lower than the control group, a high level of SA was observed in the TBI group as the majority of the TBI group (n = 8) demonstrated high levels of SA.

This lack of research interest may be a consequence of the complex interaction and overlap between psychological and neurological problems as discussed above. It may also result from the criteria within the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5; APA, 2013) for SA which state that, if a medical condition is present, anxiety or avoidance must be unrelated or out of proportion to it. This suggests that a diagnostic label of social anxiety disorder may not be appropriate for people experiencing anxiety in social situations after TBI. This may result in social anxiety not being considered in this population, or such difficulties being attributed to the cognitive or neurological consequences of TBI. However, this is not in keeping with recommendations for a broad and bio-psychosocial approach to providing support and rehabilitation following TBI (Gracey, Evans & Malley, 2009; Wilson & Gracey, 2009).

No guidance is available specific to the management of SA after TBI. However, empirically-based guidance for services in the UK (NICE, 2013) recommends cognitive

behavioural therapy (CBT) as a first-line intervention (i.e., before pharmacological interventions) for management of SA, using a specifically developed theoretical model (e.g., Clark & Wells, 1995) to guide therapy. However, a randomised controlled trial of a CBT programme for SA after acquired brain injury (ABI) found that although SA did reduce, treatment effects were not statistically significant (Hodgson, McDonald, Tate, & Gertler, 2012). A small sample size (n = 12) and variability in the ABI group (people who had experienced stroke, hypoxic brain injury and cerebral oedema were included alongside those who had experienced TBI) limits the usefulness of this study in understanding management of SA after TBI.

Despite the lack of research or guidance around SA after TBI, a literature review exploring anxiety following mild TBI (Moore et al., 2006) highlighted the potential for SA to be a significant problem in this population. Furthermore, Soo, Tate and Rapee (2012) present a theoretical rationale for high levels of SA in children and adolescents who have experienced TBI. They draw on Kendall and Terry's (1996) model for understanding individual differences and predicting psychosocial adjustment outcomes following TBI, acknowledging a role for direct (neurological and cognitive impairment) and indirect (situational and environmental) antecedent factors, but also emphasising the importance of an individual's psychological resources such as appraisal style and coping responses. This is consistent with cognitive theories of SA (e.g., Clark & Wells, 1995; Wells, 2013) and approaches to management of other anxiety problems following TBI (Williams et al., 2003; Soo & Tate, 2009). Consequently, an understanding of SA following TBI in adults must be guided by research which explores the role of potentially relevant neurological, cognitive, situational and psychological factors to guide assessment, formulation and intervention during acute and long-term rehabilitation.

Neurological damage to multiple areas of the brain is often a result of even mild TBI, both from the initial impact and from subsequent acceleration–deceleration forces. Damage to focal areas and the neural pathways which connect different areas is a common consequence of lacerations, contusions or abrasions caused by contact with the inside of the skull or twisting and shearing effects (Kolb & Whishaw, 2003; Sohlberg & Mateer, 2001). Oedema, increased inter-cranial pressure, haemorrhage and infection are common complications following more severe TBI (Goldstein & McNeil, 2012). Damage to multiple areas and the interruption of neural pathways can affect the completion of complex tasks such as emotional processing and inhibition (Moore et al., 2006).

Impairment in cognitive domains (e.g., processing speed, memory) has been associated with psychosocial problems following TBI (Antonak et al., 1993). A person may be less able to engage in social interactions if they have impaired attentional capacity or executive functioning, which can be associated with poor appraisal of social situations (Mattson & Levin, 1990). This could raise anxiety as it may lead to uncertainty about other people's thoughts and actions, while reducing a person's ability to initiate and maintain coping strategies (Soo et al., 2012). Conversely, SA may be reduced if a person has less insight into the minds of others as a consequence of cognitive impairment. However, neurological variables (e.g., severity of injury) and neuropsychological factors (e.g., extent of cognitive impairment) fail to fully explain variations in anxiety and psychosocial functioning (Antonak et al., 1993; Moore et al., 2006). As appraisal of cognitive problems may moderate this relationship (Kervick & Kaemingk, 2005), it would be useful to explore people's understanding of their cognitive difficulties following TBI as opposed to focusing solely on their neurological profile or performance on psychometric assessments.

Furthermore, as with the nature of other emotional problems, a broad range of psychological variables may be important to consider in examining SA following TBI (Soo et

al., 2012). Locus of control (LoC), the beliefs a person holds about how the behaviour of themselves and others influences their health (Wallston, Stein, & Smith, 1994), has been associated with SA (Cloitre, Heimberg, Liebowitz, & Gitow, 1992; Kennedy, Lynch, & Schwab, 1998). Higher external LoC (i.e., a person's belief that their health is outside of their control) has been associated with significantly lower emotional and physical problems in people who have experienced TBI (Moore & Stambrook, 1992). Similarly, self-efficacy, the beliefs people hold about their capabilities, may be important in the development of SA post-TBI (Soo et al., 2012). Low self-efficacy is associated with SA (Leary & Atherton, 1986) and is predictive of global life satisfaction following TBI (Cicerone & Azulay, 2007), with beliefs around perceived cognitive problems also found to mediate the relationship between community integration and life satisfaction.

A central characteristic of SA is the fear of negative evaluation, which is often linked to negative self-appraisals activated and reinforced in social situations (Wells, 2013; Clark & Wells, 1995; Rapee & Spence, 2004). Though debate continues around the consistency of the construct, self-esteem is generally defined as the affective judgements one holds about the self: a global, subjective and emotional evaluation of one's perceived worth as a person (Guindon, 2002). People who are socially anxious have been found to have lower self-esteem (Ritter, Ertel, Beil, Steffens, & Stangier, 2013) and, although self-esteem is perceived to be relatively stable[1], people who have experienced TBI have been found to have lower self-esteem compared to those who have not (Ponsford, Kelly, & Couchman, 2014). Additionally, self-esteem has been shown to predict psychosocial outcomes following TBI (Tate & Broe, 1999).

Furthermore, fear of negative evaluation may mean that people with SA perceive or experience higher levels of stigma (Anderson, Jeon, Blenner, Wiener, & Hope, 2015; Clark

[1] When self-esteem is conceptualised as a global tendency comprised of self-appraisals (for further discussion see Leary and Baumeister, 2000).

& Wells, 1995). People who are socially anxious may be rejected or perceived negatively, particularly if anxiety related behaviours (e.g., gripping hands together, avoiding eye contact) compound the anxiety symptoms or impair social performance (Wells, 2013; Rapee & Spence, 2004). As highlighted above, the physical and cognitive consequences of TBI may add further challenges to social interactions. Qualitative research has suggested stigma may be a potential factor affecting wellbeing following TBI, with participants highlighting the lack of public understanding about the consequences of TBI and how this impacts on their social engagement (Morris et al., 2005; Nochi, 1998). Furthermore, perceived stigma is strongly associated with anxiety in people with chronic physical conditions (Alonso et al., 2008) and epilepsy (Beyenburg, Mitchell, Schmidt, Elger, & Reuber, 2005).

In conclusion, despite the theoretical rationale for SA following TBI presented by Soo et al. (2012) and Moore et al., (2006), present understanding of SA following TBI is limited given the limited available research. No research to date has explored psychological factors which might contribute to the development of SA following TBI to provide guidance for assessment and intervention. While it is recognised that psychological problems may predate a brain injury (Williams et al., 2003), people who have experienced TBI may be at greater risk of developing SA due to the nature of the factors described above. Consequently, the present study aimed to investigate psychological factors associated with SA following TBI, alongside clinical and demographic variables. It was hypothesised that psychological variables such as LoC, self-efficacy, self-esteem and perceived stigma would account for an additional and significant amount of variance in SA, above that explained by demographic and clinical variables.

Methods

Design

The study employed a quantitative, cross-sectional within-subjects design to explore factors predicting SA after TBI. Self-report questionnaires were used as the data collection method. If required, participants were given support from the lead researcher to complete the questionnaires.

Participants

Participants were required to have sustained a TBI, defined as an injury caused by an external or mechanical force (Morton & Wehman, 1995) to differentiate from the broader categorisation of ABI. Participants in the study were required to be aged over 18 and able to read English (due to lack of translation resources). As the research literature regarding the developmental impact of TBI in childhood is scarce and lacking in detail (Barlow, Thompson, Johnson, & Minns, 2004), participants were required to have sustained a TBI after the age of 16. Given the present study's focus on social functioning, participants were required to be living in the community (either at home or in long-term supported accommodation) rather than a medical ward or residential rehabilitation unit. Participants were also required to have capacity to consent to participation in the study.

An a priori power calculation for multiple regression analysis, assuming a medium effect size of 0.15, 80% power and an alpha level set at $p = .05$, suggested that a sample of between 92 and 139 would be required. A total of 98 participants were recruited, with 54 participants completing the questionnaires online and 44 submitting paper copies provided via National Health Service (NHS) or third sector services (though participants recruited in this way were also informed they could complete the questionnaires online).

Five participants who completed the study online were excluded from the analysis as they described their injury as an ABI (e.g., subarachnoid haemorrhage) rather than a TBI and

therefore did not meet all the inclusion criteria. A further eight participants were excluded as a significant amount of questionnaire data (more than 10%, as recommended by Bennett, 2001) were missing.

A total of 85 participants met inclusion criteria and provided data for the analyses. Participants ranged in age from 19 to 81 years (M = 42.4, SD = 13.335). The final sample included 63.5% (n = 54) males and 32.9% (n = 28) females, with 3.5% (n = 3) reporting "Other / Prefer not to say". Further demographic information is shown in Table 1.

[INSERT TABLE 1 HERE]

Due to ethical and resource constraints, medical data regarding severity of injury were not available. Participants were asked to report the length of time they were in hospital for after their injury (M = 16.529 weeks, SD = 32.120) and time since injury (M = 7.719 years, SD = 8.733).

Measures

Outcome variable. The Social Phobia Inventory (SPIN; Connor et al., 2000) was used as the outcome measure for the study. The SPIN is a 17-item self-report measure of three domains of SA; fear, avoidance and physiological discomfort. Responses are scored from 0 (not at all) to 4 (extremely), with a maximum total score of 68 indicating high levels of SA. A cut-off score of 19 is recommended by the authors to distinguish those with SA. High levels of internal consistency (α = .95) and test-retest reliability (r = .86) have been demonstrated (Antony, Coons, McCabe, Ashbaugh, & Swinson, 2006; Connor et al., 2000). Although the measure has not been used in a TBI population in any published research to date, it has been utilised with patients with multiple sclerosis (Poder et al., 2009) and is recommended by guidance provided by NICE (2013) for use in NHS services within the UK. The SPIN's face validity and brevity make it the most appropriate measure from available measures of SA.

Predictor variables. The Applied Cognition measure (Neuro-QOL, 2012) was used to assess subjective severity of cognitive problems. This 18-item measure assesses perceived difficulties in everyday cognitive domains including memory, attention, and decision-making. Responses range from never (1) to very often (5), with a maximum score of 90. High levels of internal consistency ($\alpha = .95$) and test-retest reliability ($r = .82$) have been demonstrated in samples of patients with a range of neurological problems (e.g., stroke, epilepsy, Parkinson's disease) but data are not available for a TBI sample (Neuro-QOL, 2010).

Form C of the Multidimensional Health Locus of Control (MHLoC, Wallston, Stein, & Smith, 1994) assesses belief in one's ability to control health outcomes, in relation to a specific illness or disease. The measure encompasses four subscales of LoC: internal; chance; powerful others (doctors) and powerful others (other people). Responses are scored from 1 (strongly disagree) to 6 (strongly agree), with a higher subscale score indicating higher LoC (no total score is calculated). Wallston et al. (1994) demonstrated acceptable levels of internal consistency and test-retest reliability for each subscale; internal ($\alpha = .79$ - $.87$; $r = .80$), chance ($\alpha = .79 – .82$; $r = .72$), doctors ($\alpha = .71$; $r = .58$) and other people ($\alpha = .70$ - $.71$; $r = .40$). Despite its focus on control over one's specific illness or disease (Wallston, 2005), no published research has used Form C with a TBI population. However, Forms A and B of the MHLoC have been used in previous TBI research (Bedard et al., 2005; Moore & Stambrook, 1992), and Form C has been used to assess LoC following spinal cord injury (Waldron et al., 2010).

The Rosenberg Self-Esteem Scale (RSES, 1965) is a 10-item measure, with responses recorded on a 0 to 3 scale (reverse coded on some items) so that a low score on the RSES indicates low self-esteem. The RSE demonstrates high internal consistency ($\alpha = .92$), and test-retest reliability ($r = .85$) after two weeks (Rosenberg, 1979). This measure has been used

to examine self-esteem in people who have experienced a TBI (e.g., Anson & Ponsford, 2006a; Anson & Ponsford, 2006b; Ponsford et al., 2014).

The Self-Efficacy for Symptom Management Scale (Cicerone & Azulay, 2007) assesses confidence in managing common challenges and seeking support after TBI. The 13-items measure is scored 1 (not at all confident) to 10 (totally confident), with a maximum total score of 130 indicating high self-efficacy. High levels of internal consistency (α = .93) and test-retest reliability (r = .93) have been demonstrated (Cicerone & Azulay, 2007).

The Stigma scale published by Neuro-QOL (2012) is a 24-item measure which examines a person's perceptions of self and publically enacted prejudice and discrimination experienced as a result of neurological problems. Responses are scored from 1 (never) to 5 (always), with a maximum score of 120 indicating high levels of perceived stigma. High levels of internal reliability (α = .91) and test-retest reliability (r = .82) have been demonstrated in samples of patients with a range of neurological problems (e.g., stroke, epilepsy, Parkinson's disease) but no data are available for a TBI sample (Rao et al., 2009). For the purposes of the study, the word 'illness' was replaced with the term 'brain injury' on each item of the questionnaire.

The Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983) was designed for use with people with physical health problems and assesses anxiety and depression without relying on somatic symptoms of illness (e.g., fatigue, insomnia). The 14-item measure is scored on a 0 to 3 scale, appropriately coded so that a higher score on each subscale indicates a more severe problem with anxiety or depression. A review of its psychometric properties reports good levels of internal consistency on the anxiety (α = .68 - .93) and depression (α = .67 - .9) subscales across a variety of settings (Bjelland, Dahl, Haug, & Neckelmann, 2002), with similar findings reported by Whelan-Goodinson, Ponsford and Schönberger (2009) with a TBI sample (depression α = .88; anxiety α = .92). The HADS has

been used to measure depression and anxiety after TBI in a number of published studies (e.g., Anson & Ponsford, 2006a; Anson & Ponsford, 2006b; Downing, Stolwyk, & Ponsford, 2013).

Participants were also asked to provide details of their age, gender, relationship status, employment status and whether they lived alone, in addition to clinical information including the cause of the TBI, the amount of time since the TBI and the amount of time spent in hospital following TBI.

Procedure

Potential participants were identified and recruited through professionals working in neuropsychology teams across nine NHS Trusts in the North-West of England and third sector organisations relevant to TBI. Participants were also able to self-refer into the study and could opt to complete an online version of the study made using Qualtrics Survey Software (Qualtrics, 2013), which provided security and encryption for online information. The study was advertised via social networking websites and posters displayed in NHS neuropsychology services and third sector organisations.

Prior to completing the questionnaires, participants were required to complete a screening and consent form based on the inclusion and exclusion criteria outlined above. On the online version of the study, participants were only able to progress onto the questionnaires if they answered each item of the consent form. Capacity to consent and participate in the study was assumed in line with the Mental Capacity Act (2005). As recommended by the British Psychological Society (BPS, 2008), plans to assess capacity were in place in the event that doubts around capacity to consent arose. Participants had the option of completing the questionnaires online or on paper posting them to the lead researcher. To reduce bias, the online study was set to present questionnaires in a random

order. They were able to contact the researcher if support with reading and writing was required.

Ethical Approval

The study received ethical approval from the NHS National Research Ethics Service, followed by local approval from the Research and Development Departments of each NHS Trust involved in recruitment. This approval also covered participants recruited through third sector organisations and online.

Data Analysis Strategy

Data were analysed using IBM SPSS Statistics version 20[2]. All questionnaires were scored in accordance with scale instructions and reverse coded as required. Relationship status was recoded to a binary variable (i.e., yes / no). Due to its descriptive nature, cause of injury was not entered into the regression model. Anxiety (measured by HADS) was not entered into the regression model as it correlated highly with the outcome variable ($r = .726$, $p < .001$) and is conceptually similar, which may reduce the variance available to other variables. Additionally, depression was considered a clinical variable rather than a psychological one, due to the focus of the HADS on measuring clinical difficulties associated with depression.

Throughout the study, a p value of .05 will be used as a threshold for statistical significance in line with convention (Field, 2013). Furthermore, the decision was taken not to use Bonferroni corrections to counteract multiple comparisons as this would have resulted in a very low p value and significantly reduced statistical power.

Hierarchical multiple regression analysis was used to explore the study hypothesis. Variables were entered into the model in blocks; demographic, clinical, psychological. Consistent with the available theoretical rationale for SA following TBI discussed above, this

[2] Due to space restrictions SPSS outputs have not been included in this report. Further details are available on request.

allowed for examination of the amount of variance in SA which could be explained by psychological variables, above that explained by demographic and clinical variables.

In determining what variables were entered into the regression model, decisions for subset selection were made based on effect size instead of *p* values. While use of *p* values is common, effect sizes are less reliant on sample size (Coe, 2002). Given the relatively low sample size in this study ($n = 85$), variables were included in the multiple regression analysis if a small effect size was observed (i.e., $r > .1$; Cohen, 1988). This threshold was chosen to allow an inclusive, exploratory approach which minimised the risk of overlooking emerging effects of small magnitude (Hemphill, 2003).

Results

Data Preparation and Analysis

It did not appear that there were any systematic bias or pattern to the missing data as defined by Graham (2009), with 34 cases (40% of the sample) having incomplete data across 42 (34.43%) of the variables. Little's (1988) Missing Completely At Random (MCAR) test was not significant ($X^2 = 1921.880$, $df = 3105$, $p = 1.000$), suggesting that the null hypothesis of data being missing randomly could be assumed.

Even after removing the eight cases missing more than 10% of data, the number of other cases missing smaller amounts of data was high. Listwise or pairwise deletion methods were not considered appropriate as this would have seen a large proportion of cases deleted, thereby reducing sample size and power in addition to potentially introducing bias into the multiple regression model. Consequently, multiple imputation was conducted with the data provided by 85 participants to analyse missing data and input substituted values (Rubin, 1987; Schaffer, 1997). Five iterations of imputation were performed (Schaffer, 1997).

Constraints were set so that integer values were calculated for gender (recorded to male or female, with 'other / prefer not to say' coded as missing data in two cases), cause of

injury, employment status, relationship status (recoded to being in a relationship or not) and whether the person lives alone. Although it is recognised that use of constraining to integers for binary variables can raise the potential for bias (Horton, Lipsitz, & Parzen, 2003), the amount of missing data for these variables was low (less than 3.5% of cases). Rounding to integers was not used for questionnaire data, as recommended by Graham (2009). Normal distribution was assumed, with a parametric linear regression model used to derive the imputed values (Horton et al., 2003). No transformations were performed on the dataset as assumptions for parametric testing were met. Independent samples t-test showed no significant difference on SPIN scores between participants who completed the questionnaire online compared to those who did not (t (91) = .635, p = .527).

Clinical Characteristics of Sample

Descriptive statistics for all self-report measures used in the study are provided in Table 2. As can be seen in Table 2, all measures demonstrated acceptable levels of internal consistency (α > .6; Hair, Anderson, Tatham & Black, 2006).

[INSERT TABLE 2 HERE]

Using the cut-off scores for social anxiety as recommended by the authors of the SPIN (Connor et al, 2000), most participant scores (47.1%) lay in the 'None' category (> 20). A further 15 participants (17.6%) scored within the 'Mild' category, 13 (15.3%) scored within the 'Moderate' category, 10 (11.8%) scored in the 'Severe' category, and 7 (8.2%) participants were categorised as 'Very Severe'. Using the cut-offs provided by the scale authors (Zigmond & Snaith, 1983), 70.6% of the sample showed clinically significant levels of anxiety (with 21.2% in the severe category) while 63.5% of the sample showed clinically significant levels of depression (with 20% in the severe category).

Correlational Analysis

Correlational analysis (Pearson's *r*) was conducted on the pooled dataset comprising of all iterations of the multiple imputation process (Rubin, 1987). Correlations are shown in Tables 3 and 4.

[INSERT TABLE 3 & 4 HERE]

The following variables correlated significantly ($p < .05$) with higher SA scores on the SPIN: not being employed ($r = .239$, $p = .028$); higher levels of cognitive problems ($r = .476$, $p < .001$); higher levels of internal ($r = .248$, $p = .022$) and chance ($r = .217$, $p = .046$) LOC; lower self-esteem ($r = -.441$, $p < .001$); lower self-efficacy ($r = -.472$, $p < .001$); higher perceived stigma ($r = .654$, $p < .001$); higher levels of anxiety ($r = .726$, $p < .001$) and higher levels of depression ($r = .516$, $p < .001$). Age, gender, time since TBI, time in hospital, living alone, relationship status and the two Powerful Others subscales of the MHLoC (Doctors and Others) did not significantly correlate with SA scores.

Hierarchical Multiple Regression Analysis

Hierarchical multiple regression analysis was conducted to examine if the predictor variables were able to explain the variance in SA scores. Pearson's correlations between each predictor variable and the outcome variable (Tables 3 and 4) were used to determine the criteria for subset selection to ensure a sufficient participant-to-variable ratio. As discussed above, predictor variables which correlated with SA demonstrating a small effect size or above (Pearson's $r > 0.1$) were entered into the regression model[3].

Predictor variables were entered into the regression model in three blocks: (a) demographic variables (gender, employment status); (b) clinical variables (time since TBI,

[3] It is recognised that other options for determining subset selection are available. Gender and time since TBI had effect sizes greater than $r = .1$ and were therefore included in the regression model, although $p > .05$. No additional variables would have been included had *p* values been used the as sole criteria for subset selection.

cognitive problems, depression); (c) psychological variables (MHLoC internal, MHLoC chance, self-esteem, self-efficacy, perceived stigma).

The overall model was significant, both with the original dataset (F (2, 63) = 5.918, p < .001, explaining 51.8% (R^2 = .518, R^2_{adj} = .431) of the variance in SA scores and across all five imputations of missing data[4], with F (2, 82) values ranging from 8.006 to 8.799, with all values of p < .001. The amount of variance in SA scores explained ranged from 52% (R^2 = .520, R^2_{adj} = .455) to 54.3% (R^2 = .543, R^2_{adj} = .481) of the variance in SA scores. Table 5 provides results of the overall model across each imputation.

[INSERT TABLE 5 HERE]

The Durbin-Watson values across the imputations ranged from 1.962 to 2.000, compared to the value from the original data of 1.846. These values are close to 2 and therefore it was assumed there was no autocorrelation of residuals (Field, 2013). Examination of the VIF, tolerance and eigenvalues confirmed that there was no evidence of collinearity within the dataset, in line with relevant guidance (Bowerman & O'Connell, 1990; Menard, 1995; Field, 2013). Graphical representation of the data suggested that assumptions of homoscedasticity and normally distributed residuals could be upheld.

Block one (demographic variables) accounted for 10.3% (R^2 = .103, R^2_{adj} = .074, p = .033) of the variance in SA scores in the original dataset, rising to between 11.9% (R^2 = .119, R^2_{adj} = .097, p = .006) and 14.7% (R^2 = .147, R^2_{adj} = .126, p = .001) following imputation. The addition of block two (clinical variables) made a significant contribution to the model, increasing the total variance explained to 36.1% (ΔR^2 = .259, p < .001) for the original dataset and between 39.8% (ΔR^2 = .279, p < .001) and 41.3% (ΔR^2 = .280, p < .001) following imputation, with significant changes in F (p < .001) for both original and imputed data. The addition of block three (psychological variables) also made a significant

[4] SPSS does not provide pooled calculations for this information across imputations.

contribution to the overall model, explaining an additional 15.7% ($\Delta R^2 = .157$, $p < .001$) of the total variance for the original dataset and between 12.2% ($\Delta R^2 = .122$, $p < .001$) and 13% ($\Delta R^2 = .130$, $p < .001$) for each imputation. The change in F associated with the addition of block three was statistically significant for both original ($p = .007$) and imputed data ($p =$ .002 to .004). Further details are provided in Table 5.

The multiple regression model examined individual predictors of SA (Table 6). In relation to the overall model based on data pooled from all imputations, only higher levels of perceived stigma significantly predicted higher levels of SA ($B = .274$, $t = 2.789$, $p = .005$).

[INSERT TABLE 6 HERE]

Discussion

Key findings

The present study examined psychological variables associated with SA following TBI. The hypothesis that psychological variables would account for a significant proportion of the variance in SA was supported. The overall regression model was significant and the addition of psychological variables (MHLoC internal, MHLoC chance, self-esteem, self-efficacy, perceived stigma) made a significant additional contribution to the amount of variance explained, suggesting that psychological variables are important factors in the development of SA following TBI in addition to demographic and clinical variables. Over half the sample (52.9%) showed clinically significant levels of SA, as defined using the cut-off provided by the scale author (Connor et al., 2000). This is substantially higher than both the estimated prevalence rate of 12% observed in the general population (NICE, 2013) and the rate of 30.6% found with a sample of people diagnosed with multiple sclerosis (Poder et al., 2013).

Of the psychological variables, only perceived stigma was a significant independent predictor of SA. All other psychological variables explained some variance in SA. In terms of

the amount of variance explained by the other psychological variables, standardised beta values across imputations suggested that the internal subscale of the MHLoC (β = .116 to .123) and self-esteem (β = -.090 to -.124) predicted more variance in SA than self-efficacy (β = -.050 to -.070) and the chance subscale of the MHLoC (β = .047 to .061). Although these variables did not reach statistical significance as independent predictors, this may be due to the relatively small sample size employed in the study and further examination is warranted. Nevertheless, when self-esteem, self-efficacy and LoC are combined with perceived stigma they explain a significant amount of variance in SA, above and beyond that explained by demographic and clinical factors. It should also be noted that adding these variables as the final block in the regression model provides a particularly rigorous and robust test of their predictive power.

As outlined above, there is no previous research directly examining the role of psychological variables in the development of SA following TBI. However, the results are in keeping with theoretical and empirical understandings of psychological and psychosocial functioning following TBI. Indeed, there is growing consensus that psychological wellbeing and psychosocial functioning following TBI is influenced by a broad range of factors, with psychological variables playing a key role alongside cognitive, neurological and demographic factors (Soo et al., 2012; Moore et al., 2006; Kendall & Terry, 1996).

Furthermore, the emergence of perceived stigma as a significant independent predictor is a key finding. This offers support for Kendall and Terry's (1996) model of psychosocial functioning after TBI, in which perceived stigma is proposed as a key factor affecting primary appraisal (i.e., how events are appraised), which subsequently affects secondary appraisal (i.e., a person's beliefs around how well they can cope with an event). The findings of the present study are in keeping with this model in that perceived stigma has

a significant impact on psychological outcome, with self-efficacy and perceptions of control also appearing to be relevant (though not statistically significant in the present study).

The finding that perceived stigma is an independent predictor of higher levels of SA is also consistent with theoretical models which highlight how aversive social experiences are a key factor in the development of SA (Rapee & Spence, 2004). Furthermore, the cognitive model of SA, proposed by Clark and Wells (1995) and updated by Wells (2013), proposes that social situations activate negative automatic thoughts based on assumptions around perceived danger in social situations. Negative evaluations of how the self is processed as a social object (i.e., how the person thinks they appear to others) are often inaccurate or exaggerated and can lead to safety behaviours (e.g., avoidance), which serve to reinforce the beliefs (Wells, 2013). Safety behaviours maintain and exacerbate the problems by perpetuating the beliefs that social interactions will lead to negative outcomes (Clark & Wells, 1995; Wells, 2013; Banerjee & Henderson, 2001). Since social experiences are key to the development and maintenance of SA, it is consistent that perceived stigma would play a key role in the development of SA.

Additionally, the findings are also consistent with social models of disability which highlight the need to focus on the societal context of impairment (Oliver, 1983; 2004). Instead of focusing on the functional impairments of the individual, the social model considers disability to be caused by the economic, cultural and environmental barriers which are faced by people with physical or cognitive impairments. Consistent with the findings of the present study, Oliver (2004) discusses how cultural norms around disability, which view impairment as unattractive and unwanted, negatively impact people by creating stigmatising, discriminatory environments which devalue and actively disable people with impairments, thereby causing psychological distress. Individualistic psychiatric or psychological approaches often fail to take this into account, instead conceptualising psychological

problems as a consequence of the impairment itself and focusing on the need for people to seek treatment or adapt to the disabling environment (Simpson & Thomas, 2014; Simpson, McMillan & Reeve, 2013).

Moreover, people who develop impairments throughout their lives have been raised within these cultural norms (Oliver, 2004). The term psychoemotional disablism refers to how negative social interactions can lead to negative societal stereotypes about what it means to have an impairment being internalised, which can limit the coping resources people have to draw on and lead to reduced participation in society (Reeve, 2012; Simpson et al., 2013). Research has highlighted how stigma and poor understanding are key problems in relation to TBI (e.g., Linden & Boylan, 2010; McClure, 2011; Guilmette & Paglia, 2004). In emphasising the role of stigma in the development of SA following TBI, this study highlights the importance of considering the societal and cultural factors influencing a person's experience of impairment following TBI, guiding intervention at both an individual and social level.

Clinical implications

These findings have various implications for clinical psychologists working in these settings. It appears that SA is a problem following TBI and the application of cognitive models of SA to therapeutic work may be a useful way to conceptualise problems with psychosocial functioning following TBI. The clear role for psychological factors in the development of SA following TBI suggests a need to consider these variables during assessment and rehabilitation, supporting the development of an individual's psychological resilience during the complex process of recovery from TBI.

In particular, the significant role which stigma plays in the development of SA following TBI highlights the importance of developing contextually inclusive formulations (BPS, 2011) which explore the reactions people experience from others, in addition to the

individual psychological factors which affect how the responses of other people are perceived. This can guide intervention through use of techniques such as behavioural exposure to support people to increase social activity or adapting cognitive interventions to help people to examine their beliefs. Although cognitive-behavioural interventions for SA are well established, the application of these principles to a TBI population needs further consideration. The results also highlight the value of considering potentially relevant specific psychological constructs such as self-esteem, self-efficacy and LoC in therapeutic interventions for SA following TBI as a way of bolstering resilience and protective factors against the development of SA.

From a social disability perspective, the present study also highlights the importance of not focusing purely on the individual and instead considering the ways in which barriers, discrimination and stigma are imposed through entrenched societal and cultural norms (Simpson & Thomas, 2014; Oliver, 2004). Given the lack of knowledge and negative attitudes around TBI (Linden & Boylan, 2010; McClure, 2011; Guilmette & Paglia, 2004), the findings of the present study highlight the need for clinical psychology as a profession to consider the ways in which disability is constructed by the discriminatory social context faced by people who have experienced TBI, and to contribute to the design of interventions which can reduce stigma at a societal level.

Limitations and Implications for Future Research

The findings of the present study must be considered in the context of the following limitations. The relatively small sample size employed in the study limits the strength of the findings, as the stability of the multiple regression model is heavily reliant on the number of participants. The inclusion of more participants may have changed the nature of the results, particularly in terms of the number of significant independent predictors. Further research which examines the relationships between variables using a bigger sample is required to test

the proposed theoretical models more explicitly and to gain a fuller understanding of the role of self-esteem, self-efficacy and LoC in the development of SA.

In addition, the study used online methods to recruit but many participants were identified through NHS and third sector services. It could be possible that people with higher levels of SA are less likely to access such services. The study also focused exclusively on people living in the community. A different pattern of results may be evident with a sample in the earlier stages of recovery and future research may be useful in exploring how different kinds of interactions with professionals at an early stage affect the development of SA. Moreover, this study focused on TBI to explore specific issues relating to this population. Further research which widens the scope of the study to include people with other kinds of acquired brain injuries may increase the generalisability of these findings to clinical practice.

Furthermore, the cross-sectional nature of the study limits the potential for understanding how SA and the other variables under examination may change over time. Consequently, future research which utilises a longitudinal or prospective design would be of value. In addition, the use of multiple regression in the current study assumes a linear relationship between variables. However, as psychological variables have been shown to play a significant role in the development of SA, use of more advanced statistical techniques (e.g., structural equation modelling) would be useful next step following this study. For example, the regression model suggests that perceived stigma is predictive of SA, however it is possible that this is a bi-directional relationship and that people who are more anxious in social situations are likely to be hyper-vigilant to threat, thereby perceiving higher levels of stigmatising behaviour from others. Further research analysing hypothesised pathways between factors will allow for a more detailed understanding of the complex bi-directional interactions between predictor and outcome variables. This will be useful in guiding

intervention, in that targeting particular variables (e.g., self-esteem) in therapy may help to reduce the amount of stigma which is perceived, mitigating its effect on SA.

Additionally, many participants and professionals highlighted the length of the questionnaires as a problem. While it is not possible to calculate how many people were invited to participate but did not complete the measures, there is potential for bias in the sample if a significant number of people with particular demographic or clinical characteristics were unable to finish the questionnaires. Also, the number of variables which could be included in the study was limited to reduce the burden on participants. It would therefore be useful for future research to use more valid ways of assessing neurological and cognitive variables as opposed to self-report, for example using neuropsychological assessments to assess impairments in specific cognitive domains, or consulting medical records to obtain specific details of TBI severity. Further examination of other relevant psychological variables would also be of value, for example appraisal and coping styles following TBI.

The present study also did not explore situational factors in any great detail. Although living alone and being in a relationship did not significantly correlate with SA in this study, future research might address environmental factors hypothesised to be of importance for psychosocial wellbeing following TBI (Kendall & Terry, 1996). For example, social contact, family dynamics and perceptions of support from others might be important variables to consider in the development of SA following TBI, particularly as social learning theories of SA suggest that experience of aversive situations and lack of modelling of adaptive coping strategies for managing social situations are key to the development of SA (Rapee & Spence, 2004). Longitudinal research examining relationships post-TBI may be extremely useful in understanding SA and psychosocial wellbeing more broadly.

Even considering the limitations discussed above, the present study is the first to examine factors associated with SA following TBI. The findings of this study highlight the importance of considering SA in this population, particularly when supporting rehabilitation adjustment following TBI. The significance of perceived stigma as a predictor of SA is an important finding in this context, highlighting a clear role for clinical psychologists and other rehabilitation professionals to integrate social models of disability into their practice and make a valued contribution to the psychological wellbeing of people who have experienced TBI.

Conclusion

The current study explored factors predicting SA following TBI. Hierarchical multiple regression was used to examine the extent to which demographic, clinical and psychological variables predicted scores on a measure of SA. Psychological variables, particularly perceived stigma, explained a significant proportion of the variance in SA. Therefore it is proposed that psychological variables are important factors affecting the development of SA following TBI, above and beyond demographic and clinical variables. The study provides empirical support to the theoretical rationale for SA following TBI proposed by Soo et al. (2012) and Moore et al. (2006), highlighting the potential application of Kendall and Terry's (1996) model for psychosocial adjustment. Further research is required to examine the complex relationships between such variables using a more stable regression model, and to explore in more detail other variables which may have an influence on SA using more advanced statistical techniques which allow for the examination of non-linear relationships.

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Table 1.

Demographic characteristics (N = 85)

	n	%	Mean (SD)	Range
Gender				
Male	54	63.5%		
Female	28	32.9%		
Other / prefer not to say	3	3.5%		
Age			42.4 (13.34)	19 - 81
Cause of injury				
Road traffic accident	36	42.4%		
Assault	11	12.9%		
Sport injury	4	4.7%		
Work injury	6	7.1%		
Trip / fall	23	27.1%		
Other	3	3.5%		
Prefer not to say	2	2.4%		
Time since injury			7.72 years (8.73)	0.37 - 33
Time spent in hospital			16.53 weeks (32.12)	0 - 208
Employed				
Yes	27	31.8%		
No	57	67.1%		
Prefer not to say	1	1.2%		
Live alone				
Yes	25	29.4%		
No	59	69.4%		
Prefer not to say	1	1.2%		
Relationship status				
Single	28	32.9%		
In a relationship	44	51.8%		
Separated / divorced	12	14.1%		
Other / prefer not to say	1	1.2%		
Recruitment method				
Online	54	55.1%		

NHS / third sector	44	44.9%

Note. All data were collected via self-report.

Table 2.

Clinical characteristics of sample

	Mean (SD)	Range	n (%)	α
Social Phobia Inventory (SPIN)				
Total	25.67 (16.88)	0 - 68	85 (100%)	.944
None (< 20)			40 (47.1%)	
Mild social anxiety (21 – 30)			15 (17.6)%	
Moderate social anxiety (31 – 40)			13 (15.3%)	
Severe social anxiety (41 – 50)			10 (11.8%)	
Very severe social anxiety (> 51)			7 (8.2%)	
Applied Cognition*	67.62 (17.41)	28 - 90	85 (100%)	.960
Multidimensional Health Locus of Control (MHLoC)*				
Internal subscale	21.61 (6.72)	6 – 36	85 (100%)	.783
Chance subscale	20.22 (7.24)	6 – 36	85 (100%)	.788
Doctors subscale	10.88 (3.92)	3 – 18	85 (100%)	.696
Others subscale	10.87 (4.13)	3 - 18	85 (100%)	.764
Rosenberg Self-Esteem Scale (RSES)*	15.73 (5.97)	2 – 28	85 (100%)	.849
Self Efficacy				
Total	65.96 (30.83)	13 - 130	85 (100%)	.953
Low (13-59)			41 (48.2%)	
Moderate (60 – 114)			41 (48.2%)	
High (115 – 130)			3 (3.5%)	
Stigma*	65.50 (20.80)	24 – 120	85 (100%)	.953
Hospital Anxiety and Depression Scale (HADS):Anxiety				
Total	10.64 (4.72)	2 – 21	85 (100%)	.812
Normal (0 – 7)			25 (29.4%)	
Mild (8 – 10)			17 (20%)	
Moderate (11 – 14)			25 (29.4%)	
Severe (15 – 21)			18 (21.2%)	
HADS: Depression				

Total	9.24 (4.92)	0 - 21		.830
Normal (0 – 7)			31 (36.5%)	
Mild (8 – 10)			25 (29.4%)	
Moderate (11 – 14)			12 (14.1%)	
Severe (15 – 21)			17 (20%)	

Note. All data in this table was calculated using pooled scores, following multiple imputation of missing data items. * indicates measures where valid cut-off scores for categorisation within a TBI population are not provided by the scale authors or subsequent published research.

Table 3.

Correlation matrix for pooled demographic data following multiple imputation

	SPIN	Age	Gender	Time since TBI	Time in hospital	Employed	Live alone	In a relationship
SPIN	1							
Age	-.082	1						
Gender	.207	-.241*	1					
Time since TBI	.153	.274*	-.207	1				
Time in hospital	.037	.067	-.178	.482**	1			
Employed	.239*	.040	-.232*	.164	.125	1		
Live alone	-.090	-.308**	.002	-.175	-.120	-.167	1	
In a relationship	.065	-.008	-.172	.121	.276*	.398**	-.470**	1

Note. SPIN = Social Phobia Inventory; TBI = Traumatic brain injury.

* $p < .05$, ** $p < .01$, two-tailed

Table 4.

Correlation matrix for pooled questionnaire data following multiple imputation

	SPIN	Applied cognition	MHLoC Internal	MHLoC Chance	MHLoC Doctors	MHLoC Other	RSES	Self Efficacy	Stigma	HADS Anxiety	HADS Depression
SPIN	1										
Applied cognition	.476**	1									
MHLoC Internal	.248*	-..018	1								
MHLoC Chance	.217*	.025	.324**	1							
MHLoC Doctors	.033	-.083	.185	.167	1						
MHLoC Other	.035	.073	.026	.151	.379**	1					
RSES	-.441**	-.345**	-.013	-.085	.101	-.012	1				
Self Efficacy	-.472**	-.398**	.022	-.087	.237*	.222*	.611**	1			
Stigma	654**	.568**	.245*	.207	-.104	.079	-.481**	-.523**	1		
HADS anxiety	.726**	.384**	.199	.088	-.018	-.110*	-.492**	-.562**	.614**	1	
HADS depression	.516**	.433**	-.027	.174	-.170	.040	-.550**	-.677**	.582**	.505**	1

Note. HADS = Hospital Anxiety and Depression Scale; MHLoC = Multidimensional Health Locus of Control (Form C); RSES = Rosenberg Self-Esteem Scale; SPIN = Social Phobia Inventory. * $p < .05$, ** $p < .01$, two-tailed

Table 5.

Results of Hierarchical Multiple Regression Analyses for Individual Multiple Imputations

Imputation number	Model	R	R^2	R^2_{adj}	ΔR^2	F	Sig
Original data	1	.321	.103	.074	.103	3.612	.033
	2	.601	.361	.308	.259	6.794	.000
	3	.720	.518	.431	.157	5.918	.000
1	1	.348	.121	.100	.121	5.662	.005
	2	.635	.404	.366	.282	10.693	.000
	3	.726	.527	.463	.123	8.233	.000
2	1	.383	.147	.126	.147	7.065	.001
	2	.638	.407	.369	.260	10.832	.000
	3	.729	.532	.468	.125	8.403	.000
3	1	.363	.132	.111	.132	6.235	.003
	2	.637	.405	.368	.273	10.763	.000
	3	.730	.533	.470	.128	8.462	.000
4	1	.364	.133	.111	.133	6.270	.003
	2	.643	.413	.376	.280	11.123	.000
	3	.737	.543	.481	.130	8.799	.000
5	1	.345	.119	.097	.119	5.522	.006
	2	.631	.398	.360	.279	10.435	.000
	3	.721	.520	.455	.122	8.006	.000

Note. SPSS does not calculate these results based on pooled data following imputation. Five imputations were conducted to estimate missing data. Predictors were entered into the regression model in the following blocks:

1. Employment status, gender.
2. Employment status, gender, depression, time since injury, cognitive problems.
3. Employment status, gender, depression, time since injury, cognitive problems, locus of control (internal), locus of control (chance), self-esteem, stigma, self-efficacy.

Table 6

Variables Predicting Social Anxiety on Overall Hierarchical Multiple Regression Model

	b	*t*	*Sig.*	Standardised beta (β) range across imputations
Block 1: Demographic variables (constant)	-5.791	-.623	.533	
Gender	9.805**	2.569	.010	.248 to .295
Employment status	10.905**	2.820	.005	.284 to .311
Block 2: Clinical variables (constant)	-24.879**	-2.845	.004	
Gender	6.659*	1.968	.049	.172 to .201
Employment status	7.641**	2.326	.020	.204 to .222
Time since injury	.118	.649	.516	.055 to .064
Cognitive problems	.243**	2.505	.012	.249 to .253
Depression	1.238**	3.643	.000	.348 to .367
Block 3: Psychological variables (constant)	-22.238	-1.800	.072	
Gender	5.500	1.654	.099	.127 to .180
Employment status	5.103	1.649	.099	.134 to .146
Time since injury	.022	.126	.900	.007 to .014
Cognitive problems	.109	1.082	.279	.105 to .121
Depression	.482	1.162	.245	.132 to .149
MHLoC Internal	.297	1.298	.194	.116 to .123
MHLoC Chance	.122	.599	.549	.047 to .061
Self-esteem	-.305	-.997	.319	-.090 to -.124
Self-efficacy	-.031	-.469	.639	-.050 to -.070
Perceived stigma	.274*	2.789	.005	.334 to .341

Note. These values are based on pooled data calculated from five iterations of multiple imputation. SPSS does not provide standardised beta values (β) based on pooled data. * $p < .05$, ** $p < .01$

Section Three: Critical Appraisal

Critical Reflections on a Research Project Exploring Social Anxiety Following Traumatic Brain Injury

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Critical Reflections on a Research Project Exploring Social Anxiety Following Traumatic Brain Injury

The purpose of the research study was to investigate factors associated with social anxiety following traumatic brain injury (TBI). A total of 85 people who had experienced TBI completed self-report questionnaires measuring social anxiety, self-esteem, self-efficacy, locus of control and perceived stigma. Demographic (age, gender, relationship status, employment status) and clinical (depression, anxiety, subjective severity of cognitive problems, type of injury, time in hospital and time since TBI) variables were also collected through self-report. The study found that the addition of psychological variables (self-esteem, locus of control and self-efficacy) made a significant contribution to the overall model, accounting for an additional 12.2-13% of variance in social anxiety above that explained by demographic and clinical variables. Perceived stigma was the only significant independent predictor of social anxiety (B = .274, p = .005).

The aim of this critical review is to reflect on the process of conducting the research, discussing methodological strengths and limitations of the study and highlighting potential directions for future research in relation to social models of disability, a key theme emerging from the results of the study.

Strengths and Limitations of the Project

Sample Size and Recruitment

The sample was mostly male (63.5%) and the average age was 42.4 years, consistent with research suggesting that younger men are more likely to experience a TBI (Yates, Williams, Harris, Round & Jenkins, 2006; Feigin et al., 2013). The final sample size was 85, which was less than the 92-139 required according to the a priori power calculation. With a larger sample, other variables may have emerged as significant independent predictors of social anxiety in the final regression model. Although not significant at $p = .05$, standardised beta values across imputations for the internal subscale of the MHLoC ($\beta = .116$ to $.123$) and self-esteem ($\beta = -.090$ to $-.124$) suggest that they are potentially useful in explaining some variance in social anxiety and may be worthy of further exploration.

The sample size reflects the difficulties in recruitment in this clinical population. National Health Service (NHS) neuropsychology and third sector brain injury support services in the United Kingdom (UK) are often under considerable pressure and engaging sufficient numbers of people who had experienced TBI in the study was expected to be a challenge. A broad recruitment strategy was therefore employed which placed no limits on the cause or severity of the injury. While this meant that people who had experienced mild and severe injuries were integrated into one sample, it was decided that this would be necessary to ensure that a usable sample size could be obtained. Although it would have been possible to broaden the scope of the research further and incorporate other types of brain injury (using the wider definition of acquired brain injury [ABI]), it was considered important to build understanding of the specific experience of traumatic injuries in relation to social anxiety. Conducting this research has helped me come to recognise that ABI is an extremely heterogeneous category, limiting the reliability and validity of research which explores factors associated with emotional wellbeing and intervention. To have relevance to clinical

practice, further research which distinguishes between distinct types of brain injury is required.

Furthermore, it was expected that exploring social anxiety might bring about challenges in recruitment. While it was clear from the materials that people did not need to experience social anxiety to take part, several potential participants declined to complete the questionnaires as they felt it was not relevant to them. Moreover, people who are more socially anxious might be expected to be less likely to engage with NHS professionals or third sector support organisations. Bias may be introduced to the sample if those who are more socially anxious are less likely to be invited to participate. However, over half the sample (52.9%) showed clinically significant levels of social anxiety based on the cut-off scores for the Social Phobia Inventory (SPIN) provided by the scale's authors (Connor et al., 2000). This is substantially higher than both the estimated prevalence rate of 12% observed in the general population (National Institute of Health and Clinical Excellence, 2013) and the rate of 30.6% reported from a sample of people with multiple sclerosis (Poder et al., 2013), which suggests this bias was not a significant problem in the study. Future research exploring the challenges of recruiting people who are socially anxious would be beneficial, with a particular focus on TBI and other long-term health conditions.

The personal impact of the recruitment challenges was significant, in that it was extremely labour intensive to visit NHS and third sector services and engage staff and volunteers. However, the experience of meeting people working in and using these services was overwhelmingly positive and has certainly increased my enthusiasm for conducting future research and clinical work within neuropsychology settings.

Online Recruitment

To mediate some of the expected challenges in recruiting through NHS and third sector services, an online questionnaire was also advertised through social media websites

(e.g., Facebook, Twitter, Reddit). In total, 55% of completed questionnaires were completed online. Targeted promotion of the questionnaires towards relevant groups and profiles on the social networking websites was an effective way of raising awareness about the study, engaging participants who otherwise might not have been able to take part. Increasing the sample size in this way was also less labour intensive than visiting individual services across other areas of the country, which is particularly pertinent given the strict time limits involved in conducting research as part of a doctoral thesis. Online data collection also allowed for direct import into SPSS, reducing the burden and potential for errors during data entry. Furthermore, using online recruitment gave people more choice in how they participated. After seeing the website link or a poster, participants were able to then complete the study at a time which suited them, without any pressure or worry that it might affect their care in some way.

However, there were some drawbacks to using online recruitment. Data from five participants who completed the study online were excluded from the study as they described their injury as an ABI (e.g., subarachnoid haemorrhage) rather than a traumatic injury. Although a haemorrhage could have been caused by an external injury, participants did not report this and therefore their data had to be excluded. Although the materials stated that the study focused on traumatic injuries, this was evidently not clear enough and there was no way for the researcher to clarify in advance of the participant completing the questionnaires. Moreover, the anonymous nature of the study meant that it was impossible to inform these participants that their data could not be included, raising ethical concerns around engaging people in research but not using their data.

In addition, the absence of a researcher or professional means that there is no one to respond to misunderstandings or adverse reactions to the study materials. While this was managed by explaining sources of help on the debrief page and ensuring that the researcher's

telephone number and email was available on the information sheets, the potential impact of this must be recognised. Future research using online questionnaires in a TBI population would benefit from having a telephone number and e-mail contact for the researcher listed on each page of the online questionnaire.

Furthermore, it is recognised that combining online and paper copies of the questionnaire may have not been appropriate, in that it may have added unaccounted extraneous variables to the regression model. Although the Internet is widely used in the UK (Office for National Statistics, 2014), the need to be computer literate may limit the representativeness of the data collected. While there were no indications in the present study of any significant differences on social anxiety scores between those who submitted questionnaires online and those who submitted paper copies by post after being given them by professionals working in NHS or third sector services, future research should examine this potential source of bias carefully.

Missing Data

Incomplete questionnaires were a problem across data collected both online and through NHS and third sector services. Data from eight participants were excluded as more than 10% was missing, while multiple imputation techniques were used to mitigate the impact of missing data for the rest of the sample (Rubin, 1987; Schaffer, 1997)[1]. While employing validation rules requiring all questions to be answered on each page on the online questionnaire was an option, it was decided that this might add pressure to participants. This would eliminate their right to not answer a particular question. Additionally, it may have reduced the number of completed questionnaires if people were then more likely to get an error message and quit altogether. Although time restraints meant that this was not feasible, running a pilot study with representatives from the clinical population under study would

[1] This process is discussed in detail in the Research Paper section.

have been a useful way of exploring these difficulties from the outset. While the NHS ethics panel and representatives from the Lancaster University Public Involvement Network were consulted on the appropriateness of the study materials, piloting the questionnaires with people who have experienced TBI may have highlighted some of these issues at an earlier point in the research process.

Additionally, the high rates of missing data and unfinished questionnaires may be a consequence of the study length. Data from the online questionnaire suggests that the average completion time was 31 minutes, though some participants took over an hour. This was similar to the amount of time taken for the people I met with in person to provide support in completing the measures. While the study aimed to strike a pragmatic balance between covering a range of variables and the burden on participants, a briefer study (perhaps using short versions of questionnaires where possible) may have been more suited to the population given that fatigue and impaired attention are common problems following TBI (Hiott & Labbate, 2002).

It is not possible to compare the number of people who began the questionnaires online with those who were given paper copies. However it is recognised that drop out rates are high with Internet research (Birnbaum, 2004), potentially due to the lack of social pressure to finish. Again, piloting the questionnaire pack with people who have experienced TBI may have been useful in highlighting these issues. Despite these concerns, several participants contacted the researcher to report that they found the study interesting and were interested in hearing about the findings.

Conceptual and Measurement Issues

Other researchers discussing social anxiety following brain injury have highlighted potential issues with measurement through self-report measures, drawing attention to how psychometric tools contain somatic items (e.g., shaking, palpitations) which may be

associated with physical symptoms of the TBI rather than anxiety (Hodgson, McDonald, Tate & Gertler, 2012; Soo, Tate & Rapee, 2012). While not appropriate in the current study due to its exploratory nature and the points discussed above around brevity of the questionnaire pack, future research might compare the SPIN to other measures of social anxiety which focus more on behavioural avoidance (e.g., Liebowitz Social Anxiety Scale; Liebowitz, 1987).

Indeed the reliance on self-report, particularly in relation to cognitive ability, is potentially a significant limitation of this study. Time and resources did not allow for objective assessment of cognitive impairment in the current study through neuropsychological assessment. This approach would have resulted in a significantly smaller sample. However, it is recognised that there are questions about the validity of self-reported cognitive problems when compared to objective assessment in a TBI population (e.g., Spencer, Drag, Walker & Bieliauskas, 2010). Although care was taken to select a measure of perceived cognitive problems which was brief and demonstrated acceptable levels of internal consistency and test-retest reliability, no published data were available on use of the Applied Cognition measure (Neuro-QOL, 2012) with a TBI sample. Nevertheless, this measure provided a brief, clear and understandable assessment of cognitive problems common after TBI. The findings in relation to cognitive problems must be interpreted with some caution until future research examines the relationship between cognitive impairment and social anxiety in more detail.

In addition, it is recognised that many of the variables under examination in this study were conceptualised as uni-dimensional constructs. The use of linear analysis techniques such as correlation and hierarchical multiple regression means that the nuances of complex, bi-directional relationships between variables were not explored. However, as an exploratory

piece of research examining hypothesised associations between variables, the current study has provided a useful basis for further research exploring social anxiety following TBI.

Diagnostic Frameworks Within Quantitative Research

It is also recognised that the conceptualisation of social anxiety employed in the study may be consistent with a diagnostic approach. However, this is not always consistent with the hypothesis-driven formulation approach which is a key part of the role of a clinical psychologist (British Psychological Society [BPS], 2006; 2011a). The BPS has taken a strong stance against diagnostic categories (BPS, 2011b), emphasising the value of formulation in clinical practice. The tension between a formulation approach, which focuses on the individual, and quantitative research which focuses on categorising people to find generalisable commonalities, has been highlighted in relation to clinical psychology (e.g., Gill, Mullin & Simpson, 2013; Carr & McNulty, 2006). While clinical psychologists are expected to work in an evidence-based manner (BPS, 2006), empirically-based guidelines tend to be drawn from research which is based on a diagnostic framework and an epistemological stance which may not be compatible with a formulation-based approach.

This tension was recognised throughout this study, prompting me to reflect on my own epistemological stance within clinical practice and research. The results have been understood within a clinical psychology framework which promotes models of individual human experience and considers the impact of societal influences. Attempts have been made to avoid categorical statements about the nature of social anxiety and the study has focused on continuous scores rather than employing categorical cut-off scores in the analysis. By examining factors which predict the degree of social anxiety, the present study has been conducted in a way which is informed by the categorical and descriptive nature of the diagnostic label of social anxiety, while understanding the results in a theory-driven and

explanatory manner, considering causal and maintaining factors influencing distress (Gill et al., 2013).

Indeed, conducting this research has highlighted to me how the criteria outlined within the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5; American Psychiatric Association [APA], 2013) has limited applicability to this client group, particularly as it states that anxiety or avoidance must be unrelated to any medical condition. While categorical features of classification around social anxiety may be useful, this study highlights the importance of understanding psychological problems as part of a meaningful formulation which is multi-factorial and dynamic, considering the context in which a person's experience is grounded (Eells, 2002; Johnstone & Dallos, 2013). As Williams, Evans and Fleminger (2003) highlight, anxiety problems following brain injury may be best understood within dimensional models rather than categorical ones, with formulations developed as working hypotheses which are revised throughout the process of intervention. This is particularly pertinent in relation to the finding that stigma was a significant independent predictor of social anxiety, highlighting the need for understanding an individual's experience within a societal context, integrating factors above and beyond medical or psychiatric diagnoses and physical or cognitive impairments.

Social Models of Disability

Models designed to guide psychological therapy for social anxiety (e.g., Wells, 2013) focus on challenging an individual's beliefs around their self-image, the responses they receive and the consequences of failed performance. However by working on how people process themselves as a social entity, this conceptualisation of social anxiety is, by its nature, purely focused on the individual. The need to integrate social models of disability (Oliver, 1983; 2004) with clinical psychology practice has been increasingly highlighted, with a focus on how societal barriers (e.g., limited access to employment, inadequate disability benefits,

discriminatory services) actively disable people with impairments (Simpson & Thomas, 2014). As discussed in the Research Paper, the findings of the present study have particular relevance to the concept of psychoemotional disablism (Reeve, 2012), which suggests that people with impairments can internalise negative or stigmatising social interactions (e.g., hurtful comments or being stared at). In addition to affecting psychological wellbeing, this can lead to avoidance of further social contact and the person placing restrictions on themselves, as they come to believe negative stereotypes about what it means to have an impairment.

This is particularly pertinent in relation to the stigma facing people who have experienced TBI. Behavioural challenges and physical, communication and cognitive impairments are common following TBI, with the cause of such problems often not obvious and open to misinterpretation (e.g., problems may be attributed to alcohol intoxication), leaving the person feeling misunderstood (McClure, 2011). Qualitative research (e.g., Morris et al., 2005; Linden & Boylan, 2010) has highlighted how a lack of understanding of common consequences of TBI (e.g., mood swings, tiredness, cognitive impairment, poor concentration, memory loss, speech difficulties) leads to negative treatment of people with TBI, particularly as such difficulties are not unique to TBI and physical signs of injury may not be apparent (Krahn, 2015; McClure, 2011). Additionally recovery from TBI is often misunderstood, resulting in people either not making reasonable allowances or, conversely, over-compensating for perceived impairment (Guilmette & Paglia, 2004; Morris et al., 2005).

In relation to social anxiety following TBI, multi-directional relationships are possible between impairment, social anxiety and psychoemotional disablism. For example, people with cognitive or speech impairments might hold back from speaking in social situations, which means they receive more negative and stigmatising reactions from others as they are perceived as being unsociable. The negative reactions from others are internalised, affecting

social activity and increasing anxiety. Alongside the structural barriers limiting access to work and social integration, there is potential for psychosocial wellbeing to be significantly compromised as a result. Consequently, societal barriers and public attitudes may be key in understanding social anxiety in the context of the experience of stigma, withdrawal and isolation of people who have had a TBI (Krahn, 2015).

Furthermore, the impact of the social context in which TBI often occurs must be recognised. Research has consistently indicated that, perhaps due to increased risk-taking behaviours and drug and alcohol use, people from areas of lower socio-economic status are more likely to experience TBI and receive poorer care following injury (Mauritz et al., 2008; Yates et al., 2006). Stigma may play a key role in this process. For example, a person who has experienced TBI may be perceived to be more responsible for their injury than someone with a more medically based injury (e.g., stroke). This may reflect negative causal attributions which are being made (Weiner, 1986; McClure, 2011). It may also be harder for the person to access work or disability benefits as a result of the negative perceptions of other people and the structural disablism caused by the society in which they live (Reeve, 2012; Simpson, McMillan & Reeve, 2013). Further research might therefore be useful in exploring factors associated with social anxiety in relation to other types of brain injury. In particular, it may be valuable to explore the experience of stigma following other types of brain injury (e.g., stroke, aneurysm, brain tumour, encephalitis, hypoxic brain injury), which may be less stigmatised if they are perceived at a societal level to have primarily medical origins.

Research has highlighted stigma and lack of knowledge regarding TBI in the general population, acknowledging the potential impact on reintegrating people who have experienced TBI with their communities (Guilmette & Paglia, 2004; Linden & Boylan, 2010). It is also important to recognise that mental health problems are themselves stigmatising (Beresford, 2002), and after TBI people may be even less likely to seek help for

psychological or emotional problems. However, while social models of disability have been applied to other neurological problems such as Parkinson's Disease (Simpson, McMillan & Reeve, 2013), no research appears to have explored the interplay between TBI, psychological wellbeing and the barriers which are socially constructed in the form of stigma and disablement. Considering the importance of positive social interactions with other people in the experience of social anxiety, applying a social disability perspective may help to guide further research and intervention.

The present study focused on individual experience of perceived stigma and found that it was an important predictor of social anxiety following TBI. Although research has consistently identified the impact of TBI on social integration and made recommendations for holistic, community-based interventions and rehabilitation (e.g., Pierce & Hanks, 2006; Truelle, Fayol, Montreuil, & Chevignard, 2010; Gracey, Evans & Malley, 2009), such interventions are focused solely on the individual. Approaching the findings of the present study from a social disability perspective highlights a role for targeted approaches to tackle structural disablism and reduce the barriers which impact on what people with impairments are able to do. For example, by tackling exclusion from employment, providing information in accessible formats and ensuring that assessments for disability benefits are sensitive to the particular challenges a person who has experienced TBI might face, the psychological and psychosocial wellbeing of a person can be significantly improved.

Furthermore, given the lack of understanding regarding TBI and the consequences of negative attributions on stigma (Guilmette & Paglia, 2004; McClure, 2011), there is a role for clinical psychologists to design and deliver interventions designed to raise awareness and public understanding. Increasing familiarity with people who have experienced TBI and building public knowledge and experience of the sequelae of TBI can reduce negative stereotypes (Redpath et al., 2010; McLellan, Bishop, & McKinlay, 2010). Additionally,

Krahn (2015) highlights the value of narrative media and documentary films around TBI in helping make personal and positive connections with a wider audience. By reducing the impact of negative preconceptions and stereotypes, psychoemotional disablism can be tackled at a societal level.

There is certainly need for holistic, individually focused interventions to meet the psychological needs of people who have experienced TBI, and applying a social disability perspective highlights the importance of adaptation of the identity of the individual, as opposed to viewing TBI as a condition which must be controlled or cured (Swift & Wilson, 2001). The integration of peer support, often through access to third sector services, is also valuable in developing connectedness and a sense of belonging. However, to fully address the psychological and psychosocial problems discussed above, societal interventions must also play a significant role.

Conclusion

In conclusion, this study has identified that psychological variables are important in the development of social anxiety post-TBI. The hypothesis that clinical and demographic characteristics cannot fully predict social anxiety following TBI was supported. On reflection, this has clear links to the clinical work which guided my choice of thesis topic. Training as a clinical psychologist has taught me the value of incorporating a range of psychological, social and neurological factors into a meaningful formulation. Furthermore, the emergence of perceived stigma as a significant independent predictor is a key finding with implications for research and clinical psychology practice, particularly when considered in the context of social models of disability.

In conducting this study, I have learned the value of bringing a psychological perspective to research, integrated with social models of disability. By working to understand the factors which might explain problems with psychosocial functioning as opposed to seeing

it as a simple consequence of TBI, I hope to have provided a starting point for guiding clinical practice by identifying factors that might be amenable to change. Additional research, using a larger sample to achieve higher levels of statistical power, would be useful in expanding on the exploratory nature of this study. Moreover, this project has highlighted the need for clinical psychology as a profession to take a greater role in exploring the potential for societal interventions to target stigma and disablism affecting people who have experienced TBI.

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Section Four: Ethics

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LANCASTER UNIVERSITY
DIVISION OF HEALTH RESEARCH
Doctorate In Clinical Psychology

Social Anxiety Following Traumatic Brain Injury

Applicant: Will Curvis, Lancaster University

Research Supervisors: [redacted]

Field Supervisor: [redacted]

Project Summary

The present study aims to investigate the psychological factors influencing the development of social anxiety following traumatic brain injury. This project is being completed as part of the Doctorate in Clinical Psychology programme at Lancaster University.

Background

In addition to the physical consequences of traumatic brain injury (TBI), psychological difficulties must be considered in the treatment and rehabilitation process. TBI has been found to place individuals at greater risk of developing psychological problems such as depression and anxiety (Bryant et al., 2010; Moore, Terryberry-Spohr, & Hope, 2006) due to the complex interactions between neurological, psychological and emotional consequences of such injuries.

Dramatic changes to social functioning are common after TBI, with declines in leisure activity, social support, social contact, independence, functional status and employment opportunities often reported (Antonak, Livneh, & Antonak, 1993; Moore et al., 2006; Temkin, Corrigan, Dikmen, & Machamer, 2009; Morton and Wehman, 1995). These emotional and psychosocial difficulties create a significant challenge for professionals

working to support community reintegration and neuropsychological rehabilitation (Morton & Wehman, 1995). In addition to functional difficulties, anxiety around social interactions may account for some of this variation in functioning following TBI (Hiott & Labbate, 2002; Moore et al., 2006).

A recent review into anxiety following TBI (Moore et al., 2006) highlighted how social anxiety is potentially a significant problem in this population. Social anxiety is common in the general population, with lifetime prevalence rates estimated to be 12% (National Institute for Health and Care Excellence [NICE], 2013). Common triggers include public speaking, meeting new people, dating, social events and eating in public (American Psychiatric Association, 2000). While impairments to psychosocial functioning following TBI have been well documented (Morton and Wehman, 1995), no research to date has specifically examined social anxiety in this population.

Neurological factors may play a significant role in the development of social anxiety following TBI. In a review of the literature around anxiety after TBI, Moore et al (2006) highlights the potential role of damage to areas of the brain. Diffuse neurological damage often resulting from head injuries is discussed, for example from acceleration–deceleration forces and subsequent contusions or abrasions caused by contact with the skull. Focal and diffuse damage may affect brain regions associated with the inhibition of anxiety, subsequently becoming over-sensitive to stimuli. Conversely, traditionally frontal lobe injuries commonly affect executive and emotional processing, which may lead to disinhibition or a lack of insight – and perhaps a reduction in social anxiety. Data indicating prevalence rates which are lower than what might be expected may have important implications for understanding of neurological functioning following TBI. Research which unpicks the relationship between TBI and social anxiety is required.

Additionally, there is a need for research into the psychological factors which affect the development of social anxiety following TBI. A wide variety of disturbances following TBI are commonly observed, with neurological variables (e.g. severity of injury) failing to fully explain variations in anxiety and impaired psychosocial functioning (Antonak et al., 1993; Moore et al., 2006). Cognitive theories of social phobia emphasize the role of appraisals in the development and maintenance of social anxiety (Clark & Wells, 1995). Maladaptive beliefs and thought processes around the appraisals of the self and others are often central to the experience of social anxiety, as is the individual's perception of whether the situation is controllable. These processes may be adversely affected by the neurological and psychological impacts of a TBI in a way which is unique compared to other physical injuries. Patterns of behavioural avoidance may develop, which are maintained over time as the problems with social anxiety worsen.

Following TBI, people may feel embarrassed or self-conscious in social situations given the physical (e.g. disability, tremors, scarring, motor/speech problems, weight gain), psychological (e.g. apathy, low motivation, low self-esteem) and cognitive (e.g. word finding, attention, memory, slowness of thought) impacts of brain injuries (Hiott & Labbate, 2002; Moore et al., 2006; Wright & Telford, 1996). Qualitative research conducted by Morris et al. (2005) and Nochi (1998) highlights how participants experience 'unseen' consequences of TBI which impact on social outcomes. Participants emphasised the sense of loss and change in identity they experienced, in addition to the stigma and lack of understanding they faced regarding their difficulties. Understanding the impact of psychological variables relating to social anxiety following TBI will help guide professionals working within this population to provide interventions based on factors which are amenable to change.

This study will aim to investigate the relationship between traumatic brain injury and social anxiety. This will guide an examination of the psychological and neuropsychological

factors which might contribute to the relationship between TBI and social anxiety. In understanding the impact of these factors, it is hypothesised that psychological variables will account for an additional and significant amount of variance in social anxiety, above that explained by demographic and clinical variables.

Method

The study will employ a quantitative methodology, using a cross-sectional within-subjects design to explore which psychological factors may predict higher levels of social anxiety following TBI. Questionnaires will be used as the data collection method.

Participants

Participants will mainly be recruited through NHS Trusts in the North-West of England and relevant third sector organisations. Participants will also be able to self-refer into the study provided they meet the inclusion criteria – posters and social networking websites will be used to advertise the study. Further details on the recruitment strategy are provided below.

While there is no directly similar research from which to draw effect sizes for an *a priori* power calculation, medium to large effect sizes have been observed in relevant research (i.e. the role of psychological variables in the development of social anxiety in other populations). For a regression model including five to fifteen predictor variables, a sample size of between 92 and 139 will be required based on finding a medium effect size (0.15) at 80% power and an alpha level of p=.05.

To ensure the sample is as representative as possible, broad inclusion and exclusion criteria will be used.

Inclusion Criteria

- Individual has experienced TBI
- Ability to read English

- Brain injury sustained after age of 16
- Currently aged 18+

Exclusion Criteria

- Lacking capacity to give consent or participate in the study
- Under 18
- Currently residing on a medical ward or rehabilitation residential unit

Proposed Recruitment Procedure

Given the potential difficulties in recruiting adequate numbers of participants from this client group, a variety of recruitment strategies will be employed. A broad approach will be taken to maximise opportunities for potential participants to be involved in the study. The study will focus on participants who are medically well enough to be living in the community rather than on medical wards or specialist rehabilitation units, to allow for insight into the psychosocial recovery process.

Primarily, NHS neurology/neuropsychology departments will be approached. The Research and Development (R&D) department within [redacted] will be approached to gain approval to recruit through the neurology/neuropsychology department. The R&D department in [redacted] has agreed to act as the lead R&D department for the study.

Other NHS Trusts will be approached for R&D approval as required by the recruitment needs of the study. Site Specific Information (SSI) forms will be generated through the Integrated Research Application System (IRAS) as part of the R&D approval process for each individual NHS Trust. For logistical reasons the study will focus on NHS Trusts in the north-west of England initially, although this may be extended to departments in other areas of the country.

Following ethical approval, potential participants will be identified by staff working in the neurology/neuropsychology departments of the NHS Trusts where R&D approval has been granted. Staff will be asked to introduce the study and give potential participants a copy of the Participant Information Sheet (Appendix A). If they are interested in participating, staff can provide the Screening and Consent Form (Appendix B) and a copy of the Questionnaire Pack (Appendix C). After completing the questionnaires, the participant will be provided with a Debrief Sheet (Appendix D), which will thank participants for their time and provide details of appropriate support if required (e.g. care coordinator, GP, third sector organisations). A stamped addressed envelope will be included to allow for return of all completed items to the researcher at Lancaster University. On receiving the completed items the researcher will use the Screening and Consent Form to assess eligibility and the questionnaires will be included in the study if appropriate.

Potential participants identified by staff may also be sent a copy of the Participant Information Sheet, Screening and Consent Form, Questionnaire Pack and Debrief Sheet by post, accompanied by an introductory covering letter (Appendix E) explaining why they have been invited to participate. A follow-up letter (Appendix F) may be sent to these participants after one month if a response has not been received. The pack will include a stamped addressed envelope to enable completed questionnaires to be returned to the lead researcher at Lancaster University. As above, on receiving the completed items the researcher will use the Screening and Consent Form to assess eligibility and the questionnaires will be included in the study if appropriate.

Relevant third sector organisations (e.g. [redacted]) will also be contacted to promote the study. The lead researcher will visit the organisations to advertise the study to potential participants. Staff will be provided with materials to recruit potential participants as described above. The researcher will also display a poster in NHS and third sector

organisations (Appendix G) to advertise the project, which will include detachable slips with the lead researcher's contact details enabling potential participants to contact the researcher if interested in taking part. The project will also be advertised on the Internet using the information from the poster, with the researcher making use of social networking websites (i.e. Facebook, Twitter) and the websites of third sector organisations to reach potential participants through online support networks.

All online advertisements, the poster and the Participant Information Sheet will include a link to an online version of the questionnaires, which participants will be invited to use if they would rather do this than complete a paper copy. The online questionnaire website Qualtrix will be used to collect participant responses. Participants will be presented with the information detailed on the Participant Information Sheet, followed by the information detailed on the Screening and Consent Form. Participants will be required to confirm they meet the eligibility criteria outlined by the screening questions by ticking checkboxes on the website. A checkbox will be used to confirm they consent to taking part in the study. To maximise security around identifiable data collected online, names will not be collected to ensure anonymity.

If the screening questions highlight that a participant is not eligible for the study or if they decline to consent then they will be directed to the final page of the website containing information from the Debrief Sheet. Otherwise, the questionnaires will be presented. To minimise bias, questionnaires will be given in differing orders using the function provided by the website. After the questionnaires have been completed, the information from the Debrief Sheet will be presented on the final page. Feedback on scores will not be provided by the researcher for any participant in the study.

Participants will also have the option of having the researcher provide the questionnaires in person if they require support with completing them (e.g. due to physical

disability). The researcher's contact details will be provided on the materials for this purpose. If a participant requests a face-to-face meeting, a mutually convenient date and time will be arranged. Questionnaires will be completed at NHS premises where possible. If completed at a participant's home, the researcher will abide by the lone worker guidance in the University's Guidance on Safety in Fieldwork (which is accessible from http://www.lancaster.ac.uk/depts/safety/files/Fieldwork.pdf). The researcher will complete the Screening and Consent Form with participants first and will not continue if all eligibility criteria are not met. Questionnaires will be given in one of three pre-arranged orders to minimise bias. Questionnaires may be completed over repeated sessions if required.

Recruitment Deadline

Once ethical approval has been granted, a closing date for recruitment will be confirmed. This date will be included on the introductory and follow-up letters, in addition to the Participant Information Sheet. Questionnaires received after this date will not be used in the study.

Measures

Outcome Variable

The Social Phobia Inventory (Connor et al., 2000) will be used as the outcome measure for the study. While a variety of measures of social anxiety are available, the SPIN was selected as it is recommended by guidance provided by the National Institute of Health and Care Excellence (NICE, 2013). The SPIN is also included as part of the outcomes 'toolkit' used in many 'Improving Access to Psychological Therapies' (IAPT) primary care mental health services in the NHS.

The SPIN is a patient-rated, 17-item assessment of three clinically important symptom domains of social anxiety and is the only measure to combine fear, avoidance and physiological discomfort into one total score (Connor et al., 2000). Responses are scored

from 0 (not at all) to 4 (extremely), with a maximum total score of 64 indicating very severe problems in this area. The SPIN has been shown to demonstrate acceptable test-retest reliability, internal consistency, convergent validity and divergent reliability (Antony, Coons, McCabe, Ashbaugh, & Swinson, 2006; Connor et al., 2000).

Although this measure has not been used in a TBI population in any published research to date, its face validity and brevity make it the most appropriate measure from the available options. The lead researcher considered the SPIN to be more appropriate than other commonly used measures of social anxiety, all of which include several items which might hold less relevance to many people following TBI.

Predictor Variables

Neurological functioning and subjective severity. "Applied Cognition – General Concerns" measure published by NeuroQOL (2012). This is a brief (18-item) screening measure assessing cognitive problems across a range of domains, examining perceived difficulties in everyday cognitive abilities such as memory, attention, and decision-making. Responses range from never (1) to very often (5), with a maximum score of 90 indicating significant problems. High levels of internal reliability and test-retest reliability have been demonstrated in samples of patients with a range of neurological problems (e.g. stroke, epilepsy, Parkinson's disease) but no data are available for a TBI sample (Neuro-QOL, 2010). Despite this, the measure has been selected over other measures due to its brevity and focus on subjective severity of symptoms, as opposed to other variables (e.g. quality of life). This measure is freely available for use in the study.

Anxiety/Depression. The Hospital Anxiety and Depression Scale (Zigmond & Snaith, 1983) is a widely used measure of anxiety and depression, comprising of 14-items (seven relating to depression and seven relating to anxiety). Responses are recorded on a 0 to 3 scale, appropriately coded so that a higher score on either subscale indicates a more severe

problem. The measure was designed to assess anxiety and depression in a way which did not rely on somatic symptoms of physical illness (e.g. fatigue, insomnia). A recent review of its use found acceptable psychometric properties, with high levels of validity and reliability in a range of samples (Bjelland, Dahl, Haug, & Neckelmann, 2002). The HADS has been shown to be valid in a TBI sample (Whelan-Goodinson, Ponsford, & Schönberger, 2009). This measure has been purchased by the NHS Trust in which the study is taking place and can be used in the study.

Self-esteem. The Rosenberg Self-Esteem Scale (1965) is a widely used 10-item scale with high levels of reliability and validity. Responses are recorded on a 0 to 3 scale (reverse coded on some items). Total scores of 0–15 represent low self-esteem, scores of 15–25 indicate normal self-esteem and scores higher than 25 represent high self-esteem. This measure has been used to examine self-esteem in recent TBI research (e.g. Anson & Ponsford, 2006; Ponsford et al., 2014). This measure is freely available for use in the study.

Perceived stigma. The Stigma scale from NeuroQOL (2012) is a 24-item measure of stigma examining perceptions of self and publically enacted negativity, prejudice and discrimination as a result of neurological problems. Responses are scored from 1 (never) to 5 (always), with a maximum score of 120 indicating significant problems in this area. High levels of internal reliability and test-retest reliability have been demonstrated in a sample of patients with epilepsy. Although no research to date has support its use in a TBI population, the neurological focus of the measure increases its face validity and appropriateness for the current study. For clarity, the word ‘illness’ was replaced with the term ‘brain injury’. This measure is freely available for use in the study.

Self-efficacy. The Self-Efficacy for Symptom Management Scale (Cicerone & Azulay, 2007) is a 13-item scale adapted to assess how confident people are in managing common challenges associated with TBI. Items are scored 1 (not at all confident) to 10

(totally confident), with a maximum total score of 130 indicating high self-efficacy. The scale's authors report good internal reliability. Permission to use the scale in the study has been gained from the authors.

Locus of control. Form C of the Multidimensional Health Locus of Control (Wallston, Stein, & Smith, 1994) is a condition-specific measure of an individual's belief in their ability to control health outcomes, split into subscales for internality, powerful others externality (doctors and other people) and chance externality. Responses are scored from 1 (strongly disagree) to 6 (strongly agree). A total score is not provided, with a range for each subscale is separately reported. A higher score indicates higher locus of control. The authors of the measure report good internal reliability and validity. It has been used in previous TBI research to explore locus of control (Moore & Stambrook, 1992). This measure is freely available for use in the study.

Demographics

The following details will be collected through self-report to provide demographic information about the sample: gender, age, time since injury(-ies), type of traumatic event (i.e. road traffic accident, assault), time spent in hospital following injury (providing estimate of post-traumatic amnesia and thereby severity of injury).

Proposed analysis

After data collection is complete the questionnaires will be scored by the lead researcher and entered onto SPSS, the computer programme which will be used for the statistical analysis.

Hierarchical multiple regression analysis will be conducted to examine the data. Due to the exploratory nature of the study, Pearson's correlations will be calculated between each predictor variable and the outcome variable. Predictor variables which correlate with the

outcome variable and demonstrate a medium effect size ($r > 0.3$) will be entered into the regression model.

Predictor variables which correlate with the outcome variable will be entered into the regression model in the following blocks, in keeping with previous research: 1) demographic variables (gender, age, type of traumatic event) 2) clinical variables (time spent in hospital, neurological functioning) 3) psychological variables (anxiety/depression, self-esteem, perceived stigma, self-efficacy, locus of control).

Practical Issues

A mobile phone provided by Lancaster University will be used for potential participants to contact the lead researcher. The researcher's Lancaster University email address will also be used. The computer software required for the data analysis is provided at Lancaster University. The only other predicted costs are for use of copyrighted measures, the researcher's travel (according to LCFT guidance) and the photocopying of the questionnaire packs. The Doctorate in Clinical Psychology course at Lancaster University has agreed to cover these costs.

The Participant Information Sheet will make clear that participants are able to have help from a friend, relative, carer etc. to read the questions and write their responses. However they will be encouraged to provide the actual answers to the questions themselves. The lead researcher will provide support with reading and writing if required when completing the questionnaires face-to-face with participants but no direction on answers will be given.

Data Storage

During the study, Lancaster University's policy on data storage will be followed (http://www.lancaster.ac.uk/shm/study/doctoral_study/dclinpsy/new/onlinehandbook/ethics_and_data_storage_advice/). The university server will provide password protection and

encryption for all data collected during the study including SPSS files, consent forms and questionnaires. Files containing identifiable information (i.e. the list of names and addresses of participants being sent a follow-up letter or visited at home, and all signed consent forms) will also be individually password protected. Any paper data will be scanned and stored electronically as above, with paper copies securely disposed of. The list of names and addresses will be deleted at the end of the project. All other data will be stored electronically for ten years after submission or publication of the project. Data will be stored by the DClinPsy Research Administrator, who will be responsible for storing the data securely until the end of the storage period. At the end of the storage period all data and materials will be deleted.

Qualtrics will be used for the online questionnaires. Qualtrics provide high levels of security around data collected (full technical details available at http://www.qualtrics.com/security-statement) and they offer the researcher control over the privacy of the questionnaires (I.e. So the survey will only be accessible via a link and will not be displayed in search engine results). The university servers are also appropriately secured and password protected. Further technical details of the university's policy on data security is available at https://gap.lancs.ac.uk/policy-info-guide/5-policies-procedures/Documents/New-Information-Security-Policy-November-2012.pdf. Data will be stored in line with relevant legislation (e.g. Data Protection Act, 1998) and information governance policy.

Ethical issues

The Integrated Research Application System (IRAS) will be used to apply for ethical review from the NHS Research and Ethics Committee. Appropriate R&D approval will also be sought. The proposal has been through a peer review process as part of the doctoral programme facilitated by members of the research team.

Participants will be informed that they can withdraw at any time while completing the questionnaires. Should a participant become upset they will be offered a break or the option to stop altogether. All participants will be provided with a debrief sheet after completing the questionnaires, which will contain details of appropriate sources of support (e.g. friends, family, GP, care coordinator, local third sector organisations, national helplines).

If necessary, the researcher will discuss these options with participants. The researcher will facilitate a similar conversation should a participant ask for clinical advice or support.

Due to the vulnerable nature of many individuals who have experienced TBI, the researcher will remain vigilant to any signs of potential safeguarding issues. Should any concerns be raised, the researcher will liaise with the research supervisor and take appropriate steps in line with local safeguarding policy. This may involve liaising with the individual's GP or care co-ordinator as appropriate. Should urgent concerns be raised about a participant's immediate safety, the researcher will liaise with social services or the police as required.

The researcher will not provide feedback on questionnaire scores. The debrief sheet provided to all participants after the questionnaires are completed will provide an overview of what will happen with the findings and detail what support they can access if they are affected by any of the issues discussed. A paper copy of this will be given to participants who complete the measures face to face. A paper copy will be included with the questionnaire packs sent to participants. The information will be provided on-screen after completion of the questionnaires for individuals who complete the questionnaires online. Participants will be informed that they are able to contact the lead researcher through the contact details on the Participant Information Sheet should they have further questions.

To maximise security, paper versions of consent forms will be scanned and shredded, but stored separately to questionnaires to ensure that names cannot be linked to questionnaire

responses. The online questionnaires will utilise tick boxes to establish consent and will not collect names. Non-identifiable demographic information will be collected and analysed as part of study (e.g. age, gender, details of injury type). All participants will be informed that identifiable information will not be included in the report and all information will be stored securely as described above. Participants will be informed that they are able to stop at any time, however once questionnaires are submitted it will not be possible to remove their data from the analysis as responses will not be identifiable.

The limits of confidentiality will be made clear on the information sheets. The materials will state that if issues around risk to self or others are identified, it may be necessary for the researcher to share information. In the event that risk concerns are identified by the researcher, a management plan will be agreed with the participant which may involve informing their GP or care co-ordinator. The research supervisor will be informed immediately to support the management of any risk issues.

Appropriate privacy settings will be employed on the internet sites used to recruit to ensure that potential participants cannot access personal information about the researcher. Any potential participants who attempt to make contact through social networking sites will be responded to by asking them to contact the researcher via the e-mail or telephone contact details listed on the recruitment materials.

Questionnaires provided by the researcher will be given at NHS premises where possible. If an interview is conducted at a participant's home the researcher will adhere to the lone worker guidance in the University's Guidance on Safety in Fieldwork (which is accessible from www.lancaster.ac.uk/depts/safety/files/Fieldwork.pdf). This will involve identifying potential hazards through dynamic risk assessment, withdrawing immediately if necessary, carrying a mobile phone provided by the University, making a colleague aware of the meeting and staying in contact before and after, and leaving the situation should any risk

issues be identified. The researcher will utilise regular supervision to manage the practical and emotional demands of the project.

Consent and Capacity

In line with the Mental Capacity Act (2005) and the guidance provided by the British Psychological Society (2008), all participants will be assumed to have capacity to consent to participating in the study unless evidence to the contrary arises. Should doubts arise about a person's ability to make an informed decision about participation, the researcher will conduct a capacity assessment in line with the four criteria laid out within the Mental Capacity Act (2005). The person must be able to show that they comprehend the information about the study, as detailed on the Participant Information Sheet. They must be able to retain this information long enough to make a decision, using the information to reach a decision based on the consequences of participating or not participating. The participant will also be required to communicate their decision, with support from the researcher if required. If these criteria are met then the researcher will provide the questionnaires.

Participants who choose to submit the questionnaires by post or online will be assumed to have capacity to consent. All participants will be asked to indicate on a consent form that they understand and consent to the study – any questionnaires which are not accompanied by this will not be used in the analysis. The researcher's contact details will be clearly provided on the consent forms so that potential participants can seek advice if they are unsure about any aspect of the study.

Dissemination

The project will be written up and submitted as a thesis for the Doctorate in Clinical Psychology at Lancaster University. A report will also be prepared for publication in a peer reviewed journal.

Proposed Timescale

- Feb - May 2014: Prepare and submit a proposal to ethics
- July 2014: Receive ethical approval
- Aug - Oct 2014: Data collection and write drafts
- Nov 2014: Analyse data
- Dec 2014 - Jan 2015: Write drafts
- Feb 2015: Submit drafts to supervisors
- March 2015: Revise 3rd draft and submit to supervisors for review
- April 2015: Make last revisions
- May 2015: Submit Thesis
- June 2015: Viva

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Appendices to Research Protocol

Appendix A: Participant Information Sheet

Appendix B: Screening & Consent Form

Appendix C: Questionnaire Pack

Appendix D: Debrief Sheet

Appendix E: Introductory Covering Letter

Appendix F: Follow-up Letter

Appendix G: Poster

LANCASTER UNIVERSITY
DIVISION OF HEALTH RESEARCH
Doctorate In Clinical Psychology

Social Anxiety Following Traumatic Brain Injury

Participant Information Sheet

What is the study?

As part of my training to become a clinical psychologist I am doing a research project on how people who have experienced a traumatic brain injury (e.g. resulting from a road traffic accident or assault) feel and/or behave in social situations (e.g. being around people, giving speeches, going to a party).

We are asking if you would like to join in this research project. Before you decide if you want to take part, it's important to understand why the research is being done and what it will involve for you. Please consider this leaflet carefully and please feel free to talk to your family, friends, doctor or nurse about your decision to take part.

Why have you asked me?

I am interested in the experiences of people who have experienced a traumatic brain injury after the age of 16 who are currently living in the community. I am working with NHS departments and 'third sector' organisations (such as charities and support groups) to identify people who have experienced a traumatic brain injury and who might want to take part in the study.

What will happen?

You will be provided with a pack containing some questionnaires The questionnaires cover a range of topics relating to how you feel about yourself and social situations. You will also be asked some questions about the nature and impact of your brain injury. When you have completed all the questionnaires, you can return them to me using the pre-paid stamped addressed envelope.

If you prefer, you can complete the questionnaires online instead at http://tinyurl.com/o54eehs. The lead researcher for the project, Will Curvis, can come and meet with you to help you complete the questionnaires if necessary. If you would like to arrange a meeting, you can contact Will using the details at the bottom of this information sheet.

How long will it take?
Filling in the questionnaires will take around 30 minutes.

What information will you collect?
In addition to the questionnaires, you will be asked some questions about some personal details (e.g. age, gender, details of injury).

Details which might be used to identify you (e.g. name, address) will not be collected. Consent forms (which will have your signature on) will be scanned and stored separately to the questionnaire data to ensure that names cannot be linked to questionnaire responses. The online questionnaire uses tick-boxes for the consent form and does not ask for your name or signature.

Will it be private?
All of your responses will be kept confidential and stored securely. The only identifiable information collected will be on the consent form and these will be stored separately from the questionnaire responses to ensure your privacy. If the lead researcher meets with you in person to complete the questionnaires, your details will not be shared or kept on file.

However if information comes to light which gives us reason to worry that you or someone else might come to harm, I might have to share this information with other professionals (e.g. GP, care co-ordinator). I would always make sure you knew this was happening and would only share information that was absolutely necessary.

Who will see my responses?
The lead researcher will be the only person with access to all of the data. As questionnaire responses will be stored anonymously, other members of the research team will only see the summarised scores from the questionnaires and will not have access to any identifiable information.

Can I see the research?
Of course! I plan to write a brief summary of the findings to send out to people who take part. If you like, I can also send you a copy of the full report.

What are the benefits?
While taking part in the research might not help you directly, I am hoping that developing our understanding of the factors that best help people with a brain injury manage social situations will help professionals who work with people with these difficulties, improving our ability to support people in their recovery journey.

What are the risks?
Some people can find answering personal questions upsetting. However, you can take a break or stop answering questions altogether whenever you like. At the end of the questionnaires you will be provided with suggestions for ways to get help or support should you feel that you need it.

Do I have to say yes?
No, it is completely up to you. We will ask you for your consent and you will need to sign a form to say you are happy to take part. If you decide not to take part it will not affect the care you receive. You can discuss this invitation to take part with anyone you like.

What if I change my mind?
You can stop filling in the questionnaires at any time without giving a reason. Once the answers are submitted (either online or by post), it will not be possible to remove your answers as the responses will be stored anonymously.

How long will the information be kept?
All data will be stored electronically, with paper copies scanned and securely disposed of. Lancaster University will provide password protection and encryption for all data files, consent forms and questionnaires. All data will be stored electronically for ten years after the project is submitted. At this point data will be deleted.

Will I get paid?
Unfortunately we are unable to pay people to participate. We will be able to reimburse travel claims of up to £10 where appropriate.

When do I have to decide?
The study will be recruiting participants until 31st December 2014. Any questionnaires received after this date will not be included in the study.

I'm interested - how do I find out more or get involved?
If you have been given a copy of the questionnaires, simply fill them in and return them to me using the pre-paid stamped addressed envelope provided.

If you don't have the questionnaires but would like to take part, contact me on the phone number or e-mail address below and I can send them out or arrange a time to meet with you. If you prefer, you can complete the questionnaires online at http://tinyurl.com/o54eehs

If you're not sure about anything or have any questions about getting involved, please feel free to give me a phone call or e-mail using the details below.

This research is being conducted under the supervision of [redacted] at Lancaster University. Please direct any complaints to [redacted], Lancaster University ([redacted]@lancaster.ac.uk). Ethical approval has been granted by the Hampstead NRES Committee London on 14th July 2014.

Thank you,

Will Curvis
Trainee Clinical Psychologist, Lancaster University

e-Mail: w.curvis@lancaster.ac.uk
Tel: 07508 375640

Participant Consent Form

Before you consent to participating in the study, we ask that you read the Participant Information Sheet in full. If you have any questions or queries, please speak to Will Curvis, the lead researcher on the project. If you are happy to take part, please read each statement and mark each box with your initials if you agree.

	Please tick to agree
I have read the Participant Information Sheet and fully understand what is expected of me within this study.	
I have had enough information about the study.	
I have been able to ask any questions and have had them answered.	
I understand that I do not have to take part in the study and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	
I understand that information from my questionnaire responses will be pooled with other participants' responses, anonymised, and may be published in an academic journal.	
I understand that any information I give will be stored confidentially and anonymously for ten years after the study is complete.	
I understand that if there is a risk of harm to myself or others the researcher may need to share information with other professionals.	
I understand that relevant data collected during the study may be looked at by individuals from Lancaster University, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to this data.	
I agree to take part in the study.	

Signed _____ (participant)

Date _____

Signed _____ (researcher)

Date _____

Please answer the following screening questions:

Age		
Gender		
I experienced a traumatic brain injury after the age of 16	Yes	No

Please tick the box which best describes how you experienced your injury:

Road traffic accident	
Assault	
Sport injury	
Work injury	
Trip / Fall	
Other (please state) ……..	

How long ago did you experience your injury?

..... weeks …… months …… years

How long were you in hospital for following your injury?

…… days ..... weeks …… months …… years

Are you currently in paid employment?	Yes	No
Do you live alone?	Yes	No

Please tick the box which best describes your relationship status:

Single	
In a relationship	
Separated / Divorced	

If you have experienced more than one brain injury, please provide details of all of them (continue overleaf if required)

Social Phobia Inventory (SPIN)

Please indicate how much the following problems have bothered you during the past week. Mark only one box for each problem, and be sure to answer all items.

		Not at all	A little	Somewhat	Very much	Extremely
1	I am afraid of people in authority	☐	☐	☐	☐	☐
2	I am bothered by blushing in front of people	☐	☐	☐	☐	☐
3	Parties and social events scare me	☐	☐	☐	☐	☐
4	I avoid talking to people I don't know	☐	☐	☐	☐	☐
5	Being criticized scares me a lot	☐	☐	☐	☐	☐
6	Fear of embarrassment causes me to avoid doing things or speaking to people	☐	☐	☐	☐	☐
7	Sweating in front of people causes me distress	☐	☐	☐	☐	☐
8	I avoid going to parties	☐	☐	☐	☐	☐
9	I avoid activities in which I am the centre of attention	☐	☐	☐	☐	☐
10	Talking to strangers scares me	☐	☐	☐	☐	☐
11	I avoid having to give speeches	☐	☐	☐	☐	☐
12	I would do anything to avoid being criticized	☐	☐	☐	☐	☐
13	Heart palpitations bother me when I am around people	☐	☐	☐	☐	☐
14	I am afraid of doing things when people might be watching	☐	☐	☐	☐	☐
15	Being embarrassed or looking stupid is among my worst fears	☐	☐	☐	☐	☐
16	I avoid speaking to anyone in authority	☐	☐	☐	☐	☐
17	Trembling or shaking in front of others is distressing to me	☐	☐	☐	☐	☐

Applied Cognition

Please respond to each question or statement by marking one box per row.

		Never	Rarely (once)	Sometimes (2-3 times)	Often (once a day)	Very often (several times a day)
1	I had to read something several times to understand it	☐	☐	☐	☐	☐
2	I had trouble keeping track of what I was doing if I was interrupted	☐	☐	☐	☐	☐
3	I had difficulty doing more than one thing at a time	☐	☐	☐	☐	☐
4	I had trouble remembering new information, like phone numbers or simple instructions	☐	☐	☐	☐	☐
5	I had trouble thinking clearly	☐	☐	☐	☐	☐
6	My thinking was slow	☐	☐	☐	☐	☐
7	I had to work really hard to pay attention or would make a mistake	☐	☐	☐	☐	☐
8	I had trouble concentrating	☐	☐	☐	☐	☐
9	I made simple mistakes more easily	☐	☐	☐	☐	☐
10	Words I wanted to use seemed to be on the “tip of my tongue”	☐	☐	☐	☐	☐
11	I had trouble remembering whether I did things I was supposed to do, like taking a medicine or buying something I needed	☐	☐	☐	☐	☐
12	I walked into a room and forgot what I meant to get or do there	☐	☐	☐	☐	☐
13	I had trouble remembering the name of a familiar person	☐	☐	☐	☐	☐
14	I reacted slowly to things that were said or done	☐	☐	☐	☐	☐
15	I had trouble forming thoughts	☐	☐	☐	☐	☐
16	I had trouble getting started on very simple tasks	☐	☐	☐	☐	☐
17	I had trouble making decisions	☐	☐	☐	☐	☐
18	I had trouble planning out steps of a task	☐	☐	☐	☐	☐

Multidimensional Health Locus of Control

Each item below is a belief statement about your medical condition with which you may agree or disagree. For each item we would like you to circle the number that represents the extent to which you agree or disagree with that statement. Please make sure that you answer EVERY ITEM and that you circle ONLY ONE number per item. This is a measure of your personal beliefs; obviously, there are no right or wrong answers.

		Strongly disagree	Moderately disagree	Slightly disagree	Slightly agree	Moderately agree	Strongly agree
1	If my condition worsens, it is my own behaviour which determines how soon I will feel better again	☐	☐	☐	☐	☐	☐
2	As to my condition, what will be will be	☐	☐	☐	☐	☐	☐
3	If I see my doctor regularly, I am less likely to have problems with my condition	☐	☐	☐	☐	☐	☐
4	Most things that affect my condition happen to me by chance	☐	☐	☐	☐	☐	☐
5	Whenever my condition worsens, I should consult a medically trained professional	☐	☐	☐	☐	☐	☐
6	I am directly responsible for my condition getting better or worse	☐	☐	☐	☐	☐	☐
7	Other people play a big role in whether my condition improves, stays the same, or gets worse	☐	☐	☐	☐	☐	☐
8	Whatever goes wrong with my condition is my own fault	☐	☐	☐	☐	☐	☐
9	Luck plays a big part in determining how my condition improves	☐	☐	☐	☐	☐	☐
10	In order for my condition to improve, it is up to other people to see that the right things happen	☐	☐	☐	☐	☐	☐
11	Whatever improvement occurs with my condition is largely a matter of good fortune	☐	☐	☐	☐	☐	☐
12	The main thing which affects my condition is what I myself do	☐	☐	☐	☐	☐	☐
13	I deserve the credit when my condition improves and the blame when it gets worse	☐	☐	☐	☐	☐	☐
14	Following doctor's orders to the letter is the best way to keep my condition from getting any worse	☐	☐	☐	☐	☐	☐
15	If my condition worsens, it's a matter of fate	☐	☐	☐	☐	☐	☐
16	If I am lucky, my condition will get better	☐	☐	☐	☐	☐	☐
17	If my condition takes a turn for the worse, it is because I have not been taking proper care of myself	☐	☐	☐	☐	☐	☐
18	The type of help I receive from other people determines how soon my condition improves	☐	☐	☐	☐	☐	☐

Rosenberg Self-Esteem Scale

Below is a list of statements dealing with your general feelings about yourself. Circle one response for each of the following ten items:

		Strongly Agree	Agree	Disagree	Strongly Disagree
1	On the whole, I am satisfied with myself	☐	☐	☐	☐
2*	At times, I think I am no good at all	☐	☐	☐	☐
3	I feel that I have a number of good qualities	☐	☐	☐	☐
4	I am able to do things as well as most other people	☐	☐	☐	☐
5*	I feel I do not have much to be proud of	☐	☐	☐	☐
6*	I certainly feel useless at times	☐	☐	☐	☐
7	I feel that I'm a person of worth, at least on an equal plane with others	☐	☐	☐	☐
8*	I wish I could have more respect for myself	☐	☐	☐	☐
9*	All in all, I am inclined to feel that I am a failure	☐	☐	☐	☐
10	I take a positive attitude toward myself	☐	☐	☐	☐

Self-Efficacy for Symptom Management Scale

We would like to know how confident you are in doing certain activities. For each of the following questions, please circle the number that corresponds to your confidence that you can do the tasks regularly at the present time.

1. Get family and friends to help you with things you need to do around your home (such as household chores, shopping, paying bills, or transportation)?

1	2	3	4	5	6	7	8	9	10
Not at all confident									Totally confident

2. Get emotional support from friends and family (such as listening to you or talking over your concerns)?

1	2	3	4	5	6	7	8	9	10
Not at all confident									Totally confident

3. Get emotional support from people other than friends or family, if needed?

1	2	3	4	5	6	7	8	9	10
Not at all confident									Totally confident

4. Get help with your daily tasks (like housecleaning, yard work, shopping) from resources other than family or friends, if needed?

1	2	3	4	5	6	7	8	9	10
Not at all confident									Totally confident

5. Keep any physical symptoms caused by your injury (such as fatigue, dizziness, or difficulty walking) from interfering with the things that you want to do?

1	2	3	4	5	6	7	8	9	10
Not at all confident									Totally confident

6. Keep any problems with concentration caused by your injury from interfering with the things that you want to do?

1	2	3	4	5	6	7	8	9	10
Not at all confident									Totally confident

7. Keep any problems with memory caused by your injury from interfering with the things that you want to do?									
1	2	3	4	5	6	7	8	9	10
Not at all confident									Totally confident

8. Keep any problems with thinking caused by your injury from interfering with the things that you want to do?									
1	2	3	4	5	6	7	8	9	10
Not at all confident									Totally confident

9. Compensate for any cognitive difficulties caused by your injury so that they don't interfere with the things that you want to do?									
1	2	3	4	5	6	7	8	9	10
Not at all confident									Totally confident

10. Keep from feeling frustrated or overwhelmed by things that you are trying to do?									
1	2	3	4	5	6	7	8	9	10
Not at all confident									Totally confident

11. Keep from feeling sad or discouraged?									
1	2	3	4	5	6	7	8	9	10
Not at all confident									Totally confident

12. Keep from feeling lonely?									
1	2	3	4	5	6	7	8	9	10
Not at all confident									Totally confident

13. Do something to control your emotions or make yourself feel better?									
1	2	3	4	5	6	7	8	9	10
Not at all confident									Totally confident

Stigma

Please respond to each question or statement by marking one box per row.

		Never	Rarely	Sometimes	Often	Always
1	Because of my brain injury, some people avoided me	☐	☐	☐	☐	☐
2	Because of my brain injury, I felt left out of things	☐	☐	☐	☐	☐
3	Because of my brain injury, people avoided looking at me	☐	☐	☐	☐	☐
4	I felt embarrassed about my brain injury	☐	☐	☐	☐	☐
5	Because of my brain injury some people seemed uncomfortable with me	☐	☐	☐	☐	☐
6	I felt embarrassed because of my physical limitations	☐	☐	☐	☐	☐
7	Because of my brain injury, people were trying to me	☐	☐	☐	☐	☐
8	Some people acted as though it was my fault I have this brain injury	☐	☐	☐	☐	☐
9	Because of my brain injury, I felt embarrassed in social situations	☐	☐	☐	☐	☐
10	Because of my brain injury, I felt emotionally distant from other people	☐	☐	☐	☐	☐
11	Because of my brain injury, people tended to ignore my good points	☐	☐	☐	☐	☐
12	Because of my brain injury, I was treated unfairly by others	☐	☐	☐	☐	☐
13	Because of my brain injury, I felt different from others	☐	☐	☐	☐	☐
14	Because of my brain injury, I worried about other peoples attitudes towards me	☐	☐	☐	☐	☐
15	Because of my brain injury, I worried that I was a burden to others	☐	☐	☐	☐	☐
16	Because of my brain injury, people made fun of me	☐	☐	☐	☐	☐
17	I was unhappy about how my brain injury affected my appearance	☐	☐	☐	☐	☐
18	Because of my brain injury, strangers tended to stare at me	☐	☐	☐	☐	☐
19	I lost friends by telling them that I have this brain injury	☐	☐	☐	☐	☐
20	Because of my brain injury, it was hard for me to stay neat and clean	☐	☐	☐	☐	☐
21	I felt embarrassed about my speech	☐	☐	☐	☐	☐
22	I avoided making new friends to avoid telling others about my brain injury	☐	☐	☐	☐	☐
23	I tended to blame myself for my problems	☐	☐	☐	☐	☐
24	People with my brain injury lost their jobs when their employers found out about it	☐	☐	☐	☐	☐

Read each item and place a firm tick in the box opposite the reply that comes closest to how you have been feeling in the past week

Don't take too long over your replies; your immediate reaction to each item will probably be more accurate than a long thought-out response.

Tick only one box in each section

I feel tense or 'wound up':
- Most of the time
- A lot of the time
- Time to time, occasionally
- Not at all

I feel as if I am slowed down:
- Nearly all the time
- Very often
- Sometimes
- Not at all

I still enjoy the things I used to enjoy:
- Definitely as much
- Not quite so much
- Only a little
- Hardly at all

I get a sort of frightened feeling like butterflies' in the stomach:
- Not at all
- Occasionally
- Quite often
- Very often

I get a sort of frightened feeling as if something awful is about to happen:
- Very definitely and quite badly
- Yes, but not too badly
- A little, but it doesn't worry me
- Not at all

I have lost interest in my appearance:
- Definitely
- I don't take so much care as I should
- I may not take quite as much care
- I take just as much care as ever

I can laugh and see the funny side of things:
- As much as I always could
- Not quite so much now
- Definitely not so much now
- Not at all

I feel restless as if I have to be on the move:
- Very much indeed
- Quite a lot
- Not very much
- Not at all

Worrying thoughts go through my mind:
- A great deal of the time
- A lot of the time
- From time to time but not too often
- Only occasionally

I look forward with enjoyment to things:
- As much as I ever did
- Rather less than I used to
- Definitely less than I used to
- Hardly at all

I feel cheerful:
- Not at all
- Not often
- Sometimes
- Most of the time

I get sudden feelings of panic:
- Very often indeed
- Quite often
- Not very often
- Not at all

I can sit at ease and feel relaxed:
- Definitely
- Usually
- Not often
- Not at all

I can enjoy a good book or radio or TV programme:
- Often
- Sometimes
- Not often
- Very seldom

LANCASTER UNIVERSITY
DIVISION OF HEALTH RESEARCH
Doctorate In Clinical Psychology

Debrief Sheet

Thank you for taking part in this study. As part of my training to become a clinical psychologist I am researching what affects people with a traumatic brain injury's thoughts and behaviours when they are in a social situation. I am interested in understanding how different psychological factors (e.g. self-esteem, feelings of control, experience of stigma and level of memory and other 'thinking' problems) might contribute whether people who have a brain injury feel anxious or not in social situations. The questionnaires you have completed will be pooled with responses from many other people to allow us to develop our understanding of these processes.

Taking part in this study will not affect any of the care or support you receive. No personal details or identifiable information will go into the final report and all data will be stored securely and confidentially.

I plan to share the findings with other professionals by publishing the report in an academic journal, so that other people who work in this area can learn from it. If you are interested in receiving a brief summary of the findings or a copy of the full report, please let me know by contacting me on the below details. We are hoping that the full report will be finished by May 2015.

If you feel you have been affected by any of the issues raised in the study, your GP can provide details on support available through the NHS in your area. The following organisations also provide support to people who have experienced a traumatic brain injury:

Headway - https://www.headway.org.uk/
BASIC – http://www.basiccharity.org.uk/

This research is being conducted under the supervision of [redacted] at Lancaster University. Please direct any complaints to [redacted] ([redacted]@lancaster.ac.uk), [redacted], Lancaster University.

We are able to reimburse travel claims of up to £10 where appropriate. To claim, please contact Will Curvis on the details below and ask for an expenses form.

Thank you again for your time and participation.

Will Curvis
Trainee Clinical Psychologist, Lancaster University

e-Mail: w.curvis@lancaster.ac.uk
Tel: 07508 375640

[Name]
[Address]

LANCASTER UNIVERSITY
DIVISION OF HEALTH RESEARCH
Doctorate In Clinical Psychology

Dear XXXX,

I am a trainee clinical psychologist at Lancaster University. As you are under the care of [organisation name], I am writing to invite you to take part in a new research study looking at social anxiety and traumatic brain injury. This project aims to help us understand how people who have experienced a traumatic brain injury feel or behave in social situations.

The study will be recruiting participants until 31st January 2015. Any questionnaires received after this date will not be included in the study.

Taking part is easy. I have enclosed some questionnaires which ask about the kinds of problems we are researching. You can either fill in the questionnaires and post them back to me using the enclosed prepaid envelope, or you can complete the questionnaires online at http://tinyurl.com/o54eehs

I have enclosed with this letter a copy of the Participant Information Sheet which provides further details on the study. Please read this information carefully. If you decide you would like to take part, please sign the consent form attached to the questionnaires before completing them.

After you have completed the questionnaires, please be sure to read the Debrief Sheet. The questionnaire pack, complete with a signed consent form, can then be returned to me using the prepaid envelope provided (you do not need a stamp). If you choose to complete the questionnaires online, the website will ask for your consent to participate and you do not need to send anything through the post.

Please contact me on the below telephone number or e-mail address if you require another copy of the questionnaires or any help completing any of the measures. I am also happy to discuss any questions or concerns you may have around taking part in the study.

Thank you for your time and I look forward to hearing from you.

Yours sincerely,

Will Curvis
Trainee Clinical Psychologist
Lancaster University

e-Mail: w.curvis@lancaster.ac.uk
Tel: 07508 375640

Enclosed:
Participant Information Sheet
Questionnaire Pack
Debrief Sheet

LANCASTER UNIVERSITY

DIVISION OF HEALTH RESEARCH
Doctorate In Clinical Psychology

[Name]

[Address]

Dear XXXX,

I am a trainee clinical psychologist at Lancaster University. As you are under the care of [organisation name], I am writing to invite you to take part in a new research study looking at social anxiety and traumatic brain injury.

Hopefully you have received a letter from me around a month ago introducing the study and inviting you to participate. There is still time to join the study and help develop our understanding of how social anxiety develops following traumatic brain injuries. The study will be recruiting participants until 31st December 2014. Any questionnaires received after this date will not be included in the study.

Taking part is easy – you can either fill in the questionnaires you have received and post them back to me using the enclosed envelope, or you can complete the questionnaires online at http://tinyurl.com/o54eehs. I have enclosed with this letter a copy of the Participant Information Sheet which provides further details on the study.

Please contact me on the below telephone number or e-mail address if you require another copy of the questionnaires or any help completing any of the measures. I am also happy to discuss any questions or concerns you may have around taking part in the study.

If you have already completed the questionnaires, please disregard this letter.

Thank you for your time and I look forward to hearing from you.

Yours sincerely,

Will Curvis
Trainee Clinical Psychologist
Lancaster University

e-Mail: w.curvis@lancaster.ac.uk

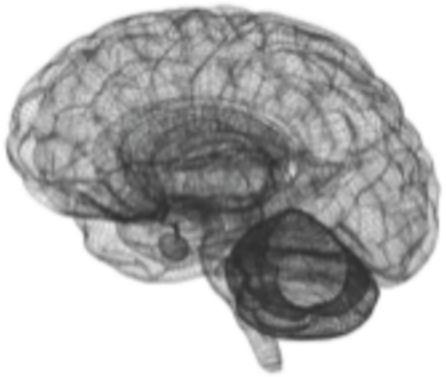
Tel: 07508 375640

Enclosed:
Participant Information Sheet

Have you experienced a traumatic brain injury?

(e.g. because of a road traffic accident, assault, trip/fall, work/sport injury etc.)

LANCASTER UNIVERSITY
DIVISION OF HEALTH RESEARCH
Doctorate In Clinical Psychology



Would you like to help with a research study?

We are looking for people who have experienced a brain injury to help us with a project. We are researching how people feel in social situations (e.g. being around people, giving speeches, going to a party)

Taking part is easy and involves completing a small number of questionnaires

You can access the questionnaires at http://tinyurl.com/o54eehs

If you prefer, contact me on the below details if you would like a paper copy to be sent through the post or if you would like to meet in person to complete the questionnaires

n injury & social
ty research study
nyurl.com/o54eehs
ntact Will Curvis
7508375640
s@lancaster.ac.uk

Appendices

Appendix 4-A: NHS Research Ethics Committee approval letter

Appendix 4-B: Approval letters for amendments

Appendix 4-C: Site-specific application and approval from individual NHS Trust (see note)

Appendix 4-D: Integrated Research Application System (IRAS) Research Ethics Committee application form

Appendix 4-E: Covering Letter

Appendix 4-F: Letter of Sponsorship

Note on Content

Due to the word limit for this section some materials have not been included. Approval was gained from the research and development departments of nine NHS Trusts. Rather than include all nine application forms and approval letters, a sample from one NHS Trust is provided in Appendix 4-C. Additionally, due to similarities to the form provided in Appendix 4-D, the R&D IRAS form was not included to avoid duplication. Further details are available on request. Some information has been redacted to maintain confidentiality.

Appendix 4-A: NHS Research Ethics Committee approval letter

Health Research Authority

National Research Ethics Service

NRES Committee London - Hampstead
Barlow House
3rd Floor
4 Minshull Street
Manchester
M1 3DZ

Telephone: 0161 625 7821
Fax:0161 625 7299

14 July 2014

Mr Will Curvis
Clinical Psychology
Furness Building, Lancaster University
Lancaster
LA1 4YG

Dear Mr Curvis

Study title:	**Social Anxiety Following Traumatic Brain Injury**
REC reference:	**14/LO/1281**
IRAS project ID:	**155803**

The Proportionate Review Sub-committee of the NRES Committee London - Hampstead reviewed the above application on 09 July 2014.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable 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 the REC Manager, Miss Shehnaz Ishaq, nrescommittee.london-hampstead@nhs.net

Ethical opinion

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

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

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Appendix 4-A: NHS Research Ethics Committee approval letter

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

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

Guidance on applying for NHS permission for research is available in the Integrated Research Application System 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 approvals 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 contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

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

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").

Summary of discussion at the meeting

Recruitment arrangements and access to health information, and fair research participant selection

It was noted that Question 7 on the project filter questions stated that this was not intrusive research in adults lacking capacity. Clarification was sought that this study was not going to involve adults lacking capacity to consent.

You confirmed that the study was not going to involve adults who lacked the capacity to consent. As detailed in the protocol, should doubts arise around capacity to consent, an assessment was to be conducted to allow the individual to demonstrate their ability to understand and make an

informed choice about participation. If they are deemed unable to consent they would not be involved in the study.

Favourable risk benefit ratio; anticipated benefits/risks for research participants (present and future)

The Committee noted that many individuals would be vulnerable after TBI. The Committee asked for clarification on what would happen about adult safeguarding policy/procedure for the researcher if disclosed by TBI patient.

You clarified that due to the vulnerable nature of many individuals who have experienced TBI, the researcher will remain vigilant to any signs of potential safeguarding issues. Should any concerns be raised, the researcher will liaise with the research supervisor and take appropriate steps in line with local safeguarding policy. This may involve liaising with the individual's GP or care co-ordinator as appropriate. Should urgent concerns be raised about a participant's immediate safety, the researcher will liaise with social services or the police as required.

A6-2 on the IRAS Form stated that during the research 'If necessary the researcher will discuss support the systems available'. The Committee asked whether these would be automatic.

You explained that all participants (whether they submit questionnaires in person, by post or online) will be automatically and routinely be provided with a debrief sheet which would highlight appropriate sources of support. The researcher would give this sheet to any participants who completed the questionnaires during a face-to-face meeting and discuss if required.

A27-1 referred to patients being left to complete the questionnaires themselves. The Committee asked whether participants would have benefited from completing the questionnaires with a member of the research team. The Committee agreed that this would also allow the participants to discuss the supports systems that were available to them.

You clarified that to achieve a balance between providing support to participants and protecting their privacy, participants will be given the choice as to how they would like to complete the questionnaires. The lead researcher's contact details would be provided on the information sheets, and it would be made clear that they could contact the researcher if they would like face-to-face support in completing the questionnaires. As many participants will not desire or require support, they would also be able to submit questionnaires anonymously via post, or complete them online.

Care and protection of research participants; respect for potential and enrolled research participants' welfare & dignity

A30 and A36 on the IRAS Form discussed options for filling items in online and also storage on university computers. The Committee asked for clarification on the level of security and that all information governance requirements were covered.

You commented that Qualtrics would be used for the online questionnaires. Qualtrics provide high levels of security around data collected (full technical details available at http://www.qualtrics.com/security-statement) and they offer the researcher control over the privacy of the questionnaires (I.e. So the survey will only be accessible via a link and will not be displayed in search engine results). The university servers are also appropriately secured and password protected. Further technical details of the university's policy on data security is available at https://gap.lancs.ac.uk/policy-info-guide/5-policies-procedures/Documents/New-Information-Security-Policy-November-2012.pdf. Data would be stored in line with relevant legislation (e.g. Data Protection Act, 1998) and information governance policy.

The Committee noted that A50 on the IRAS form stated that the study was not going to be registered on a public database. The Committee requested justification on this point.

Appendix 4-A: NHS Research Ethics Committee approval letter

You clarified, with input from your supervisor that it was not standard for thesis projects to be registered as this tends to be only for publicly funded research. The project would be available on the university systems which are open to the public.

A76-3 had both options ticked for indemnity (NHS and Non NHS). Clarification was sought on this point.

You explained that the first box on A76-3 was ticked in error; the study was going to involve both NHS and non-NHS sites.

Informed consent process and the adequacy and completeness of research participant information

The Committee asked for justification as to why the GP was not going to be informed.

You clarified that should any concerns around a participant's safety or wellbeing be identified, the GP may be involved as part of a management plan (as detailed in the risk assessment sections). However GP's would not routinely be informed as identifiable information about participants (i.e. names) were not going to be collected. Additionally, you commented that this was a cross-sectional questionnaire based study and involved no active intervention, meaning that routinely making contact with GP's simply to inform them about participation would be unnecessary.

The Committee noted that the Information Sheet stated that patients should have had the injury after 18 but the application form (A17-1) and protocol stated after 16. The Committee requested clarification on this point.

You explained that this was an error on the protocol and application form; participants would need to be currently aged 18+, but the TBI needed to have happened when they were 16 or older. You amended the documentation accordingly and provided this.

The Committee noted that the Consent Form should request signatures from those those who are involved in the consent process, e.g. the participant, the researcher. The standard template on the HRA website should be followed, following link was provided http://www.hra-decisiontools.org.uk/consent/content-form.html which detailed guidance on what a standard consent form should look like.

You updated consent form accordingly ncluding the standard paragraph detailing access to data by regulatory authorities etc.

Suitability of supporting information

The Committee asked whether the SPIN questionnaire was validated

You explained that the SPIN has been shown to demonstrate acceptable levels of test-retest reliability, internal consistency, convergent validity and divergent reliability in a variety of published papers. No study to date has used it in a TBI population as this is a novel area of research. However it has been deemed by the researcher to have acceptable face validity for use in the study.

Approved documents

The documents reviewed and approved were:

Appendix 4-A: NHS Research Ethics Committee approval letter

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Poster]	1	01 June 2014
Covering letter on headed paper [Covering letter]	1	04 June 2014
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance Confirmation]	1	15 July 2013
IRAS Checklist XML [Checklist_07072014]		07 July 2014
Letter from sponsor [Letter from Sponsor]	1	01 July 2014
Letters of invitation to participant [Introductory Letter]	1	04 June 2014
Letters of invitation to participant [Follow-up Letter]	1	04 June 2014
Other [Email containing response to PR SC queries]		11 July 2014
Participant consent form [Appendix B Screening and Consent Form]	3	10 July 2014
Participant information sheet (PIS) [Appendix A]	2	11 June 2014
REC Application Form [REC_Form_07072014]		07 July 2014
Research protocol or project proposal	3	11 July 2014
Summary CV for Chief Investigator (CI) [Chief Investigator CV]	1	01 June 2014
Summary CV for supervisor (student research) [Supervisor CV]	1	02 July 2014
Summary CV for supervisor (student research) [Dr Weatherhead CV]		
Validated questionnaire [Questionnaire Pack]	1	01 June 2014

Membership of the Proportionate Review Sub-Committee

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

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.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service 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/

Appendix 4-A: NHS Research Ethics Committee approval letter

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

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

14/LO/1281	**Please quote this number on all correspondence**

Yours sincerely

Signed on behalf of
Miss Stephanie Ellis
Chair

Email: nrescommittee.london-hampstead@nhs.net

Enclosures: List of names and professions of members who took part in the review

"After ethical review – guidance for researchers"

Copy to: Ms Debbie Knight

[redacted]

Appendix 4-A: NHS Research Ethics Committee approval letter

NRES Committee London - Hampstead

Attendance at PRS Sub-Committee of the REC meeting on 09 July 2014

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Rahul Chodhari	Consultant Paediatrician	Yes	
Miss Stephanie Ellis (Chairing)	Former Civil Servant	Yes	
Mrs Wendy Spicer	Pharmacist	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Shehnaz Ishaq	Deputy Regional Manager – HRA Centre Manchester

Appendix 4-B: Approval letters for amendments

NHS
Health Research Authority
National Research Ethics Service
NRES Committee London – Hampstead
3rd Floor
Barlow House
4 Minshull Street
Manchester
M1 3DZ

Telephone: 0161 625 7434

23 July 2014

Mr Will Curvis
Clinical Psychology
Furness Building, Lancaster University
Lancaster
LA1 4YG

Dear Mr Curvis

Study title:	**Social Anxiety Following Traumatic Brain Injury**
REC reference:	**14/LO/1281**
Amendment number:	**One**
Amendment date:	**15 July 2014**
IRAS project ID:	**155803**

- Incorporate the Debrief Sheet into the original application documents, to provide to all participants at the end of the study.

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Notice of Substantial Amendment (non-CTIMP)	One	15 July 2014
Other [Debrief Sheet]		04 June 2014

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Appendix 4-B: Approval letters for amendments

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.

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

14/LO/1281:	**Please quote this number on all correspondence**

Yours sincerely

Miss Stephanie Ellis
Chair

E-mail: nrescommittee.london-hampstead@nhs.net

Enclosures: *List of names and professions of members who took part in the review*

Copy to: [redacted]

Appendix 4-B: Approval letters for amendments

NRES Committee London - Hampstead

Attendance at Sub-Committee of the REC meeting on 22 July 2014

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Rahul Chodhari	Consultant Paediatrician	Yes	
Miss Stephanie Ellis	Former Civil Servant	Yes	

Appendix 4-B: Approval letters for amendments

NHS
Health Research Authority

National Research Ethics Service

NRES Committee London - Hampstead
Barlow House
3rd Floor
4 Minshull Street
Manchester
M1 3DZ

Tel: 0161 625 7815
Fax: 0161 625 7299

21 August 2014

Mr Will Curvis
Clinical Psychology
Furness Building
Lancaster University
Lancaster
LA1 4YG

Dear Mr Curvis

Study title:	**Social Anxiety Following Traumatic Brain Injury**
REC reference:	**14/LO/1281**
Amendment number:	**Substantial Amendment 2**
Amendment date:	**24 July 2014**
IRAS project ID:	**155803**

- The amendment proposes to collect additional demographic data.

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

There were no ethical issues.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Notice of Substantial Amendment (non-CTIMP)	Substantial Amendment 2	24 July 2014
Participant consent form [Appendix B - Screening and Consent Form]	4	27 July 2014

Appendix 4-B: Approval letters for amendments

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

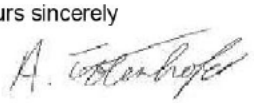
Statement of compliance

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.

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

14/LO/1281:	**Please quote this number on all correspondence**

Yours sincerely



Signed on behalf of:
Miss Stephanie Ellis
Chair

E-mail: nrescommittee.london-hampstead@nhs.net

Enclosures: *List of names and professions of members who took part in the review*

Copy to: [redacted]

Ms Debbie Knight – Lancaster University

Dr Stephen Weatherhead – Lancaster University

Dr Jane Simpson – Lancaster University

Appendix 4-B: Approval letters for amendments

NRES Committee London - Hampstead

Attendance at Sub-Committee of the REC meeting on 21 August 2014

Committee Members:

Name	*Profession*	*Present*	*Notes*
Miss Stephanie Ellis (Chair)	Former Civil Servant	Yes	Chaired the meeting
Dr Jane Lees-Millais	General Practitioner	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Dr Ashley Totenhofer	REC Manager

Appendix 4-B: Approval letters for amendments

Health Research Authority

National Research Ethics Service
NRES Committee London - Hampstead
Barlow House
3rd Floor
4 Minshull Street
Manchester
M1 3DZ

Tel: 0161 625 7819

07 October 2014

Mr Will Curvis
Clinical Psychology
Furness Building
Lancaster University
Lancaster
LA1 4YG

Dear Mr Curvis

Study title:	**Social Anxiety Following Traumatic Brain Injury**
REC reference:	**14/LO/1281**
Amendment number:	**Minor Amendment 1**
Amendment date:	**08 September 2014**
IRAS project ID:	**155803**

- The amendment consists of a change to a typographical error regarding recruitment end date.

Thank you for your letter of 08 September 2014, notifying the Committee of the above amendment.

The Committee does not consider this to be a "substantial amendment" as defined in the Standard Operating Procedures for Research Ethics Committees. The amendment does not therefore require an ethical opinion from the Committee and may be implemented immediately, provided that it does not affect the approval for the research given by the R&D office for the relevant NHS care organisation.

Documents received

The documents received were as follows:

Document	*Version*	*Date*
Letters of invitation to participant [Appendix E]	2	08 September 2014
Notice of Minor Amendment [E-mail]	Minor Amendment 1	08 September 2014

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research

Appendix 4-B: Approval letters for amendments

Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

14/LO/1281:	Please quote this number on all correspondence

Yours sincerely

Regina Caden.

Miss Regina Caden
REC Assistant

E-mail: nrescommittee.london-hampstead@nhs.net

Copy to: [redacted]

Ms Debbie Knight, Lancaster University

Dr Stephen Weatherhead, Lancaster University

Dr Jane Simpson, Lancaster University

Appendix 4-B: Approval letters for amendments

NHS
Health Research Authority

National Research Ethics Service

NRES Committee London - Hampstead
Barlow House
3rd Floor
4 Minshull Street
Manchester
M1 3DZ

Tel: 0161 625 7815
Fax: 0161 625 7299

21 January 2015

Mr Will Curvis
Clinical Psychology
Furness Building
Lancaster University
Lancaster
LA1 4YG

Dear Mr Curvis

Study title:	**Social Anxiety Following Traumatic Brain Injury**
REC reference:	**14/LO/1281**
Amendment number:	**Minor Amendment 2**
Amendment date:	**22 December 2014**
IRAS project ID:	**155803**

- The amendment proposes to extend the recruitment period until 16th February 2015.

Thank you for your email of 22 December 2014, notifying the Committee of the above amendment.

The Committee does not consider this to be a "substantial amendment" as defined in the Standard Operating Procedures for Research Ethics Committees. The amendment does not therefore require an ethical opinion from the Committee and may be implemented immediately, provided that it does not affect the approval for the research given by the R&D office for the relevant NHS care organisation.

Documents received

The documents received were as follows:

Document	*Version*	*Date*
Notice of Minor Amendment	Minor Amendment 2	22 December 2014

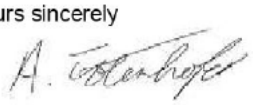
Statement of compliance

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.

Appendix 4-B: Approval letters for amendments

14/LO/1281:	Please quote this number on all correspondence

Yours sincerely



Dr Ashley Totenhofer
REC Manager

E-mail: nrescommittee.london-hampstead@nhs.net

Copy to: [redacted]

Ms Debbie Knight – Lancaster University

Appendix 4-C: Site-specific application and approval from individual NHS Trust

NHS SSI IRAS Version 3.5

Welcome to the Integrated Research Application System

IRAS Project Filter

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

Please enter a short title for this project (maximum 70 characters)
Social Anxiety Following Traumatic Brain Injury

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

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

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

( ) Other study

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

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

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

[x] England
[ ] Scotland
[ ] Wales
[ ] Northern Ireland

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

Appendix 4-C: Site-specific application and approval from individual NHS Trust

- (●) England
- ( ) Scotland
- ( ) Wales
- ( ) Northern Ireland
- ( ) This study does not involve the NHS

4. Which review bodies are you applying to?

- [x] NHS/HSC Research and Development offices
- [ ] Social Care Research Ethics Committee
- [x] Research Ethics Committee
- [ ] National Information Governance Board for Health and Social Care (NIGB)
- [ ] National Offender Management Service (NOMS) (Prisons & Probation)

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

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

(●) Yes ( ) No

5a. Are all the research costs and infrastructure costs for this study provided by an NIHR Biomedical Research Centre, NIHR Biomedical Research Unit, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC) or NIHR Research Centre for Patient Safety & Service Quality in all study sites?

( ) Yes (●) No

If yes, NHS permission for your study will be processed through the NIHR Coordinated System for gaining NHS Permission (NIHR CSP).

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) support and inclusion in the NIHR Clinical Research Network (CRN) Portfolio? Please see information button for further details.

( ) Yes (●) No

If yes, NHS permission for your study will be processed through the NIHR Coordinated System for gaining NHS Permission (NIHR CSP) and you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form immediately after completing this project filter and before completing and submitting other applications.

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

( ) Yes (●) No

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

( ) Yes (●) No

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

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

○ Yes ◉ No

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

◉ Yes ○ No

Please describe briefly the involvement of the student(s):
The research will form part of a thesis project within a Doctorate in Clinical Psychology programme. The student will be the Chief Investigator.

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

◉ Yes ○ No

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

○ Yes ◉ No

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

○ Yes ◉ No

Appendix 4-C: Site-specific application and approval from individual NHS Trust

Site-Specific Information Form (NHS sites)

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

- (●) NHS site
- ( ) Non-NHS site

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

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

The data in this box is populated from Part A:

Title of research:
Social Anxiety Following Traumatic Brain Injury

Short title: Social Anxiety Following Traumatic Brain Injury

Chief Investigator:	Title	Forename/Initials	Surname
	Mr	Will	Curvis

Name of NHS Research Ethics Committee to which application for ethical review is being made:
London Hampstead

Project reference number from above REC: 14/LO/1281

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

[redacted]

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

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

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

( ) Yes (●) No

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

Appendix 4-C: Site-specific application and approval from individual NHS Trust

Select the appropriate title: ○ Principal Investigator ◉ Local Collaborator

	Title Forename/Initials Surname
	Dr [redacted]
Post	Clinical Psychologist
Qualifications	
Organisation	[redacted]
Work Address	
PostCode	
Work E-mail	
Work Telephone	
Mobile	
Fax	

a) Approximately how much time will this person allocate to conducting this research? *Please provide your response in terms of Whole Time Equivalents (WTE).*
Minimal time required - less than 0.1WTE

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

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

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

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

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

	Location	Activity/facilities
1	[redacted]	Recruitment / data collection

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

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

○ Yes ◉ No

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

Start date: 01/09/2014
End date: 01/09/2015

Duration (Months): 12

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

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

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

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

Intervention or procedure	1	2	3	4	5
Complete questionnaire pack	1	n/a	30 minutes	Participants will complete questionnaires themselves, with support from lead researcher available if required.	[redacted]

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

○ Yes ◉ No

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

Are there any changes other than those noted in the table?

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

20

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

As outlined in protocol.

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

Name	Expertise/training
Will Curvis	Through programme of study included in doctorate in clinical psychology.

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

Participants can contact the lead researcher directly using the details provided on the information packs.

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

Participants can contact the lead researcher directly using the details provided on the information packs.

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

No changes.

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

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

Not applicable for this study.

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

Not applicable for this study.

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

As described in protocol.

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

As described in protocol.

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

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

How will the costs of the research be covered?
Lancaster University

23. Authorisations required prior to R&D approval

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

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

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

Appendix 4-C: Site-specific application and approval from individual NHS Trust

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

Declaration:

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

Please give the name and contact details for the NHS R&D office staff member you have discussed this application with:

Please note that for some sites the NHS R&D office contact may not be physically based at the site. For contact details refer to the guidance for this question.

Title Forename/Initials Surname

Work E-mail [redacted]

Work Telephone

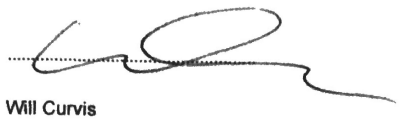
Declaration by Principal Investigator or Local Collaborator

1. The information in this form is accurate to the best of my knowledge and I take full responsibility for it.
2. I undertake to abide by the ethical principles underpinning the World Medical Association's Declaration of Helsinki and relevant good practice guidelines in the conduct of research.
3. If the research is approved by the main REC and NHS organisation, I undertake to adhere to the study protocol, the terms of the application of which the main REC has given a favourable opinion and the conditions requested by the NHS organisation, and to inform the NHS organisation within local timelines of any subsequent amendments to the protocol.
4. If the research is approved, I undertake to abide by the principles of the Research Governance Framework for Health and Social Care.
5. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to the conduct of research.
6. I undertake to disclose any conflicts of interest that may arise during the course of this research, and take responsibility for ensuring that all staff involved in the research are aware of their responsibilities to disclose conflicts of interest.
7. I understand and agree that study files, documents, research records and data may be subject to inspection by the NHS organisation, the sponsor or an independent body for monitoring, audit and inspection purposes.
8. I take responsibility for ensuring that staff involved in the research at this site hold appropriate contracts for the duration of the research, are familiar with the Research Governance Framework, the NHS organisation's Data Protection Policy and all other relevant policies and guidelines, and are appropriately trained and experienced.
9. I undertake to complete any progress and/or final reports as requested by the NHS organisation and understand that continuation of permission to conduct research within the NHS organisation is dependent on satisfactory completion of such reports.
10. I undertake to maintain a project file for this research in accordance with the NHS organisation's policy.
11. I take responsibility for ensuring that all serious adverse events are handled within the NHS organisation's policy for reporting and handling of adverse events.
12. I understand that information relating to this research, including the contact details on this application, will be held

Appendix 4-C: Site-specific application and approval from individual NHS Trust

by the R&D office and may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 1998.

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

Signature of Principal Investigator or Local Collaborator: 

Print Name: Will Curvis

Date: 03/09/2014

Appendix 4-C: Site-specific application and approval from individual NHS Trust

[redacted] NHS
NHS Foundation Trust

[redacted]

Tel. 01772 52(8268)
Fax. 01772 52(3184)

[redacted]

Our Ref: GW/HAA 27 August 2014

Mr Will Curvis
Clinical Psychology
Furness Building, Lancaster University
Lancaster
LA1 4YG

Dear Will

R&I Ref 1906

Study title:	Social Anxiety Following Traumatic Brain Injury
REC reference:	14/LO/1281
Amendment number:	Two
Amendment date:	**24 July 2014**
IRAS project ID:	155803

Thank you for sending the documentation for the above amendment.

The amendment has been reviewed by the Research Directorate at [redacted] NHS Trust and I am pleased to inform you that the study can continue.

Documents received and reviewed:

Document	Version	Date
Notification of Amendment	Substantial Amendment 2	24 July 2014
Participant consent form [Appendix B - Screening and Consent Form]	4	27 July 2014
NRES acknowledgement letter		21 August 2014

The Trust is happy to endorse the amendment and for the study to continue with these changes. Please notify any other department who may be affected by the amendment.

Yours sincerely

[redacted]
Head of Research and Innovation

Cc

[redacted]

Appendix 4-D: Integrated Research Application System (IRAS) Research Ethics Committee application form

NHS REC Form | Reference: 14/LO/1281 | IRAS Version 3.5

Welcome to the Integrated Research Application System

IRAS Project Filter

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

Please enter a short title for this project (maximum 70 characters)
Social Anxiety Following Traumatic Brain Injury

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

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

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

( ) Other study

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

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

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

[x] England
[ ] Scotland
[ ] Wales
[ ] Northern Ireland

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

- (●) England
- ( ) Scotland
- ( ) Wales
- ( ) Northern Ireland
- ( ) This study does not involve the NHS

4. Which review bodies are you applying to?

- [x] NHS/HSC Research and Development offices
- [ ] Social Care Research Ethics Committee
- [x] Research Ethics Committee
- [ ] National Information Governance Board for Health and Social Care (NIGB)
- [ ] National Offender Management Service (NOMS) (Prisons & Probation)

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

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

(●) Yes ( ) No

5a. Are all the research costs and infrastructure costs for this study provided by an NIHR Biomedical Research Centre, NIHR Biomedical Research Unit, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC) or NIHR Research Centre for Patient Safety & Service Quality in all study sites?

( ) Yes (●) No

If yes, NHS permission for your study will be processed through the NIHR Coordinated System for gaining NHS Permission (NIHR CSP).

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) support and inclusion in the NIHR Clinical Research Network (CRN) Portfolio? Please see information button for further details.

( ) Yes (●) No

If yes, NHS permission for your study will be processed through the NIHR Coordinated System for gaining NHS Permission (NIHR CSP) and you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form immediately after completing this project filter and before completing and submitting other applications.

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

( ) Yes (●) No

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

( ) Yes (●) No

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

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

○ Yes ◉ No

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

◉ Yes ○ No

Please describe briefly the involvement of the student(s):
The research will form part of a thesis project within a Doctorate in Clinical Psychology programme. The student will be the Chief Investigator.

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

◉ Yes ○ No

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

○ Yes ◉ No

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

○ Yes ◉ No

Appendix 4-D: Integrated Research Application System (IRAS) Research Ethics Committee application form

Integrated Research Application System
Application Form for Research administering questionnaires/interviews for quantitative analysis or mixed methodology study

NHS Health Research Authority

Application to NHS/HSC Research Ethics Committee

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting Help.

Please define any terms or acronyms that might not be familar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
Social Anxiety Following Traumatic Brain Injury

Please complete these details after you have booked the REC application for review.

REC Name:
London Hampstead

REC Reference Number:
14/LO/1281

Submission date:
02/07/2014

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

Social Anxiety Following Traumatic Brain Injury

A2-1. Educational projects

Name and contact details of student(s):

Student 1

Title	Forename/Initials	Surname
Mr	Will	Curvis

Address: Clinical Psychology
Furness Building, Lancaster University
Lancaster
Post Code: LA1 4YG
E-mail: w.curvis@lancaster.ac.uk
Telephone:
Fax:

Give details of the educational course or degree for which this research is being undertaken:

Name and level of course/ degree:
Doctorate in Clinical Psychology

Name of educational establishment:
Lancaster University

Name and contact details of academic supervisor(s):

Academic supervisor 1

	Title	Forename/Initials	Surname
	Dr	Stephen	Weatherhead
Address	Furness Building		
	Lancaster University		
	Lancaster		
Post Code	LA1 4YG		
E-mail	s.weatherhead@lancaster.ac.uk		
Telephone	01524592974		
Fax			

Academic supervisor 2

	Title	Forename/Initials	Surname
	Dr	Jane	Simpson
Address	Furness Building		
	Lancaster University		
	Lancaster		
Post Code	LA1 4YG		
E-mail	j.simpson2@lancaster.ac.uk		
Telephone			
Fax			

Please state which academic supervisor(s) has responsibility for which student(s):
Please click "Save now" before completing this table. This will ensure that all of the student and academic supervisor details are shown correctly.

Student(s)	Academic supervisor(s)
Student 1 Mr Will Curvis	☑ Dr Stephen Weatherhead ☐ Dr Jane Simpson

A copy of a current CV for the student and the academic supervisor (maximum 2 pages of A4) must be submitted with the application.

A2-2. Who will act as Chief Investigator for this study?

- ◉ Student
- ○ Academic supervisor
- ○ Other

Appendix 4-D: Integrated Research Application System (IRAS) Research Ethics Committee application form

A3-1. Chief Investigator:

	Title	Forename/Initials	Surname
	Mr	Will	Curvis
Post	Trainee Clinical Psychologist		
Qualifications			
Employer	Lancaster University		
Work Address	Clinical Psychology		
	Furness Building, Lancaster University		
	Lancaster		
Post Code			
Work E-mail	w.curvis@lancaster.ac.uk		
* Personal E-mail	w.curvis@lancaster.ac.uk		
Work Telephone			
* Personal Telephone/Mobile			
Fax			

** This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.*
A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?
This contact will receive copies of all correspondence from REC and R&D reviewers that is sent to the CI.

	Title	Forename/Initials	Surname
	Ms	Debbie	Knight
Address	Research Support Office		
	B58 Bowland Main		
	Lancaster University		
Post Code	LA1 4YT		
E-mail	ethics@lancaster.ac.uk		
Telephone	01524592605		
Fax			

A5-1. Research reference numbers. *Please give any relevant references for your study:*

Applicant's/organisation's own reference number, e.g. R & D (if available):
Sponsor's/protocol number:
Protocol Version:
Protocol Date:
Funder's reference number:
Project website:

Additional reference number(s):

Ref.Number Description	Reference Number

Registration of research studies is encouraged wherever possible. You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you have registered your study please give details in the "Additional reference number(s)" section.

Appendix 4-D: Integrated Research Application System (IRAS) Research Ethics Committee application form

A5-2. Is this application linked to a previous study or another current application?

○ Yes ◉ No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

A6-1. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, this summary will be published on the website of the National Research Ethics Service following the ethical review.*

The present study aims to investigate the psychological factors influencing the development of social anxiety following traumatic brain injury.

The study will employ a quantitative methodology, using a cross-sectional within-subjects design to explore which psychological factors may predict higher levels of social anxiety following traumatic brain injury. Questionnaires will be used as the data collection method.

Participants will be recruited from NHS sites and via third sector organisations. The project will also be advertised via social networking websites.

A6-2. Summary of main issues. *Please summarise the main ethical, legal, or management issues arising from your study and say how you have addressed them.*

Not all studies raise significant issues. Some studies may have straightforward ethical or other issues that can be identified and managed routinely. Others may present significant issues requiring further consideration by a REC, R&D office or other review body (as appropriate to the issue). Studies that present a minimal risk to participants may raise complex organisational or legal issues. You should try to consider all the types of issues that the different reviewers may need to consider.

It is not expected that completing the questionnaires will cause participants undue distress. However, participants will be informed that they can withdraw at any time whilst completing the questionnaires. Should a participant become upset they will be offered a break or the option to stop altogether. All participants will be provided with a debrief sheet after completing the questionnaires, which will contain details of appropriate sources of support (e.g. friends, family, GP, care coordinator, local third sector organisations, national helplines).
If necessary, the researcher will discuss these options with participants. The researcher will facilitate a similar conversation should a participant ask for clinical advice or support.

The researcher will not provide feedback on questionnaire scores. The debrief sheet provided to all participants after the questionnaires are completed will provide an overview of what will happen with the findings and detail what support they can access if they are affected by any of the issues discussed. A paper copy of this will be given to participants who complete the measures face to face. A paper copy will be included with the questionnaire packs sent to participants. The information will be provided on-screen after completion of the questionnaires for individuals who complete the questionnaires online. Participants will be informed that they are able to contact the lead researcher through the contact details on the Participant Information Sheet should they have further questions.

To maximise security, paper versions of consent forms will be scanned and shredded, but stored separately to questionnaires to ensure that names cannot be linked to questionnaire responses. The online questionnaires will utilise tick boxes to establish consent and will not collect names. Non-identifiable demographic information will be collected and analysed as part of study (e.g. age, gender, details of injury type). All participants will be informed that identifiable information will not be included in the report and all information will be stored securely as described above. Participants will be informed that they are able to stop at any time, however once questionnaires are submitted it will not be possible to remove their data from the analysis as responses will not be identifiable.

Appendix 4-D: Integrated Research Application System (IRAS) Research Ethics Committee application form

The limits of confidentiality will be made clear on the information sheets. The materials will state that if issues around risk to self or others are identified, it may be necessary for the researcher to share information. In the event that risk concerns are identified by the researcher, a management plan will be agreed with the participant which may involve informing their GP or care co-ordinator. The research supervisor will be informed immediately to support the management of any risk issues.

Appropriate privacy settings will be employed on the internet sites used to recruit to ensure that potential participants do not have access to personal information about the researcher. Any potential participants who attempt to make contact through social networking sites will be responded to by asking them to contact the researcher via the e-mail or telephone contact details listed on the recruitment materials.

Questionnaires provided by the researcher will be given at NHS premises where possible. If an interview is conducted at a participant's home the researcher will adhere to the lone worker guidance in the University's Guidance on Safety in Fieldwork (which is accessible from http://www.lancaster.ac.uk/depts/safety/files/Fieldwork.pdf).

. This will involve identifying potential hazards through dynamic risk assessment, withdrawing immediately if necessary, carrying a mobile phone provided by the University, making a colleague aware of the meeting and staying in contact before and after, and leaving the situation should any risk issues be identified. The researcher will utilise regular supervision to manage the practical and emotional demands of the project.

A6-3. Proportionate review of REC application *The initial project filter has identified that your study may be suitable for proportionate review by a REC sub-committee. Please consult the current guidance notes from NRES and indicate whether you wish to apply through the proportionate review service or, taking into account your answer to A6-2, you consider there are ethical issues that require consideration at a full REC meeting.*

(●) Yes - proportionate review ( ) No - review by full REC meeting

Further comments (optional):

Note: This question only applies to the REC application.

3. PURPOSE AND DESIGN OF THE RESEARCH

A7. Select the appropriate methodology description for this research. *Please tick all that apply*:

- [ ] Case series/ case note review
- [ ] Case control
- [ ] Cohort observation
- [ ] Controlled trial without randomisation
- [x] Cross-sectional study
- [ ] Database analysis
- [ ] Epidemiology
- [ ] Feasibility/ pilot study
- [ ] Laboratory study
- [ ] Metanalysis
- [ ] Qualitative research
- [x] Questionnaire, interview or observation study
- [ ] Randomised controlled trial
- [ ] Other (please specify)

A10. What is the principal research question/objective? *Please put this in language comprehensible to a lay person.*

This study will aim to investigate the relationship between traumatic brain injury and social anxiety. This will guide an examination of the psychological and neuropsychological factors which might contribute to the relationship between TBI and social anxiety. In understanding the impact of these factors, it is hypothesised that psychological variables will

account for an additional and significant amount of variance in social anxiety, above that explained by demographic and clinical variables.

A11. What are the secondary research questions/objectives if applicable? *Please put this in language comprehensible to a lay person.*

n/a

A12. What is the scientific justification for the research? *Please put this in language comprehensible to a lay person.*

In addition to the physical consequences of traumatic brain injury (TBI), psychological difficulties must be considered in the treatment and rehabilitation process. TBI has been found to place individuals at greater risk of developing psychological problems such as depression and anxiety (Bryant et al., 2010; Moore, Terryberry-Spohr, & Hope, 2006) due to the complex interactions between neurological, psychological and emotional consequences of such injuries.

Dramatic changes to social functioning are common after TBI, with declines in leisure activity, social support, social contact, independence, functional status and employment opportunities often reported (Antonak, Livneh, & Antonak, 1993; Moore et al., 2006; Temkin, Corrigan, Dikmen, & Machamer, 2009; Morton and Wehman, 1995). These emotional and psychosocial difficulties create a significant challenge for professionals working to support community reintegration and neuropsychological rehabilitation (Morton & Wehman, 1995). In addition to functional difficulties, anxiety around social interactions may account for some of this variation in functioning following TBI (Hiott & Labbate, 2002; Moore et al., 2006).

A recent review into anxiety following TBI (Moore et al., 2006) highlighted how social anxiety is potentially a significant problem in this population. Social anxiety is common in the general population, with lifetime prevalence rates estimated to be 12% (National Institute for Health and Care Excellence [NICE], 2013). Common triggers include public speaking, meeting new people, dating, social events and eating in public (American Psychiatric Association, 2000). While impairments to psychosocial functioning following TBI have been well documented (Morton and Wehman, 1995), no research to date has specifically examined social anxiety in this population.

Neurological factors may play a significant role in the development of social anxiety following TBI. In a review of the literature around anxiety after TBI, Moore et al (2006) highlights the potential role of damage to areas of the brain. Diffuse neurological damage often resulting from head injuries is discussed, for example from acceleration–deceleration forces and subsequent contusions or abrasions caused by contact with the skull. Focal and diffuse damage may affect brain regions associated with the inhibition of anxiety, subsequently becoming over-sensitive to stimuli. Conversely, traditionally frontal lobe injuries commonly affect executive and emotional processing, which may lead to disinhibition or a lack of insight – and perhaps a reduction in social anxiety. Data indicating prevalence rates which are lower than what might be expected may have important implications for understanding of neurological functioning following TBI. Research which unpicks the relationship between TBI and social anxiety is required.

Additionally, there is a need for research into the psychological factors which affect the development of social anxiety following TBI. A wide variety of disturbances following TBI are commonly observed, with neurological variables (e.g. severity of injury) failing to fully explain variations in anxiety and impaired psychosocial functioning (Antonak et al., 1993; Moore et al., 2006). Cognitive theories of social phobia emphasize the role of appraisals in the development and maintenance of social anxiety (Clark & Wells, 1995). Maladaptive beliefs and thought processes around the appraisals of the self and others are often central to the experience of social anxiety, as is the individual's perception of whether the situation is controllable. These processes may be adversely affected by the neurological and psychological impacts of a TBI in a way which is unique compared to other physical injuries. Patterns of behavioural avoidance may develop, which are maintained over time as the problems with social anxiety worsen.

Following TBI, people may feel embarrassed or self-conscious in social situations given the physical (e.g. disability, tremors, scarring, motor/speech problems, weight gain), psychological (e.g. apathy, low motivation, low self-esteem) and cognitive (e.g. word finding, attention, memory, slowness of thought) impacts of brain injuries (Hiott & Labbate, 2002; Moore et al., 2006; Wright & Telford, 1996). Qualitative research conducted by Morris et al. (2005) and Nochi (1998) highlights how participants experience 'unseen' consequences of TBI which impact on social outcomes. Participants emphasised the sense of loss and change in identity they experienced, in addition to the stigma and lack of understanding they faced regarding their difficulties. Understanding the impact of psychological variables relating to social anxiety following TBI will help guide professionals working within this population to provide interventions based on factors which are amenable to change.

A13. Please summarise your design and methodology. *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

The study will use a cross-sectional design, with participants completing one set of questionnaires at one time point. Participants will be recruited via NHS sites, third sector organisations or through social networking websites. Participants will be able to complete the questionnaire pack online or on paper. The lead researcher will be available to support the completion of questionnaires should this be requested, either at a participant's home or at an NHS/third sector organisation site. Potential participants may be contacted by post and send copies of the questionnaire pack. It is expected that most participants will be able to complete the questionnaires in less than 30 minutes.

Following data collection, the researcher will use multiple regression analyses to build a statistical model which is able to answer the research question.

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

- [x] Design of the research
- [ ] Management of the research
- [x] Undertaking the research
- [ ] Analysis of results
- [x] Dissemination of findings
- [ ] None of the above

Give details of involvement, or if none please justify the absence of involvement.
Design - The Lancaster University Public Involvement Network (LUPIN) will be consulted on the design and content of all materials sent to participants.

Undertaking - Patients / users of services are the target population for this study.

Dissemination of findings - The findings of the study will be presented to LUPIN members and any interested third sector organisations, in addition to any participants who wish to recieve information on the study or a copy of the report.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

Individual has experienced traumatic brain injury
Ability to read English (due to lack of available funding for translation)
Brain injury sustained after age of 16

A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).

Lacking capacity to give consent or participate in the study
Under 18 years old
Currently residing on a medical ward or rehabilitation residential unit

RESEARCH PROCEDURES, RISKS AND BENEFITS

A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. *These include seeking consent, interviews, non-clinical observations and use of questionnaires.*

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?

3. Average time taken per intervention/procedure (minutes, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
Complete questionnaire pack	1	n/a	30 minutes	Participants will complete questionnaires themselves, with support from lead researcher available if required.

A21. How long do you expect each participant to be in the study in total?

It is expected that completing the questionnaires should take most participants no longer than 30 minutes.

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

No adverse effects expected. There is potential that some people may find completing the questionnaires upsetting, however all participants will be informed in advance that they are able to stop at any point.

A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

(●) Yes ( ) No

If Yes, please give details of procedures in place to deal with these issues:

Whilst the questionnaires are unlikely to cause distress, all participants will be informed that they can withdraw at any time whilst completing the questionnaires. Should a participant become upset they will be offered a break or the option to stop altogether. All participants will be provided with a debrief sheet after completing the questionnaires, which will contain details of appropriate sources of support (e.g. friends, family, GP, care coordinator, local third sector organisations). If necessary, the researcher will discuss these options with participants. The researcher will facilitate a similar conversation should a participant ask for clinical advice or support.

The researcher will not provide feedback on questionnaire scores. The debrief sheet provided to all participants after the questionnaires are completed will provide an overview of what will happen with the findings and detail what support they can access if they are affected by any of the issues discussed. A paper copy of this will be given to participants who complete the measures face to face. A paper copy will be included with the questionnaire packs sent to participants. The information will be provided on-screen after completion of the questionnaires for individuals who complete the questionnaires online. Participants will be informed that they are able to contact the lead researcher through the contact details on the Participant Information Sheet should they have further questions.

A24. What is the potential for benefit to research participants?

There is no direct benefit to individual participants from taking part in the study and this will be made clear on the Participant Information Sheets. However, it is hoped that conducting this research into social anxiety following traumatic brain injury will develop understanding in the literature around factors which can predict psychological wellbeing. It is hoped that this will have relevance to clinical staff working in this field, making them better able to support the psychosocial and psychological functioning of people who have sustained a brain injury.

A26. What are the potential risks for the researchers themselves? *(if any)*

Appropriate privacy settings will be employed on the internet sites used to recruit to ensure that potential participants do not have access to personal information about the researcher. Any potential participants who attempt to make contact through social networking sites will be responded to by asking them to contact the researcher via the e-mail or telephone contact details listed on the recruitment materials.

Questionnaires provided by the researcher will be given at NHS premises where possible. If an interview is conducted at a participant's home the researcher will adhere to the Lancaster University Lone Worker Policy

(http://www.lancs.ac.uk/shm/study/doctoral_study/dclinpsy/new/han dbook/appendices/lone_worker_policy.pdf). This will involve identifying potential hazards through dynamic risk assessment, withdrawing immediately if necessary, carrying a mobile phone provided by the University, making a colleague aware of the meeting and staying in contact before and after, and leaving the situation should any risk issues be identified. The researcher will utilise regular supervision to manage the practical and emotional demands of the project.

RECRUITMENT AND INFORMED CONSENT

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used? *For example, identification may involve a disease register, computerised search of GP records, or review of medical records. Indicate whether this will be done by the direct healthcare team or by researchers acting under arrangements with the responsible care organisation(s).*

Given the potential difficulties in recruiting adequate numbers of participants from this client group, a variety of recruitment strategies will be employed. A broad approach will be taken to maximise opportunities for potential participants to be involved in the study. The study will focus on participants who are medically well enough to be living in the community rather than on medical wards or specialist rehabilitation units, to allow for insight into the psychosocial recovery process.

Primarily, NHS neurology/neuropsychology departments will be approached. The Research and Development (R&D) department within [redacted] will be approached to gain approval to recruit through the neurology/neuropsychology department. The R&D department in [redacted] has agreed to act as the lead R&D department for the study.

Other NHS Trusts will be approached for R&D approval as required by the recruitment needs of the study. Site Specific Information (SSI) forms will be generated through the Integrated Research Application System (IRAS) as part of the R&D approval process for each individual NHS Trust. For logistical reasons the study will focus on NHS Trusts in the north-west of England initially, although this may be extended to departments in other areas of the country.

Following ethical approval, potential participants will be identified by staff working in the neurology/neuropsychology departments of the NHS Trusts where R&D approval has been granted. Staff will be asked to introduce the study and give potential participants a copy of the Participant Information Sheet (Appendix A). If they are interested in participating, staff can provide the Screening and Consent Form (Appendix B) and a copy of the Questionnaire Pack (Appendix C). After completing the questionnaires, the participant will be provided with a Debrief Sheet (Appendix D), which will thank participants for their time and provide details of appropriate support if required (e.g. care coordinator, GP, third sector organisations). A stamped addressed envelope will be included to allow for return of all completed items to the researcher at Lancaster University. On receiving the completed items the researcher will use the Screening and Consent Form to assess eligibility and the questionnaires will be included in the study if appropriate.

Potential participants identified by staff may also be sent a copy of the Participant Information Sheet, Screening and Consent Form, Questionnaire Pack and Debrief Sheet by post, accompanied by an introductory covering letter (Appendix E) explaining why they have been invited to participate. A follow-up letter (Appendix F) may be sent to these participants after one month if a response has not been received. The pack will include a stamped addressed envelope to enable completed questionnaires to be returned to the lead researcher at Lancaster University. As above, on receiving the completed items the researcher will use the Screening and Consent Form to assess eligibility and the questionnaires will be included in the study if appropriate.

Relevant third sector organisations (e.g. BASIC, Headway) will also be contacted to promote the study. The lead researcher will visit the organisations to advertise the study to potential participants. Staff will be provided with materials to recruit potential participants as described above. The researcher will also display a poster in NHS and third sector organisations (Appendix G) to advertise the project, which will include detachable slips with the lead researcher's contact details enabling potential participants to contact the researcher if interested in taking part. The project will also be advertised on the Internet using the information from the poster, with the researcher making use of social networking websites (i.e. Facebook, Twitter) and the websites of third sector organisations to reach potential participants through online support networks.

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

○ Yes ◉ No

Please give details below:

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

◉ Yes ○ No

If Yes, please give details of how and where publicity will be conducted, and enclose copy of all advertising material (with version numbers and dates).

Posters will be displayed at NHS neurology/neuropsychology departments and relevant third sector services (e.g. BASIC, Headway) with appropriate permission from management. These organisations will also be asked to advertise the study on their websites. Social networking websites (e.g. Facebook, Twitter) will be used to advertise the study to potential participants by targeting relevant networking groups.

A29. How and by whom will potential participants first be approached?

Several options -

- Direct care team / Staff at third sector organisations will provide copy of questionnaires
- Direct care team / Staff at third sector organisations will identify potential participants and send copy of questionnaires by post
- Participants will self-refer after seeing poster or details of study online

(Participants will be able to contact the lead researcher to request support with completing the questionnaires but this will not be offered routinely)

A30-1. Will you obtain informed consent from or on behalf of research participants?

◉ Yes ○ No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

In line with the Mental Capacity Act (2005) and the guidance provided by the British Psychological Society (2008), all participants will be assumed to have capacity to consent to the study unless evidence to the contrary arises. Should doubts arise about a person's ability to make an informed decision about participation, the researcher will conduct a capacity assessment in line with the four criteria laid out within the Mental Capacity Act (2005). The person must be able to show that they comprehend the information about the study, as detailed on the Participant Information Sheet. They must be able to retain this information long enough to make a decision, using the information to reach a decision based on the consequences of participating or not participating. The participant will also be required to communicate their decision, with support from the researcher if required. If these criteria are met then the researcher will provide the questionnaires.

Participants who choose to submit the questionnaires by post or online will be assumed to have capacity to consent. All participants will be asked to indicate on a consent form that they understand and consent to the study – any questionnaires which are not accompanied by this will not be used in the analysis. The researcher's contact details will be clearly provided on the consent forms so that potential participants can seek advice if they are unsure about any aspect of the study.

If you are not obtaining consent, please explain why not.

Please enclose a copy of the information sheet(s) and consent form(s).

A30-2. Will you record informed consent (or advice from consultees) in writing?

◉ Yes ○ No

A31. How long will you allow potential participants to decide whether or not to take part?

Once ethical approval has been granted, a closing date for recruitment will be confirmed. This date will be included on the introductory and follow-up letters, in addition to the Participant Information Sheet. Questionnaires received after this date will not be used in the study.

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs? *(e.g. translation, use of interpreters)*

Due to a lack of resources available for translation, questionnaires will only be available in English.

The Participant Information Sheet will make clear that participants can ask for help from family/friends or the lead researcher with help reading/recording responses to the questionnaires if they have any communication needs.

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? *Tick one option only.*

- (●) The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.
- ( ) The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.
- ( ) The participant would continue to be included in the study.
- ( ) Not applicable – informed consent will not be sought from any participants in this research.
- ( ) Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be assumed.

Further details:

Once completed questionnaires have been received it will not be possible to remove individual responses from the study as no identifiable data will be stored with the questionnaires.

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

Storage and use of personal data during the study

A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)? *(Tick as appropriate)*

- [ ] Access to medical records by those outside the direct healthcare team
- [ ] Electronic transfer by magnetic or optical media, email or computer networks
- [ ] Sharing of personal data with other organisations
- [ ] Export of personal data outside the EEA
- [x] Use of personal addresses, postcodes, faxes, emails or telephone numbers
- [ ] Publication of direct quotations from respondents
- [ ] Publication of data that might allow identification of individuals
- [ ] Use of audio/visual recording devices
- [x] Storage of personal data on any of the following:
  - [ ] Manual files including X-rays

- [ ] NHS computers
- [ ] Home or other personal computers
- [x] University computers
- [ ] Private company computers
- [ ] Laptop computers

Further details:
Questionnaires and consent forms will be scanned and stored on the university network.

Names and addresses will only be collected to allow for contact by post, or if the participant requests a home visit. All details will be stored securely (as described below) and will not be linked to any questionnaire responses.

A38. How will you ensure the confidentiality of personal data? *Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.*

As above. Only the lead researcher will have access to data containing participants' personal information (i.e. signed consent forms, details of name/address if collected for recruitment or data collection purposes).

To ensure anonymity the signed consent forms will be scanned and stored separately to questionnaires. No other identifiable data will be collected or used in the research.

A40. Who will have access to participants' personal data during the study? *Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.*

Only the lead researcher will have access to the signed consent forms and contact information during the research project.

Storage and use of data after the end of the study

A43. How long will personal data be stored or accessed after the study has ended?

- ○ Less than 3 months
- ○ 3 – 6 months
- ○ 6 – 12 months
- ○ 12 months – 3 years
- ◉ Over 3 years

If longer than 12 months, please justify:
Data will be stored for ten years in line with university policy

INCENTIVES AND PAYMENTS

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

◉ Yes ○ No

If Yes, please give details. For monetary payments, indicate how much and on what basis this has been determined.
Participants will be able to claim up to £10 travel expenses if appropriate.

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

○ Yes ◉ No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

○ Yes ◉ No

NOTIFICATION OF OTHER PROFESSIONALS

A49-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?

○ Yes ◉ No

If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.

PUBLICATION AND DISSEMINATION

A50. Will the research be registered on a public database?

○ Yes ◉ No

Please give details, or justify if not registering the research.
No suitable register exists

Registration of research studies is encouraged wherever possible.
You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you are aware of a suitable register or other method of publication, please give details. If not, you may indicate that no suitable register exists. Please ensure that you have entered registry reference number(s) in question A5-1.

A51. How do you intend to report and disseminate the results of the study? *Tick as appropriate:*

- ☑ Peer reviewed scientific journals
- ☐ Internal report
- ☑ Conference presentation
- ☑ Publication on website
- ☐ Other publication
- ☐ Submission to regulatory authorities
- ☐ Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
- ☐ No plans to report or disseminate the results
- ☐ Other (please specify)

A53. Will you inform participants of the results?

◉ Yes ○ No

Please give details of how you will inform participants or justify if not doing so.
Participants will be invited to contact the researcher if they would like to receive either a brief summary of the findings or a copy of the full manuscript.

Appendix 4-D: Integrated Research Application System (IRAS) Research Ethics Committee application form

5. Scientific and Statistical Review

A54. How has the scientific quality of the research been assessed? *Tick as appropriate:*

- ☐ Independent external review
- ☐ Review within a company
- ☐ Review within a multi−centre research group
- ☑ Review within the Chief Investigator's institution or host organisation
- ☑ Review within the research team
- ☐ Review by educational supervisor
- ☐ Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:
Proposal submitted and discussed with research team as part of review process on the clinical psychology doctorate course.

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A56. How have the statistical aspects of the research been reviewed? *Tick as appropriate:*

- ☐ Review by independent statistician commissioned by funder or sponsor
- ☐ Other review by independent statistician
- ☐ Review by company statistician
- ☐ Review by a statistician within the Chief Investigator's institution
- ☑ Review by a statistician within the research team or multi−centre group
- ☐ Review by educational supervisor
- ☐ Other review by individual with relevant statistical expertise
- ☐ No review necessary as only frequencies and associations will be assessed – details of statistical input not required

In all cases please give details below of the individual responsible for reviewing the statistical aspects. If advice has been provided in confidence, give details of the department and institution concerned.

	Title	Forename/Initials	Surname
	Dr	Jane	Simpson
Department	Division of Health Research		
Institution	Lancaster University		
Work Address	Furness Building, Lancaster University Lancaster		
Post Code	LA1 4YG		
Telephone			
Fax			
Mobile			
E-mail	j.simpson2@lancaster.ac.uk		

Please enclose a copy of any available comments or reports from a statistician.

Appendix 4-D: Integrated Research Application System (IRAS) Research Ethics Committee application form

A57. What is the primary outcome measure for the study?

Social Phobia Inventory (SPIN)

A58. What are the secondary outcome measures? *(if any)*

n/a

A59. What is the sample size for the research? *How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.*

Total UK sample size: 139

Total international sample size (including UK):

Total in European Economic Area:

Further details:

A60. How was the sample size decided upon? *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

For a regression model including five to fifteen predictor variables, a sample size of between 92 and 139 will be required based on finding a medium effect size (0.15) at 80% power and an alpha level of p=.05.

A61. Will participants be allocated to groups at random?

○ Yes ◉ No

A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

After data collection is complete the questionnaires will be scored by the lead researcher and entered onto SPSS, the computer programme which will be used for the statistical analysis.

Hierarchical multiple regression analysis will be conducted to examine the data. Due to the exploratory nature of the study, Pearson's correlations will be calculated between each predictor variable and the outcome variable. Predictor variables which correlate with the outcome variable and demonstrate a medium effect size ($r > 0.3$) will be entered into the regression model.

Predictor variables which correlate with the outcome variable will be entered into the regression model in the following blocks, in keeping with previous research: 1) demographic variables (gender, age, type of traumatic event) 2) clinical variables (time spent in hospital, neurological functioning) 3) psychological variables (anxiety/depression, self-esteem, perceived stigma, self-efficacy, locus of control).

6. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. *Please include all grant co-applicants, protocol co-authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

	Title Forename/Initials Surname
	[redacted]
Post Qualifications	Clinical Neuropsychologist
Employer	[redacted]

Work Address	[redacted]
Post Code	
Telephone	
Fax	
Mobile	
Work Email	[redacted]

A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

Status:
- ○ NHS or HSC care organisation
- ◉ Academic
- ○ Pharmaceutical industry
- ○ Medical device industry
- ○ Local Authority
- ○ Other social care provider (including voluntary sector or private organisation)
- ○ Other

Commercial status:

If Other, please specify:

Contact person

Name of organisation	Lancaster University
Given name	Debbie
Family name	Knight
Address	Research Support Office, B58
Town/city	Bowland Main
Post code	LA1 4YT
Country	
Telephone	01524 592605
Fax	
E-mail	ethics@lancaster.ac.uk

Is the sponsor based outside the UK?

○ Yes ◉ No

Under the Research Governance Framework for Health and Social Care, a sponsor outside the UK must appoint a legal representative established in the UK. Please consult the guidance notes.

A65. Has external funding for the research been secured?

- ☐ Funding secured from one or more funders
- ☐ External funding application to one or more funders in progress
- ☑ No application for external funding will be made

What type of research project is this?

- (•) Standalone project
- ( ) Project that is part of a programme grant
- ( ) Project that is part of a Centre grant
- ( ) Project that is part of a fellowship/ personal award/ research training award
- ( ) Other

Other – please state:

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

( ) Yes (•) No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68-1. Give details of the lead NHS R&D contact for this research:

Title Forename/Initials Surname

[redacted]

Organisation
Address

Post Code
Work Email
Telephone
Fax
Mobile

Details can be obtained from the NHS R&D Forum website: http://www.rdforum.nhs.uk

A69-1. How long do you expect the study to last in the UK?

Planned start date: 02/06/2014
Planned end date: 01/06/2015
Total duration:
Years: 1 Months: 0 Days: 0

A71-2. Where will the research take place? *(Tick as appropriate)*

- [x] England
- [ ] Scotland
- [ ] Wales
- [ ] Northern Ireland
- [ ] Other countries in European Economic Area

Total UK sites in study

Does this trial involve countries outside the EU?
◯ Yes ◯ No

A72. What host organisations (NHS or other) in the UK will be responsible for the research sites? *Please indicate the type of organisation by ticking the box and give approximate numbers of planned research sites:*

☑ NHS organisations in England	10
☐ NHS organisations in Wales	
☐ NHS organisations in Scotland	
☐ HSC organisations in Northern Ireland	
☐ GP practices in England	
☐ GP practices in Wales	
☐ GP practices in Scotland	
☐ GP practices in Northern Ireland	
☐ Social care organisations	
☐ Phase 1 trial units	
☐ Prison establishments	
☐ Probation areas	
☑ Independent hospitals	2
☐ Educational establishments	
☐ Independent research units	
☐ Other (give details)	
Total UK sites in study:	12

A76. Insurance/ indemnity to meet potential legal liabilities

***Note:* in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland**

A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? *Please tick box(es) as applicable.*

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

☐ NHS indemnity scheme will apply (NHS sponsors only)
☑ Other insurance or indemnity arrangements will apply (give details below)

Lancaster University legal liability cover will apply

Please enclose a copy of relevant documents.

A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? *Please tick box(es) as applicable.*

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

Appendix 4-D: Integrated Research Application System (IRAS) Research Ethics Committee application form

☐ NHS indemnity scheme will apply (protocol authors with NHS contracts only)

☑ Other insurance or indemnity arrangements will apply (give details below)

Lancaster University legal liability cover will apply

Please enclose a copy of relevant documents.

A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

☑ NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)

☑ Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

Lancaster University legal liability cover will apply

Please enclose a copy of relevant documents.

Appendix 4-D: Integrated Research Application System (IRAS) Research Ethics Committee application form

NHS REC Form | Reference: 14/LO/1281 | IRAS Version 3.5

PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. *For NHS sites, the host organisation is the Trust or Health Board. Where the research site is a primary care site, e.g. GP practice, please insert the host organisation (PCT or Health Board) in the Institution row and insert the research site (e.g. GP practice) in the Department row.*

Research site		Investigator/ Collaborator/ Contact	
Institution name	[redacted]	Title	[redacted]
Department name		First name/ Initials	
Street address		Surname	
Town/city			
Post Code			

Appendix 4-D: Integrated Research Application System (IRAS) Research Ethics Committee application form

PART D: Declarations

D1. Declaration by Chief Investigator

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

2. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.

3. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.

4. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.

5. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.

6. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.

7. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.

8. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 1998.

9. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:

    - Will be held by the REC (where applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
    - May be disclosed to the operational managers of review bodies, or the appointing authority for the REC (where applicable), in order to check that the application has been processed correctly or to investigate any complaint.
    - May be seen by auditors appointed to undertake accreditation of RECs (where applicable).
    - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
    - May be sent by email to REC members.

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

11. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

Contact point for publication*(Not applicable for R&D Forms)*

NRES would like to include a contact point with the published summary of the study for those wishing to seek further information. We would be grateful if you would indicate one of the contact points below.

(•) Chief Investigator

( ) Sponsor

Appendix 4-D: Integrated Research Application System (IRAS) Research Ethics Committee application form

- ○ Study co-ordinator
- ○ Student
- ○ Other – please give details
- ○ None

Access to application for training purposes *(Not applicable for R&D Forms)*

Optional – please tick as appropriate:

☑ I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

This section was signed electronically by Mr Will Curvis on 03/07/2014 10:45.

Job Title/Post:		
Organisation:		
Email:		
Signature:	.....	
Print Name:	Will Curvis	
Date:	22/05/2014	*(dd/mm/yyyy)*

Appendix 4-D: Integrated Research Application System (IRAS) Research Ethics Committee application form

D2. Declaration by the sponsor's representative

If there is more than one sponsor, this declaration should be signed on behalf of the co–sponsors by a representative of the lead sponsor named at A64-1.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.
2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.
3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.
4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.
5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.
6. The duties of sponsors set out in the Research Governance Framework for Health and Social Care will be undertaken in relation to this research.
7. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

This section was signed electronically by An authorised approver at ethics@lancaster.ac.uk on 04/07/2014 14:26.

Job Title/Post:	Research Support Officer
Organisation:	Lancaster University
Email:	s.c.taylor@lancaster.ac.uk

Appendix 4-D: Integrated Research Application System (IRAS) Research Ethics Committee application form

D3. Declaration for student projects by academic supervisor(s)

1. I have read and approved both the research proposal and this application. I am satisfied that the scientific content of the research is satisfactory for an educational qualification at this level.

2. I undertake to fulfil the responsibilities of the supervisor for this study as set out in the Research Governance Framework for Health and Social Care.

3. I take responsibility for ensuring that this study is conducted in accordance with the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research, in conjunction with clinical supervisors as appropriate.

4. I take responsibility for ensuring that the applicant is up to date and complies with the requirements of the law and relevant guidelines relating to security and confidentiality of patient and other personal data, in conjunction with clinical supervisors as appropriate.

Academic supervisor 1

This section was signed electronically by jane simpson on 03/07/2014 10:48.

Job Title/Post:	Research Director
Organisation:	Lancaster university
Email:	j.simpson2@lancaster.ac.uk

Academic supervisor 2

This section was signed electronically by stephen weatherhead on 06/07/2014 20:20.

Job Title/Post:	Lecturer in Health Research
Organisation:	Lancaster University
Email:	s.weatherhead@lancaster.ac.uk

Appendix 4-E: Covering Letter

To Whom It May Concern:

Please find attached my application for ethical approval for my research project examining social anxiety and traumatic brain injury.

If further details are required please contact me on the details below.

Yours sincerely,

Will Curvis
Trainee Clinical Psychologist
Lancaster University

e-Mail: w.curvis@lancaster.ac.uk
Tel: 07508 375640

Appendix 4-F: Letter of Sponsorship

LANCASTER UNIVERSITY

Applicant name: Will Curvis
Supervisor: Dr Stephen Weatherhead
Department: DHR

1 July 2014

Dear Will and Stephen,

Re: Social anxiety following traumatic brain injury

The University of Lancaster undertakes to perform the role of sponsor in the matter of the work described in the accompanying grant application. The sponsor as we understand it assumes responsibility for monitoring and enforcement of research governance. As principal investigator you will confirm that the institution's obligations are met by ensuring that, before the research commences and during the full term of the grant, all the necessary legal and regulatory requirements in order to conduct the research are met, and all the necessary licenses and approvals have been obtained. The Institution has in place formal procedures for managing the process for obtaining any necessary or appropriate ethical approval for this grant. Full ethical approval must be in place before the research commences and should be reviewed at all relevant times during the grant.

Yours sincerely,

Fiona Aiken,
University Secretary,
Chair, University Research Ethics Committee.

Cc Sarah Taylor, Secretary, UREC.

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