Associations between Illness Perceptions, Self-criticism, Self-reassurance and Recovery Outcomes following Traumatic Brain Injury

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Statement of Word Count

Thesis Sections	Main Text (including abstracts	Appendices (including tables, figures & references	Total
Thesis Abstract	296	-	296
Section One: Systematic Literature Review	7,996	4,325	12,321
Section Two: Empirical Paper	7,838	3,506	11,344
Section Three: Critical Appraisal	3,801	994	4,795
Section Four: Ethics Documentation	-	6,972	6,972
Total	19,931	15,797	35,728

Thesis Abstract

Section one presents a systematic literature review examining the relationship between injury perceptions and persistent post-concussion symptoms (PPCS), quality of life (QoL) and psychological distress outcomes in individuals following traumatic brain injury (TBI). Four databases were systematically searched using key words and thesaurus terms related to the concepts noted above. 12 papers were included in the final review. Findings suggest that the attribution of more symptoms to the TBI, a perception that symptoms will last a long time, have more negative consequences and a stronger emotional reaction to the TBI, are more likely to be associated with increased PPCS. The identity, timeline, consequences, concern, emotional representations and personal control subscales were significantly associated with QoL outcomes following TBI. Longitudinal studies emphasise the predictive ability of injury perceptions following TBI which gives attention to the role of clinical psychology in acute management and follow-up of those who have suffered a TBI. Clinical implications and limitations of the review are discussed.

Section two reports on an empirical investigation into the relationship between self-criticism and both symptomatic (PPCS) and post-TBI depression in a sample of 41 adults who sustained a mild to moderate TBI between 3 and 12 months previous. Significant moderate effect size correlations between both self-criticism and self-reassurance with each of the outcomes assessed (early onset PPCS, late-enduring PPCS and post-TBI depression) were found. A series of multiple regression analyses evidenced that self-criticism demonstrated significant predictive ability above previously known predictors for enduring PPCS and also post-TBI depression. Self-reassurance did not demonstrate predictive ability. Limitations and clinical implications are discussed and include the relevance of self-criticism to both preventative and therapeutic intervention for individuals following TBI.

Section three includes a critical appraisal of the thesis and processes involved in undertaking the above two research papers.

Declaration

This thesis was completed in part fulfilment of the Doctorate in Clinical Psychology at Lancaster University, between September 2018 and June 2020. The work has not been submitted for any other academic award. The work submitted is my own and does not contain the work of any other authors, except where due reference is made.

Lindsay Prescott

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Section One: Systematic Literature Review

The role of injury perceptions in quality of life, psychological distress and post-concussion symptoms following traumatic brain injury. A systematic review.

Word count: 7996 words (excluding tables, references and appendices)

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[1] see Additional Appendices - Appendix A for submission guidelines

Abstract

This review examined the relationships between injury perceptions following traumatic brain injury (TBI) and outcome including psychological distress, quality of life (QoL) and persistent post-concussion symptoms (PPCS). Four databases were systematically searched, and 12 quantitative research papers were reviewed. Findings indicate that the attribution of more symptoms to the TBI; a perception that symptoms will last a long time; a perception of greater negative consequences of the TBI and a stronger emotional reaction to it are more likely to be associated with increased reporting of PPCS. QoL outcomes were also associated increased levels of concern and less perceived personal control. Findings highlight the importance of injury perceptions in the early days post-TBI, giving attention to the importance of clinical psychologists' role in the multi-disciplinary team in acute care. Interventions aimed at addressing injury perceptions, individually and via training of other professions are likely to be efficacious for reducing symptomatic outcome and improving QoL and psychological well-being for individuals following TBI.

Keywords

Traumatic brain injury; illness perceptions; post-concussion; beliefs; quality of life; psychological distress

Introduction

Traumatic brain injury (TBI) is a disruption of the normal function of the brain caused by an external force (1), including blows/bangs to the head; penetrating objects or mechanical forces, such as a sudden change in speed, that cause the brain to collide with the inside of the skull. Diagnostic difficulties and likely underreporting of particularly mild TBI (mTBI; (2)) lead to difficulties in estimating the true incidence of TBI, although recent data suggests that globally, 69 million people sustain a TBI each year (3).

Recovery and adjustment following TBI is a complex and multifaceted process; influenced by physical, cognitive, emotional and behavioural factors, each unique to the individual's personal and social contexts (4). Commonly, individuals experience 'post-concussion' symptoms (PCS) following TBI which represent a cluster of symptoms such as headache, dizziness, memory and concentration difficulties, irritability and sleep disturbance (5). Despite being commonly associated with mTBI, PCS can be observed across all injury severities (6). In a subset of individuals, the duration of PCS extends beyond the expected recovery time of a few weeks or months, and becomes labelled as 'persistent' (PPCS).

Early theories posited that organic factors alone accounted for the initial PCS and psychological factors contributed to their persistence (7). However, research has since demonstrated a biopsychosocial process in PPCS development with psychological factors pre-, peri- and post-injury having significant predictive value (8–10).

Research has demonstrated that individuals who have sustained a TBI experience reduced subjective quality of life (QoL) and psychological well-being compared to non-TBI controls (11–13). A review of the literature found that psychosocial domains of QoL were most affected by TBI compared to more physical aspects of functioning (14), and research investigating possible prognostic factors for QoL outcomes was encouraged. Studies have also linked the experience of PPCS to reduced QoL (15) and depression (16,17). A systematic review of anxiety and depression following TBI reported prevalence rates of 17% for depression and 21% for anxiety within the first year post-TBI (18).

Such high prevalence rates of PCS, reduced QoL and psychological distress post-TBI warrants further investigation into possible predictors, so that more effective treatment options can be explored. One potentially important predictor is a person's 'illness perceptions', which are cognitive and emotional representations about illness and subsequent symptoms (19). TBI is increasingly conceptualised as a long-term health condition rather than a singular event due

to the implications often being lifelong (20). However, as TBI is more commonly referred to as an 'injury' as opposed to an 'illness', the term 'injury perceptions' will be used synonymously with 'illness perceptions' in this review.

Associations between illness perceptions and QoL and psychological distress outcomes have been demonstrated in several populations relevant to TBI including trauma patients (21,22), and in other neurological conditions such as multiple sclerosis (MS; (23)), epilepsy (24) and stroke (25). Such studies highlight the predictive ability of specific illness perceptions to QoL over time (21,22,25) and also suggest that illness perception subscales may be unique to the specific population and also to the type of outcome being assessed (23).

Psychological theories of PPCS following TBI have also recognised the influence of negative injury perceptions and expectations regarding injury outcome (8,26,27). Cross-sectional studies have supported the '*expectation as aetiology'* (28) theory of PPCS, demonstrating that individuals with PPCS experience the same symptom cluster as non-TBI controls would expect after reading a TBI-related vignette, highlighting the importance of expectations on actual symptom experience (29–31). Similarly, the 'good old days' bias (32), which is the tendency to underestimate the presence of symptoms present prior to the TBI resulting in an over-attribution of symptoms to the TBI, has also found support within the literature.

Accumulating evidence implicating expectations and perceptions in recovery outcomes after TBI has given rise to a number of intervention studies, specifically in relation to PPCS. Silverberg and colleagues (33) found moderate to large effect sizes across various outcomes comparing an early intervention cognitive behavioural therapy (CBT) group targeting injury beliefs, to a treatment as usual control group in a TBI sample with PCS. Other studies have reported on the positive effects of intervention in the early weeks post-TBI, targeting

expectations and injury perceptions as a preventative approach to the development of PPCS, across injury severity (34,35).

Mah, Hickling and Reed (36) recently conducted a scoping review exploring injury perceptions and health outcomes in mTBI specifically. This review provided a useful overview, defining and distinguishing between a variety of injury belief concepts including expectations, and illness perceptions. The authors advocated for further studies and the use of validated measures of illness perceptions, such as the illness perception questionnaire (IPQ; (37)) and the brief version of the IPQ (BIPQ; (38)), to improve the robustness of research findings given the limitations of self-report.

However, as a scoping review, Mah et al (36) did not assess the quality of included studies which limits confidence in the reliability and validity of study findings. A more in-depth, systematic literature review of the relationship between injury perceptions and recovery outcomes including all severities of TBI has yet to be conducted.

Understanding the role of injury perceptions in QoL and psychological recovery following TBIs of all severities post-TBI is important, as these are changeable aspects of a person's recovery.

Furthermore, investigating injury perceptions both broadly and in terms of the specific illness perception domains (i.e. illness identity, consequences, etc) is necessary in defining what specific messages would be useful to share when working with the TBI population early post-injury; so that effective, evidence-based interventions can be developed further. The current review focuses specifically on the role of injury perceptions in recovery outcomes following TBI. Outcome is defined as PPCS, psychological distress and both health-related and psychological QoL. The review aims to answer the question "What is the relationship between injury perceptions and PPCS, quality of life and psychological distress outcomes following TBI?".

Methods

Search strategy

Electronic searches were conducted using four electronic databases; Medline, PsycINFO, Cumulative Index to Nursing and Allied Health Literature (CINAHL) and Allied and Complimentary Medicine (AMED). The search strategy was defined using the PICO framework (patient/population, intervention/prognostic factor, comparison and outcome (39)) although without a 'comparison' variable . Thesaurus terms used in relevant papers identified during scoping searches were also reviewed to refine the search strategy. Free text search terms used in similar systematic literature reviews within other patient populations (40,41) were also reviewed to define search terms. Following consultation with an academic librarian to clarify and confirm the search terms and strategy, searches were conducted in May 2020.

Free text search terms were entered into each database individually in addition to the selection of subject heading terms (see Appendix A) relevant to the three main concepts being investigated i.e. TBI, illness perceptions and outcomes. Title and abstract searches were combined using AND/OR Boolean operators. Free text search terms included; "TBI" OR "traumatic brain injury" OR "mTBI" OR "post-concussion" AND "percept*" OR "belie*" OR "expectation* OR "representation" OR "cognition*" AND "symptom*" OR "outcome*" OR "quality of life" OR "QOL" OR "mood" OR "depression" OR "anxiety".

Search results were limited to academic journals as a baseline for quality control and by English language due to the resource limitations for translation. The reference lists of relevant studies and a recent scoping review (36) were reviewed to check for any articles that were missed.

Selection Criteria

The database searches returned a total of 1931 relevant studies; 585 from Medline, 608 from CINAHL, 655 from PsycINFO and 83 from AMED. Scanning reference lists of relevant articles revealed two possible studies which were enlisted for further screening.

Figure 1 outlines the literature search process according to PRISMA (42). Following the removal of duplicates, the titles and abstracts of 1162 studies were screened based on relevance to the review question. This identified 39 potential studies for inclusion. The full articles of all 39 studies were then reviewed for eligibility and 27 articles removed based on pre-determined exclusion criteria, leaving 12 articles for final inclusion.

[FIGURE 1 ABOUT HERE]

Inclusion and exclusion criteria

Only adult (over 16 years) and clinical samples (i.e. with a history of TBI) were included. There we no limits placed on year of publication or country of origin. Included studies must have employed quantitative methodology and used validated measures for both injury perceptions and outcomes as recommended in similar reviews (36,43).

Studies were excluded if they did not report on the relationship between the two variables of interest in this review, namely injury perceptions and outcome.

Data Extraction

Study, participant and outcome data were extracted from each of the included studies. Extracted data included:

- Authors, year of publication, country, study design and recruitment location.
- Total sample size, number of participants assigned to each study condition (where appropriate), mean age, gender ratio, injury severity, time since injury, prior TBI and mental health history.
- Measures relating to injury perceptions and recovery outcomes (PPCS, psychological distress and QoL).

- Analysis summary statistics

Quality Appraisal Strategy

The Effective Public Health Practice Project (EPHPP) quality assessment tool for quantitative studies (44) was used in the assessment of quality of all included studies. The EPHPP tool assesses eight quality criteria including selection bias, study design, confounders, blinding, data collection methods, withdrawals and dropouts, intervention integrity and analyses. As the aims of this review were not specific to intervention studies, the blinding and intervention integrity criteria were removed. A three-point rating of either 'weak', 'moderate' or 'strong' is given to each criterion. An overall global rating is then assigned based on the number of 'weak' ratings across the eight quality criteria. Whilst no studies were excluded based on quality ratings, consideration of quality was given when drawing conclusions from the synthesis of study results.

Data Analysis

Due to the heterogeneity of sample characteristics and the variability in the use of specific measures, a meta-analysis was not appropriate. Similar to other reviews in this area (43), a narrative approach to the synthesis of findings was utilised.

Results

Overview of Studies Included

Table 1 summarises the study and sample characteristics taken from each of the 12 included studies.

[TABLE 1 ABOUT HERE]

Study characteristics

Seven cross-sectional (45–51) and five longitudinal (27,52–55) studies were included. Three of the studies by Snell and colleagues (51,52,55) appeared to have used the same core sample of participants. The 2013 study (52) reported on follow-up data gathered from the

sample reported on in the 2011 study (51). In the 2015 study (55), the data for the same sample was re-analysed using cluster analysis. While these will be reported as separate papers, participant numbers will be combined. The two studies by Var and Rajeswaran (46,47) also report very similar samples. The study authors were emailed to clarify whether these two papers were based on the same sample of participants but not response was received.

The majority of papers were based in New Zealand (49,51,52,54,55), three from the UK (27,48,53), two from India (46,47), one from Australia (45) and one from the USA (50). Most studies recruited participants from clinical services which included accident & emergency departments (27,51–53,55), rehabilitation services (48,49), outpatient services (46,47,51,52,55) and inpatient services (45). One study recruited from a veterans association (50) and one study used data taken from a large population-based study (54).

Sample characteristics

Taking into account the papers by Snell and colleagues (51,52,55), a total of 812 individual participants were included across 10 separate studies. The mean age of participants ranged from 31.48 years (50) to 46.48 years (49) across eleven of the selected studies and one study (48) only reported an age range and SD (age range 19-65, SD=12). The majority of studies reported between 50% and 70% male ratios. Nine papers reported only on mTBI, two reported on mild-moderate severity (46,47) and only one paper included participants with severe TBI (48).

There was considerable variability in the time since injury of participants across the studies. Of the seven cross-sectional studies, two reported on samples with a mean time of four years or more since injury (48,50); two with a mean time of between one and four years (47,49) and three studies (45,46,51) reported on samples of less than one year post-TBI. Of the longitudinal studies, three studies used a baseline of less than four weeks post-TBI (27,53,54) and two used a baseline of three months post-TBI (52,55). Follow-ups were usually held at six

months (27,52,55), although one study reported follow-up data at three months (53) and one study at four years (54).

Three studies did not report history of previous TBI in the sample (27,48,53) and two studies excluded individuals with a history of prior TBI (46,47). Of those remaining, between 26% and 48% of participants reported previous TBIs. Five studies did not report on mental health history in their sample (27,48,50,53,54) and two studies excluded individuals with mental health history (46,47). Of those remaining, between 27% and 42% of participants reported a mental health history.

Table 2 summarises the key characteristics and main findings from the included studies.

[TABLE 2 ABOUT HERE]

Study Outcomes

Illness perception measures

Two versions of the illness perception questionnaire (IPQ), a brief version (BIPQ; (38)) and a revised version (IPQ-R; (37)), were used across the studies. The IPQ-R (37) consists of three scales: identity, beliefs and causal attributions. The identity scale lists common symptoms and asks the participant to note which they experience and are attributable to their illness. The beliefs scale consists of 38 items assessing beliefs about illness timeline acute/chronic (duration); timeline cyclical (course and predictability of symptoms); consequences; perceived control (through treatment and personal action); coherence (understanding of the illness) and emotional representations (emotional reaction as a result of the injury). The causal attribution scale uses a five-point Likert scale to assess the participants' level of agreement with perceived causes of their illness. The IPQ-R has demonstrated good reliability and validity across various health populations (37,56) and more recently, a factor analysis demonstrated that it is also an acceptable measure for use in an mTBI sample with some adaptation to the causal and control sub-scales (57).

The BIPQ (38) consists of nine questions: eight of which assess the cognitive and emotional representations of illness, as in the IPQ-R identity and belief scales, using a Likert scale ranging from 0-10. The ninth item asks participants to note perceived causes of illness, similar to the causal attribution scale of the IPQ-R. The BIPQ has good psychometric properties demonstrated across a range of health populations (58).

Eight studies used the IPQ-R to measure illness perceptions (45,48–53,55) and four studies used the BIPQ (27,46,47,54). While the BIPQ was used relatively consistently (some studies included a total score and others just the individual items), use of the IPQ-R varied. For example, several studies did not use all of the subscales of the IPQ-R (48–50,52,55) and in the three papers by Snell and colleagues (51,52,55), additional mTBI symptoms (e.g., memory and concentration problems) were added to the identity scale.

Outcome measures

All three types of outcomes, ongoing PCS, quality of life and psychological distress, were assessed across the 12 included studies. The majority of studies focused on PPCS as measured by the Rivermead Post-concussion symptoms Questionnaire (RPQ; (59)). The RPQ contains a list of common symptoms requiring participants to rate on a five-point Likert scale how much of a problem they are considering the last 24 hours. The RPQ has been used as a total score with a cut-off score of 16, demonstrating 97% sensitivity and 87% specificity (60) in diagnosing PPCS. This approach was used to classify individuals as having PPCS or being recovered in several studies. Other studies split the RPQ into early (RPQ3; based on the first three items of headache, dizziness and nausea/vomiting) and late-enduring symptoms (RPQ13; based on items 4-16 which include fatigue, poor concentration forgetfulness etc), which is reported to improve construct validity (61).

In two papers (51,52), outcome was defined using a combination of the RPQ and the Rivermead Head Injury Follow-up Questionnaire (RHIFUQ, (62)). The RHIFUQ assesses both

functional and social outcomes following TBI, comparing pre- and post-injury abilities. One paper also defined PCS outcome based on a combination of deficits in at least one cognitive domain of the RPQ; at least three other complaints on the RPQ and functional impairment according to the Sydney Psychosocial Reintegration Scale (SPRS; (63)). The SRPS assesses participation following TBI and has demonstrated strong psychometric properties in this population (reliability coefficients above .9; (63)).

While many of the studies administered measures of psychological distress, only two studies investigated the association between illness perceptions and psychological distress as an outcome (48,50). One study used the Hospital Anxiety and Depression Scale (HADS; (64)) and the other used the PTSD checklist – civilian version (PCL-C; (50)).

Finally, only one study assessed quality of life outcomes (46) using the World Health Organisation's Quality of Life assessment tool (WHOQOL; (65)). The WHOQOL assesses four QoL domains; physical, psychological, environmental and overall. Given the focus on PCS and psychological distress in this study, only the physical and psychological domains were extracted from this paper.

Quality Assessment

Ratings from the quality assessment using the EPHPP quality assessment tool are presented in Appendix B. Overall, three studies were rated globally as strong; four were moderate and five were of weak quality. Of those rated weak or moderate, selection bias and study designs, such as cohort studies recruited through opportunity sampling methods, were frequent criteria for reduced quality ratings: common difficulties when recruiting from clinical populations where informed consent and patient choice is central. Some studies received ratings of 'weak' quality due to failing to report withdrawal rates and reasons.

Synthesis of results

The following section is divided into three: injury perceptions, psychological distress and QoL. Given that the majority of included studies reported on PPCS, this first section will be subdivided into each of the injury perception concepts.

Injury perceptions and post-concussion symptoms (PCS)

Of the nine studies assessing outcomes based on symptoms as measured using the RPQ, four were cross-sectional (45,47,49,51) and five were longitudinal (27,52–55).

Employing cluster analyses methodology, Snell and colleagues (55) found significant differences in the recovery trajectories and outcomes (on the RPQ at six months) of three distinct groups based on a combination of the identity and beliefs subscales of the IPQ-R and the HADS. Specifically, they found that compared to those in the medium and high adapter groups, those in the 'low adapter' cluster reported stronger negative injury beliefs relating to identity (moderate effect size); acute/chronic timeline (moderate effect size); cyclical timeline (moderate effect size); consequences (large effect size); emotional representations (large effect size) and coherence (small effect size).

Identity

Four studies demonstrated significant relationships between the PCS outcome and the identity subscale of the IPQ-R (45,49,51,53) using cross-sectional analyses: three reported on participants within 8 weeks post-TBI (45,51,53) and one an average of 32 months post-TBI (49). Of these, two studies (49,51) demonstrated significant differences on the identity subscale between recovered and non-recovered PCS groups. Anderson and Fitzgerald (45) reported a positive correlation with moderate effect size between the identity subscale and the RPQ13 highlighting that those endorsing stronger beliefs that their current symptoms were attributable to the TBI have an increased likelihood of poor symptomatic outcome. Using regression analysis, they also found that the identity subscale was a significant independent predictor of

RPQ3 (p=.002) and also RPQ13 (p=.003) when entered into a model with psychological distress and coping approach.

Within the longitudinal studies, Hou and colleagues (27) used logistic regression analyses to demonstrate that higher scores on the identity subscale measured at baseline (within two weeks post-TBI) was significantly associated with higher RPQ scores at three months and six months post-TBI albeit with small effect sizes. Snell and colleagues' follow-up data (52) also revealed a small effect for the relationship between higher ratings on the identity domain measured within three months post-TBI and poor outcome six months later. However, when entered into a logistical regression model alongside other predictor variables including coping, depression, anxiety, IPQ-R consequences and IPQ-R emotional representations, the identity subscale completed within three months post-TBI was not found to be a significant independent predictor of PCS outcome six months later.

Overall, the higher quality studies concur that the identity subscale demonstrates moderate to strong effects cross-sectionally across various time points post-TBI and for both early and late-enduring symptoms. Longitudinal data (27,52) also suggests that early identity beliefs are predictive of future PCS albeit with limited findings.

Timeline acute/chronic

Four out of five studies reporting on cross-sectional analyses demonstrated significant associations between the timeline acute/chronic subscale and symptomatic outcome, suggesting that those endorsing stronger beliefs that their symptoms will last a long time report more severe PCS (47,49,51,52). Using correlational analyses based on participants who were an average of 12 months post-TBI, Var and Rajeswaran (47) found a positive correlation with moderate effect between the acute/chronic timeline subscale of the BIPQ and the RPQ3 only; suggesting that beliefs about how long PCS will last were only associated with earlier symptoms. Two studies by Snell et al. (49,51) used the total RPQ score and found significant

between group differences such that the recovered groups endorsed significantly stronger beliefs that their symptoms would last a long time compared to those in the non-recovered groups. In the 2013 follow-up paper, Snell et al (52) also found that cross-sectionally, those with poor PCS outcome at approximately nine months post-TBI endorsed stronger timeline acute/chronic beliefs compared to those with good PCS outcome.

Whittaker et al (53) used the IPQ-R in a correlation study similar to Var and Rajeswaran (47) however, here, no significant correlation between the timeline acute/chronic subscale and the RPQ total score (reported between one and three weeks post-TBI) was found. The difference in time since injury between studies may account for such differences, particularly on this domain relating to perceived duration of symptoms, in addition to the varied use of the RPQ across these two studies (RPQ total Vs RPQ3 and RPQ13). In another study which controlled for psychological distress in their partial correlation, Anderson and Fitzgerald (45) found that the correlation between the timeline subscale and both RPQ3 and the RPQ13 had minimal effect.

The association between the timeline-acute/chronic subscale and PCS outcome was supported by several longitudinal studies. Logistical regression analyses by Hou and colleagues (27) demonstrated that the acute/chronic timeline subscale of the BIPQ completed within two weeks post-TBI was significantly associated with PCS outcome at three months and six months (both with small effect sizes). This highlights that early post-injury beliefs that symptoms would last a long time were associated with greater symptoms several months later. Using the IPQ-R and multiple regression analyses, Whittaker and colleagues (53) found that the timeline acute/chronic subscale completed less than three weeks post-TBI was also a significant predictor of RPQ scores at three months post-TBI above measures of psychological distress. However, the timeline subscale did not reach significance when included in a logistical regression model to predict PCS based on the RPQ and a measure of functional impairment

(using the SPRS). In the follow-up paper by Snell and colleagues (52), a lack of significant difference between recovered and non-recovered groups at nine months post-TBI was reported for the timeline acute/chronic subscale which was completed within three months post-TBI.

Despite mixed results, the stronger quality studies concur that those endorsing stronger beliefs that their injury will last a long time are more likely to report more PCS. Longitudinally, the timeline acute/chronic subscale rated within the initial weeks post-TBI has also demonstrated significant predictive ability of PCS severity both three and six months later.

Timeline Cyclical

Five papers included the timeline cyclical subscale of the IPQ-R (45,49,51,52,55) which examines how predictable participants perceive their injury to be. Both cross-sectional studies by Snell and colleagues (49,51) reported significant differences in the timeline cyclical subscale between recovered and non-recovered groups completed within three months post-TBI and also at six months cross-sectionally. These findings indicate that those in the non-recovered group at both three and six months post-TBI endorsed stronger beliefs that their injury was unpredictable. In their six-month follow up study, a lack of significant difference on the timeline cyclical subscale completed within three months post-TBI between the good and poor outcome groups six months later was reported.

While controlling for psychological distress, Anderson and Fitzgerald (45) reported a positive significant correlation with moderate effect between the cyclical timeline subscale and late-enduring symptoms (RPQ13) in participants with a mean of 62 days post-injury. A lack of significant relationship and minimal effect was found with the RPQ3.

Overall, the timeline cyclical subscale gathers some evidence cross-sectionally from the stronger quality studies, particularly for late-enduring symptoms. However, no support for its association with PCS longitudinally has been reported in the included studies.

Concern

Only one cross-sectional study reported on the concern subscale (47). Using the BIPQ with participants on average 12 months post-injury, Var and Rajeswaran (47) found that concern only correlated with early symptoms with moderate effect, demonstrating that those with more concern regarding their injury reported more severe ongoing early symptoms (e.g. headache, nausea/vomiting and dizziness). The effect size was small, and correlation was non-significant for the relationship with late symptoms (RPQ13).

Only Hou and colleagues' (27) longitudinal study reported on the concern subscale using the BIPQ with participants within two weeks post-injury. They reported that the concern subscale rated two weeks post-TBI was a significant predictor of RPQ score at six months but not at three months post-TBI.

While limited by a paucity of studies, these findings suggest that the subjective level of concern about symptoms following mTBI may be an important variable in the experience of, particularly early, PPCS. However, the number of high quality studies supporting this is minimal.

Consequences

Cross-sectional findings demonstrated significant associations between the consequences subscale and PCS (47,49–51,53), indicating that those who held beliefs that their injury had more negative consequences were more likely to report ongoing PPCS. Three papers demonstrated significant between group differences in the consequences scale for those who had ongoing symptoms compared to those whose symptoms had mainly resolved (49,51,52). This relationship appeared to be consistent across time with one study reporting on participants who were an average of 41 days post-TBI; the follow-up study six months later (approx. 9 months post-TBI) and the final one at 33 months post-TBI (49,51).

Two studies (47,53) used correlational analysis to demonstrate a significant positive relationship between the consequences subscale and the RPQ with moderate to large effect

sizes. When controlling for psychological distress in the study by Anderson and Fitzgerald (45), these relationships failed to reach significance for both early and late symptoms.

Three of the longitudinal studies also evidenced significant associations between the consequences domain and outcome over time (27,52,53). Snell and colleagues (52) found a significant difference in the consequences subscale completed within three months post-TBI between good and poor outcome groups categorised six months later. However, when entered into a logistical regression model alongside coping and psychological distress variables, the consequences subscale completed within 3 months post-TBI was not a significant predictor of outcome six months later. Hou and colleagues (27) found that the consequences domain measured within a few weeks post-TBI was a significant predictor of PCS outcome at both three and six months. In the linear regression analysis by Whittaker and colleagues (53) however, the consequences domain was only predictive of functional outcome (as measured by the SRPS) and not symptomatic outcome (as measured by the RPQ). However, when entered into their logistical regression, the consequences domain was found to be a significant predictor or PCS outcome (defined by a combination of both symptoms and functioning).

Overall, higher quality papers concur that the consequences subscale appears to be an important injury perception associated with PCS severity with moderate to large effect sizes demonstrated cross-sectionally. Early beliefs about the consequences of their injury appears to be a significant predictor of PCS both three and six months later, although the salience of this subscale becomes less clear when compared with coping and psychological distress variables.

Emotional representations

Four of the five studies reporting cross-sectional analyses found significant associations between the emotional representations subscale and PCS (47,49–51) suggesting that those who report a stronger negative emotional impact as a result of the injury also report more symptoms. In their 2011 study, Snell and colleagues (51) found that of participants who were on average

41 days post-TBI, those categorised as having poor PCS outcome also perceived having significantly stronger emotional reactions to the injury compared to those in the good outcome group. However, in the 2018 study with a mean time since injury of 32 months (49), differences on this subscale between the mTBI recovered and mTBI non-recovered groups were not significant.

Using correlational analyses, Var and Rajeswaran (47) found a moderate effect size correlation between the emotional representations subscale and late symptoms only (RPQ13). The small effect size did not achieve significance for early symptoms (RPQ3). Unsurprisingly, after controlling for psychological distress, correlations between the emotional representations subscale and both the RPQ3 and RPQ13 failed to reach significance in the study by Anderson and Fitzgerald (45).

Longitudinal findings by Hou and colleagues (27) demonstrated that the emotional representations subscale rated within two weeks post-TBI was significantly associated with PCS at six months but not at three months. Effect sizes were small at both timepoints. Snell and colleagues (52) found a significant difference in the emotional representations subscale completed within three months post-TBI between good and poor outcome groups six months later. However, when coping and psychological distress variables were entered in their logistical regression model, emotional representations completed within three months post-TBI were not a significant predictor of outcome six months later.

Overall, the emotional representations subscale appears to be significantly associated with PCS severity. Higher quality studies suggest that this is particularly important over time and for late-enduring symptoms. Despite some contradictory findings, ratings on this scale in the first few weeks post-injury seem to be predictive of later PCS reporting although further high quality evidence is needed.

Coherence

Cross-sectional findings are mixed regarding the significance of the coherence subscale, that is how well an individual perceives their understanding of the injury. Snell and colleagues (51) found a significant difference in the coherence subscale between good and poor outcome groups of participants who were on average 41 days post-TBI, highlighting that those in the poor outcome group reported less understanding of their injury. However, this difference between groups failed to reach significance in a similar cross-sectional study with participants an average of 32 months post-TBI (49). Large differences in time since injury between these two studies may account for the discrepancy in findings. Anderson and Fitzgerald also reported a lack of significance in their partial correlation between the coherence subscale and both the RPQ3 (early symptoms) and RPQ13 (late symptoms) when controlling for psychological distress.

Two of the longitudinal studies reported non-significant results regarding the relationship between the coherence subscale completed within the first 3 months and outcome several months later (27,52).

Overall, the importance of the coherence subscale in PCS severity has received limited support both cross-sectionally and longitudinally.

Control (personal and treatment)

Three cross-sectional studies included the control subscales of the IPQ-R (45,47,51) with mixed findings reported between the personal and treatment control subscales. Snell and colleagues (51) reported no significant differences between good and poor outcome groups for either personal control or treatment control when measured on average 41 days post-TBI. Whittaker and colleagues (53) also did not report significant correlation between the control subscale and RPQ scores for participants within a few weeks post-TBI. In contrast, Var and Rajeswaran (47) found that the personal control subscale demonstrated a positive correlation with large effect for the RPQ13 only (and not the RPQ3) with participants on average 12

months post-TBI. They also found a moderate effect between the treatment control subscale and the RPQ13 only. These results suggest that perceptions of lower personal and treatment control are related to increased late-enduring symptoms over time. Anderson and Fitzgerald found no significant correlations between either of the control subscales with early and late RPQ scores (45) in participants with a mean of 62 days post-TBI when controlling for psychological distress.

Hou and colleagues (27) only included personal control in their longitudinal study and found that perceived personal control rated within two weeks post-TBI was significantly associated with PCS with small effect size at both three and six months post-TBI, indicating that those who believe they have less personal control over their symptoms are more likely to report higher levels of PCS. However, Snell and colleagues (52) reported no significant differences in the control subscales completed within three months post-TBI between those categorised as good and poor outcome groups six months later.

Limited evidence exists demonstrating the association between the personal control subscale. Non-significant findings taken from participants early post-TBI suggest that this domain may become more important over time; although one higher quality study did demonstrate its predictive ability from ratings early post-injury for PCS outcome at three and six months. Little evidence supporting the importance of the treatment control subscale exists other than a single, weak quality study (47) finding a moderate effect size with late-enduring symptoms 12 months post TBI.

Summary

Overall, based on the stronger quality papers, the identity, timeline (acute/chronic), consequences and emotional representations subscales all repeatedly demonstrate significant associations with PCS. The control (personal and treatment), coherence, concern and cyclical timeline domains demonstrated very limited support at present.

Injury perceptions and quality of life (QoL)

Only one study (rated as weak quality) reported on the relationship between injury perceptions and QoL outcome (46). Var and Rajeswaran (46) analysed the relationship between the injury perception domains of the BIPQ with QoL using the WHOQOL, (only the psychological and physical QoL domains will be reported here).

Significant positive correlations with moderate to large effect sizes were found between consequences, emotional representations, personal control and concern subscales with physical QoL. This indicates those who perceive more negative consequences; experience a stronger emotional impact; perceive less control and have a higher level of concern regarding their injury are more likely to experience a reduced physical quality of life. The timeline domain failed to reach significance and demonstrated a small effect.

The timeline subscale revealed moderate effect size correlations with psychological QoL highlighting that those endorsing stronger beliefs that their injury is going to last a long time are more likely to rate a poorer psychological QoL. Correlations between the consequences and the concern subscales with the psychological QoL domain demonstrated moderate effect sizes also and approached significance. The emotional representations subscale revealed a moderate effect size although the correlation was non-significant.

Injury perceptions and psychological distress

Three studies investigated psychological distress as an outcome relating to injury perceptions following TBI (48,50,55). Rogan and colleagues (48) investigated the relationship between injury perceptions using the IPQ-R and self-reported anxiety and depression using the HADS. They found significant weak to moderate effect size correlations between the identity, timeline and treatment control subscales of the IPQ-R with the HADS, suggesting that those who attribute more symptoms to the injury; believe symptoms will last a long time and perceive less treatment control will report increased psychological distress. As might be expected from

the wider research regarding injury perceptions and psychological distress, a large effect size for the correlation with emotional representations subscale and the HADS was also found.

Using cluster analysis based on the IPQ-R and HADS scores, Snell and colleagues (55) found that the 'low-adapter' cluster group (who reported stronger negative injury beliefs about identity, timeline (cyclic and acute/chronic), consequences and emotional representations) endorsed more anxiety (moderate effect) and depression (large effect) symptoms as measured using the HADS.

Bahraini and colleagues (50) compared mTBI participants with and without PTSD on the IPQ-R subscales consequences, emotional representations and coherence only. They reported significant differences between groups on the consequences and emotional representations subscales but not the coherence subscale. This suggests that those who perceive greater injury consequences and have a stronger emotional reaction to the injury are more likely to experience psychological distress in the form of PTSD post-TBI.

Discussion

This systematic review aimed to explore the relationships between injury perceptions and PPCS, QoL and psychological distress outcomes following TBI. Collectively, the results of this review corroborate previous research findings that injury perceptions are important recovery factors following TBI, particularly in those with milder injuries (36,66). These results also support previous research, highlighting significant associations between illness perceptions, reduced QoL and increased psychological distress (67).

Within this review, and in agreement with other reviews of illness perceptions in health populations (40,68), studies repeatedly demonstrated that the identity, timeline acute/chronic, consequences and emotional representations domains of illness perceptions, are particularly salient following TBI with regards to symptomatic outcome both cross-sectionally and as predictors over time. Therefore, those who attribute more symptoms to the injury; perceive that

these will last a longer time; perceive greater negative consequences and have a stronger emotional reaction to the injury are more likely to experience more PCS.

Several other illness perception domains demonstrated associations with symptomatic outcome (i.e. personal control and concern), although these were limited by inconsistent findings and few studies including them in their analyses. Discrepancies in findings across the studies may have been accounted for by a heterogeneity of injury variables, such as time since injury; however, it is difficult to decipher these from only a limited number of comparable studies.

Little support was found for the importance of the coherence or treatment control domains in PCS recovery although they did demonstrate significant relationships with psychological distress outcomes (48). In contrast to studies that demonstrate significant associations between outcome and the treatment control subscale, such as that with haemodialysis patients (69), a lack of significant findings with the treatment control subscale in this population is not particularly surprising. This is because there isn't a defined 'medical treatment' following post-acute care after TBI and, instead, a holistic approach to rehabilitation and psychosocial adjustment ensues. However, the lack of significance regarding the coherence subscale, i.e. the perceived level of understanding about their injury, is surprising given that psychoeducation is often one of the main interventions recommended following (predominantly mild) TBI (70–72). This finding contradicts results from a study on individuals and their carers following stroke (25) which found that patients' distress soon after the stroke was significantly associated with low coherence. However, this study controlled for other variables including disability and social support which may account for such differences.

Anderson and Fitzgerald (45) controlled for psychological distress in their cross-sectional analyses examining injury perceptions and PCS. Here, only the identity and cyclical timeline subscales remained significant, suggesting their importance in PCS above and beyond

the influence of psychological distress. As research has already demonstrated strong correlations between PPCS and depression, it is unsurprising that controlling for this in statistical analyses leaves little variance left for illness perceptions to explain. Large amounts of covariance within PCS literature contributes to the difficulties in empirically investigating and untangling prognostic and covariate factors, thus perhaps more complex statistical models are required to further understand outcomes in this population. With regards to the investigation of injury perceptions specifically, coping behaviours in particular are important to consider given that they are a key component of Leventhal's models of illness behaviour (19,73).

Results from this review contrast other studies with trauma patients investigating the association between illness perceptions and QoL (21,22). Comparison of results suggests that perceived consequences and possibly level of concern and personal control are more salient to the TBI population compared to the orthopaedic trauma population, albeit with some mixed and limited results. A variety of factors may account for such differences for example potential societal beliefs about the association between the brain and the 'self'. Understandably, increasing concerns about a loss or change in the self may be more likely to follow a TBI compared to an orthopaedic injury may ensue, influencing more negative perceived consequences and a lack of control recovery and rehabilitation.

The identity, timeline, treatment control, consequences and emotional representations subscales all demonstrated significant relationships with psychological distress outcomes. However, one might argue that these findings are unsurprising and as only cross-sectional studies have been conducted to date, it is difficult to determine the direction of these relationships. Moreover, these findings are somewhat concordant with findings that psychological distress was associated with stronger illness identity, more negative consequences and stronger causal beliefs regarding psychological factors in individuals several months following a stroke (25). The significance of timeline, treatment control and emotional

representations may be more relevant to individuals following TBI, although such generalisations are limited by results from a single study.

Limitations of included studies

A number of common limitations were reported across the studies: predominantly recruitment bias and the reliance on self-report measures. As most studies recruited through clinical services, it is likely that a significant proportion of the mildest severity of TBI patients may have been missed as many might not attend hospital or access specialist services. However, individuals with mTBI were over-represented in this review as only two out of twelve studies reported on moderate and severe TBI. Perhaps one reason contributing to this over-representation of mTBI is the view that ongoing difficulties following mTBI are largely considered to be psychological in nature, attracting more research into injury perceptions. However, as several studies demonstrate PPCS in moderate to severe TBI also (6), these concepts may also apply to those with more severe injuries also, albeit with due consideration of cognitive difficulties, and may well be useful in informing psychological adjustment and recovery.

Furthermore, reporting bias was acknowledged in the majority of included studies due to reliance on self-report measures: an inevitability when investigating participants' internal worlds. More objective means of assessing outcome than the RPQ, for example, may be useful. The inclusion of studies using only validated measures increases confidence that higher quality data was reviewed.

A further difficulty in interpretation, particularly of cross-sectional studies, is that those with ongoing difficulties as a result of their TBI are understandably more likely to have different beliefs about their injury compared to those who have made a good recovery. Consequently, the direction of this relationship is difficult to understand; i.e. whether injury perceptions influence symptoms or vice versa, using correlational analyses alone. Longitudinal

studies offer more towards investigating the predictive ability of injury perceptions and changes in beliefs over time in keeping with Leventhal's CSM of health and illness behaviour (19).

Interestingly, in their analysis of mean changes in injury perceptions from three to nine months post-TBI, Snell and colleagues (52) found that participants had weaker identity beliefs over time following natural recovery, but stronger beliefs about the expected duration and consequences of their injury and a greater understanding of it. This evidences part of the evolving nature of injury perceptions which are likely to be both influenced by, and influencing, the experience of PPCS. However, as noted above and in line with neuropsychological models of TBI recovery (8,26), the relationship between injury perceptions and TBI outcome is likely to be much more complex and influenced by a range of biopsychosocial factors.

Limitations of this review

Limitations in synthesising data across studies where there is heterogeneity of injury variables between participants (e.g. time since injury) were present, making it difficult to draw clear conclusions (74), particularly with only a small number of studies investigating each type of outcome. A scarcity of studies investigating the role of illness perceptions is consistent with other clinical populations and indeed a very similar systematic literature review published in 2020 investigating illness perceptions after paediatric TBI found just six papers (43).

Cultural differences between participants across the studies included in this review may also have influenced disparities in findings reported. Several studies have reported on significant differences in injury perceptions and outcomes between English-speaking and culturally diverse groups following TBI (75,76).

As with all systematic literature reviews, despite careful consideration of search terms and cross-checking of reference lists, it cannot be guaranteed that all relevant studies were

included in the review, particularly due to the variability in definitions and terminology surrounding TBI, PPCS and psychological distress.

Clinical implications and future research

Despite a dearth of studies in this area, emerging evidence indicates the predictive value of injury perceptions, particularly on symptomatic and QoL outcomes following TBI.

While it is difficult to provide an all-encompassing message regarding illness perceptions that is relevant to all individuals following TBI, the current literature review suggests that normalising early post-concussion symptoms; providing basic emotional management strategies and emphasising personal control in dealing with symptoms and recovery are likely to be clinically efficacious.

Previous research targeting illness perceptions through cognitive behavioural interventions have demonstrated some efficacy in reducing the incidence of PPCS in the TBI population (33–35). However, some of the difficulty in creating a consistent and unified approach to such interventions following mTBI is the range of professional disciplines who support a person in the early weeks and months post-injury. Each discipline brings a unique level of knowledge and experience of mTBI and a variable awareness of the psychological research literature. Often by the time a person is seen by a psychologist for support with PPCS, they are much further in their journey of PPCS and so negative perceptions may have been reinforced over time. Given that injury perceptions and beliefs will be developing in the early days post-injury, a role for clinical psychology within acute care, informing the MDT and guiding information giving (e.g. prognosis), will likely be the most efficacious preventative approach to PPCS. Embedding knowledge of the specific injury perceptions that relate to reduced PPCS in other professionals is key in order to ensure this becomes part of routine practice.

Finally, the significance of findings highlighted within the current review calls for more

research exploring the relationship between injury perceptions and TBI outcome. Longitudinal studies using robust outcome measures would be useful in further understanding injury perceptions over time and their impact on PCS, QoL and psychological wellbeing outcomes. The majority of studies in this review focused on mTBI, so the importance of injury perceptions in moderate to severe TBI warrants further investigation also. Studies should attempt to control for confounding variables identified already within the research literature and ideally, outcome measures chosen should be consistent across studies to improve comparability.

Conclusions

In conclusion, the available research indicates that injury perceptions have important implications for QoL outcomes and the experience of PPCS following TBI. Specifically, the attribution of more symptoms to the TBI; more negative perceived consequences; a longer perceived duration of post-TBI symptoms and a stronger emotional reaction are important factors affecting outcome. However, the evidence base remains limited and further high-quality, longitudinal research exploring the relationships between specific injury perceptions is needed across TBI severities using validated measures. It is hoped that an increasing awareness of the importance of injury perceptions and working towards addressing these routinely within services may contribute to improvements in recovery following TBI.

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Tables and figures

Figure 1. PRISMA diagram for literature search screening process

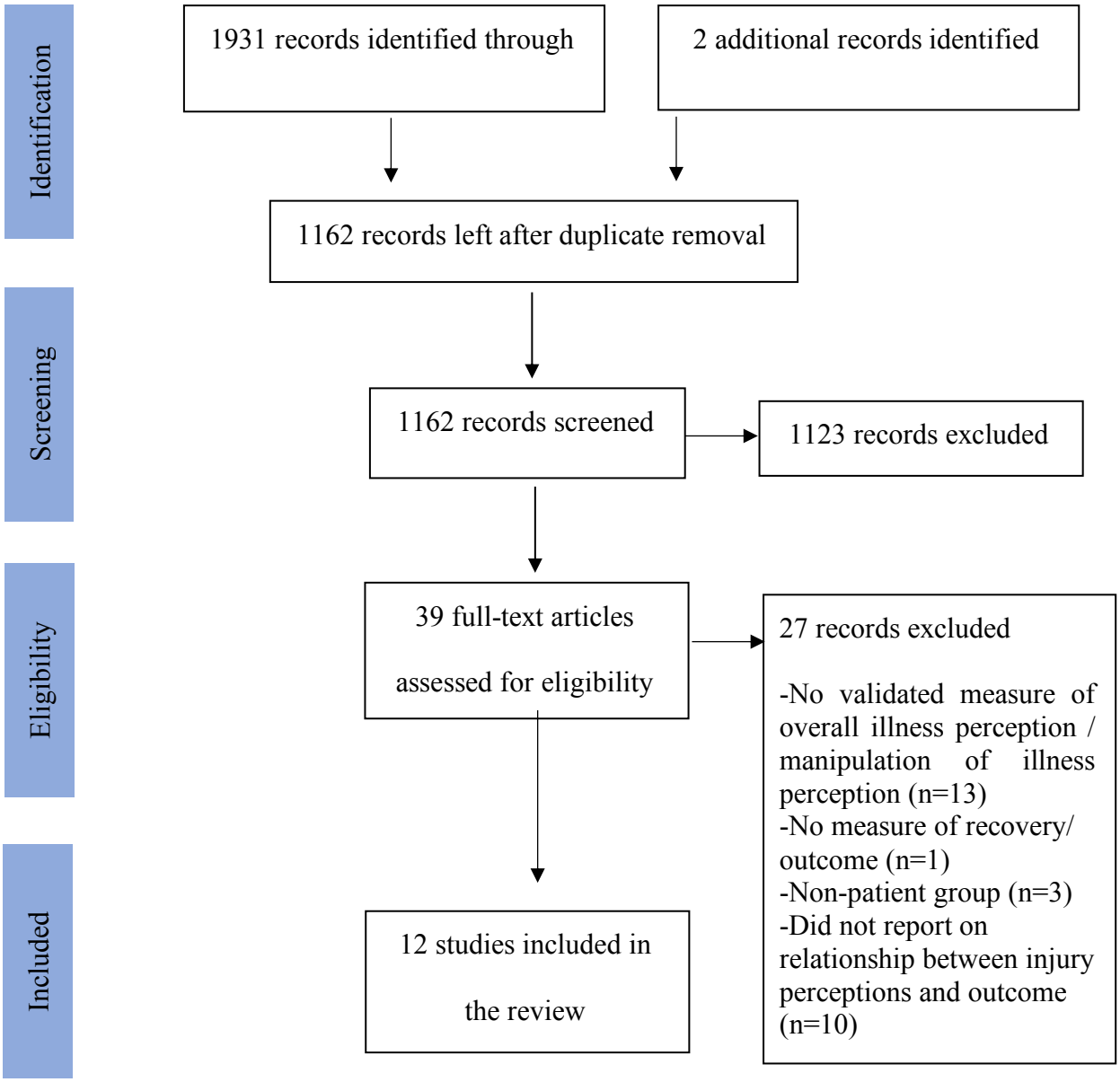

Table 1 - Summary of Study and Sample Characteristics

Author (year)	Country	Sample size	Recruitment Site	Demographic characteristics		Clinical characteristics			
				Age (Mean, SD)	**Gender (% male)**	**TBI severity**	**Time since injury (Mean (SD))**	**Previous TBI (%)**	**Mental health history (%)**
Anderson & Fitzgerald (2018)	Australia	61	Hospital inpatient ward	36.10, (13.46)	62%	Mild	62.05 days (11.21)	26%	27%
Bahraini, Monteith, Gerber, Forster, Hostetter & Brenner (2017)	USA	80 (22 mTBI +PTSD, 20 mTBI no PTSD, 15 non-TBI + PTSD, 23 non-TBI no PTSD)	Veterans affairs Eastern Colorado Healthcare system	31.43 (5.96)	82.5%	Mild	Mean 6 years post-injury in conditions 1,2 and 3, mean 4 years for condition 4 (No SDs reported)	"mTBI+PTSD" group: mean of 1.9 previous TBI's, "mTBI no PTSD" group: mean 1.6 previous TBI's	Not reported
Hou & Moss-Morris (2012)	UK	126	Hospital emergency department	38.32 (14.14)	63%	Mild	Baseline (< 2 weeks post-injury) Follow-ups at 3 months and 6 months	Not reported	Not reported
Jones, Theadom, Barker-	New Zealand	92	Identified as part of prospective	39.42 (17.33)	60%	Mild	Baseline of 1 month and follow-up 4	45%	Not reported

Collo, Broadbent & Feigin (2019)			population-based TBI incidence and outcomes study				years post-injury		
Rogan, Fortune & Prentice (2013)	UK	70 (56% TBI, 31% CVA, 13% other types of brain injury e.g. hypoxia, tumour, abcess and encephalitis)	Post-acute rehabilitation service	Range 19-65 (SD = 12)	70%	Of the 56% TBI: 87% severe, 13% moderate. Of the 44% non-TBI: all moderate	70.43 months (55.30)	Not reported	Not reported
Snell, Siegert, Hay-Smith & Surgenor (2011)	New Zealand	147	Emergency Department and outpatient concussion clinic	41.8 (15.7)	44.2%	Mild	41.1 days (24.2)	27.9%	34.2%
Snell, Hay-Smith, Surgenor & Siegert (2013)	New Zealand	125 (follow-up from same participants as above)	Emergency Department and outpatient concussion clinic	43.6 (15.8)	44.2%	Mild	Baseline 3 months post-injury, follow-up 6 months later	27.9%	34.2%
Snell, Surgenor, Hay-Smith,	New Zealand	147	Emergency Department and outpatient	41.8 (15.7)	44.2%	Mild	Baseline 3 months post-injury,	27.9%	34.2%

Williman & Siegert (2015)		(same participants as above)	concussion clinic				follow-up 6 months later		
Snell, Martin, Macleod, Surgenor, Siegert, Hay-Smith et al (2018)	New Zealand	102	Specialist Concussion service and Pain Management Service based at a Rehabilitation Hospital	46.48 (14.01)	49.02%	Mild	32.34 months (51.85)	48.04%	42.16%
Var & Rajeswaran (2012)	India	31	Neurosurgery and Neuropsychology Outpatient services	38.13 (8.82)	100%	Mild to moderate	12.43 months (12.95)	Excluded	Excluded
Var & Rajeswaran (2013)	India	30	Neurosurgery and Neuropsychology Outpatient services	38.13 (8.82)	100%	60% mild, 40% moderate	3 months post-injury	Excluded	Excluded
Whittaker, Kemp & House (2007)	UK	73	Accident & Emergency Department	41.8 (1.0)	43%	Mild	Baseline 1-3 weeks post injury, follow-up 3 months	Not reported	Not reported

Table 2 - Key Characteristics and Findings of Included Studies

Author (year, reference number)	Study design	Study Outcomes			Analysis	Main findings / outcomes
		Illness Perception measure used	**Primary outcome measure used**	**Additional outcomes**		
Anderson & Fitzgerald (2018, (45))	Cross-sectional	IPQ-R	RPQ (RPQ-3 and RPQ-13)		Pearson's product moment correlation (r), hierarchical linear regression	Significant moderate positive correlation between the identity subscale of the IPQ-R and both RPQ3 ($r=.453$, $p<.005$) and RPQ 13 ($r=.511$, $p<.005$). Significant positive weak correlation between timeline cyclical subscale of the IPQ-R and the RPQ 13 ($r=.314$, $p<.05$) Hierarchical regression analyses found that adding the identity subscale of the IPQ-R plus coping style significantly contributed to the predictability of the model for both RPQ 1-3 ($R^2=.216$, $p=.001$) and RPQ 4-16 ($R^2=.171$, $p=.002$), explaining 43% and 45% of the variance respectively.
Bahraini, Monteith, Gerber, Forster, Hostetter &	Observational 2x2 factorial Group 1: mTBI/PTSD	IPQ-R	PCL-C	NSI	Analysis of variance, chi-squared tests and factorial analysis of covariance	Significant difference between group 1 and group 2 on the consequences ($p=.005$) and emotional representations ($p=.0003$) subscales but not the coherence subscale.

Brenner (2017, (50))	Group 2: mTBI/no PTSD Group 3: physical injury/PTSD Group 4: physical injury/no PTSD					Significant differences between group 1 and 2 on all NSI domains; somatic (p=.0001), cognitive (p=.0001) and affective (p=.0001).
Hou & Moss-Morris (2012, (27))	Prospective cohort study Time 1: baseline within 2 weeks of mTBI Time 2: 3 months post-TBI Time 3: 6 months post-TBI	B-IPQ	RPQ (cut-off score divided participants into probable PCS and probable non-PCS)		Logistic regression analysis, multivariate analysis	Total BIPQ score was a significant predictor of continuing PCS symptoms at 3 months (OR=1.047, p=.003, CI [1.016-1.079]) and 6 months (OR=1.066, p=.000, CI [1.030-1.104]). The identity (OR=1.156, p=.046), control (OR=1.188, p=.013), timeline (OR=1.426, p=.001) and consequences (OR=1.257, p=.006) subscales of the B-IPQ were significant predictors of PCS at 3 months and also at 6 months with emotional representations (OR=1.196, p=.014) and concern (OR=1.210, p=.007) also becoming significant predictors at 6 months. Logistic regression found illness perceptions was significant independent predictor of PCS (OR=1.053, p=.021).
Jones, Theadom, Barker-Collo, Broadbent & Feigin (2019, (54))	Prospective longitudinal Time 1: 1 month post-TBI	B-IPQ	RPQ (RPQ-3 and RPQ-13)	Brain drawings,	Spearman's rho correlations and stepwise linear regression for association with outcomes,	Using linear regression, total B-IPQ scores (p<.001) and history of prior TBI (p=.01) showed significant linear relationships with late-onset PCS development (RPQ-13).

	Time 2: 4 years post-TBI Divided into groups based on brain-drawings: Group 1: no damage drawn Group 2: <10% damage drawn Group 3: 10-100% damage drawn				analysis of variance for between group comparisons	Greater percentage damage depicted on drawings was significantly positively correlated with negative illness perceptions (consequences ($p<.001$), timeline ($p<.001$), identity ($p<.001$) and emotional representations ($p<.002$)) at 4 years post-injury. Greater damage depicted at 1 month was significantly positively correlated with total RPQ-13 ($p=.001$), taking longer to think ($p<.001$) and sensitivity to light ($p=.002$) but no other RPQ symptoms.
Rogan, Fortune & Prentice (2013, (48))	Cross-sectional	IPQ-R	HADS,		Correlation and hierarchical multiple regression	Several BIPQ domains significantly positively associated with distress; identity ($r=.442$, $p<.01$), timeline ($r=.238$, $p<.05$), treatment control ($r=-.272$, $p<.05$) and emotional representations ($r=.609$, $p<.01$).
Snell, Siegert, Hay-Smith & Surgenor (2011, (51))	Prospective study with repeated measures Good outcome and poor outcome groups created based on set criteria inc RPQ and RHIFUQ	IPQ-R	RPQ (total)	HADS	Chi-square, t-tests	Those categorised as having 'poor outcome' had higher symptom reports (RPQ scores), greater social and functional problems (RHIFUQ scores), increased distress (HADS scores) and stronger beliefs regarding the identity, consequences, timeline (both acute/chronic and cyclic), and less coherence as per the IPQ-R. Significant differences between good outcome and poor outcome groups on each domain of the IPQ-R (all $p<.05$)

						with the exception of the personal control (p=.084) and treatment control (p=.128) domains.
Snell, Hay-Smith, Surgenor & Siegert (2013, (52))	Prospective study with repeated measures Good outcome and poor outcome groups created based on set criteria inc RPQ and RHIFUQ Time 1: within 3 months post-TBI Time 2: 6 months later	IPQ-R	RPQ (total)	HADS	Chi-squared tests, t-tests and logistic regression	Significant associations between RPQ at 6 months and baseline IPQ-R identity (*d*=.5), consequences (*d*=.6) and emotional representations (*d*=.6) and RPQ scores. Univariate relationships between negative injury perceptions at baseline and poor outcome after 6 months were demonstrated for IPQ-R domains; identity (*d*=.3), consequences (*d*=.2), timeline (*d*=.2) and emotional representations (*d*=.3). Logistic regression analyses did not reach significance with identity, consequences or emotional representations subscales (only the Brief-COPE approach dimension reached significance).
Snell, Surgenor, Hay-Smith, Williman & Siegert (2015, (55))	Prospective study with repeated measures Sample split into three clusters (based on IPQ-R identity and beliefs subscales and HADS): high,	IPQ-R	RPQ (total)	HADS	Two-step cluster analysis and linear mixed effects regression modelling	Cluster analysis (based on the identity and beliefs subscales of the IPQ-R and the HADS) revealed 3 distinct clusters; 'high', 'medium' and 'low' adapters. 'Low-adapters' had stronger negative beliefs about identity (*r*=.4), timeline cyclic (*r*=.3), timeline acute/chronic (*r*=.3), emotional representations (*r*=.6), and coherence (*r*=.2). 'Low

	medium and low adapters					adapters' also reported greater anxiety (*r=.4)* and depression (*r*=.6) than the other two groups using the HADS. Significant differences in RPQ scores between the three cluster groups found at time one. High adapters endorsed fewer symptoms at times 1 and 2. Low and medium adapters endorsed similar symptoms at time 1, but by time 2 RPQ scores for medium adapters were akin with the high adapters group. Significant differences found between low adapters and both other groups at time 2 (p<.001).
Snell, Martin, Macleod, Surgenor, Siegert, Hay-Smith et al (2018, (49))	Cross-sectional matched control Group 1: mTBI recovered Group 2: mTBI non-recovered Group 3: chronic pain	IPQ-R	RPQ (total, somatic, cognitive, emotional)	QOLIBRI, HADS	Chi-squared tests, analysis of variance and multiple regression	Significant differences (p<.05), between mTBI recovered and mTBI non-recovered groups on the identity, timeline (acute/chronic), timeline (cyclic) and consequences domains of the IPQ-R. Significant differences between groups on RPQ scores, HADS scores and QOLIBRI scores.
Var Rajeswaran (2012, (47))	Cross-sectional	B-IPQ	RPQ (RPQ-3 and RPQ-13)		Correlation	Significant positive weak-moderate correlations between RPQ3 and IPQ-R (timeline (r=.369, p<.05), concern (r=.402, p<.05) and total score (r=.384, p<.05)). Significant weak-moderate positive correlation between RPQ13 and IPQ-R (consequences (r=.568, p<.01),

					personal control (r=.609, p<.01), treatment control (r=.383, p<.05), Emotional response (r=.442, p<.05) and total score (r=.622, p<.01).
Var & Rajeswaran (2013, (46))	Cross-sectional WHOQOL-BREF scores split into physical, psychological, environmental and overall.	B-IPQ	WHOQOL-BREF,	Correlation	Significant correlation between physical QoL and overall B-IPQ, consequences and emotional responses (p< .01) and also with personal control and concern (p<.05) but not timeline. Significant correlation between psychological QoL and overall B-IPQ (p<.01) and timeline (p<.05) domains. Significant correlation between environmental QoL and overall B-IPQ only (p<.05). Significant correlation between total QoL and the overall B-IPQ (p<.05) and emotional response (p<.05).
Whittaker, Kemp & House (2007, (53))	Longitudinal Time 1: 1-3 weeks post-TBI Time 2: 3 months post-TBI	IPQ-R	RPQ (total)	Hierarchical logistic regression	Significant positive correlation between RPQ scores and IPQ-R scores at time 1 for the identity subscale (r=.859, p<.004) and consequences subscale (r=.526, p<.004). No significant association between RPQ and IPQ-R timeline scores. IPQ-R consequences subscale was a significant independent predictor of symptom outcome (RPQ). IPQ-R consequences and timeline subscales combined predicted development of PCS in 80% of cases.

Notes. RPQ = Rivermead Post-concussion Symptoms Questionnaire, IPQ-R = The Illness Perceptions Questionnaire – Revised, B-IPQ = Brief Illness Perceptions Questionnaire, NSI = Neurobehavioural Symptom Inventory, HADS = Hospital Anxiety and Depression Scale, WHOQOL-B = World Health Organisation Quality of Life – Brief version, QOLIBRI = Quality of Life after Brain Injury, PCL-C = PTSD Checklist – Civilian version.

Appendices

Appendix A – Search terms used during search strategy

Free-text search terms in Title/Abstract fields across all databases	
Concept 1: TBI	"TBI" OR "traumatic brain injury" OR "mTBI" OR "post-concussion"
AND	
Concept 2: Illness perceptions	"percept*" OR "belie*" OR "expectation* OR "representation" OR "cognition*"
AND	
Concept 3: Recovery / Outcome	"symptom*" OR "outcome*" OR "quality of life" OR "QOL" OR "mood" OR "depression" OR "anxiety"

MeSH/ Thesaurus terms used across individual databases			
Database	Concept 1: TBI	Concept 2: Illness perceptions	Concept 3: Recovery / outcome
MEDLINE	(MH "Brain Concussion") OR (MH "Brain Injuries, Traumatic")	/	(MH "Patient Reported Outcome Measures+") OR (MH "Quality of Life") OR (MH "Affective Symptoms") OR (MH "Depression") OR (MH "Mood Disorders")
CINAHL	(MH "Brain Injuries") OR (MH "Brain Concussion") OR (MH "Postconcussion Syndrome")	(MH "Health Beliefs") OR (MH "Attitude to Illness")	(MH "Patient-Reported Outcomes") OR (MH "Recovery") OR (MH "Quality of Life") OR (MH "Psychological Well-Being") OR (MH

			"Affective Disorders") OR (MH "Depression") OR (MH "Affective Symptoms") OR (MH "Postconcussion Syndrome")
PsycINFO	(DE “traumatic brain injury”) OR (DE “brain concussion”)	(DE “Physical Illness (Attitudes Toward)”) OR (DE “Illness Behavior”)	(DE "Quality of Life") OR (DE "Health Related Quality of Life") OR (DE "Quality of Life Measures") OR (DE "Depression (Emotion)") OR (DE "Anxiety Disorders") OR (DE "Affective Disorders") OR (DE "Major Depression") OR (DE "Symptoms") OR (DE "Spontaneous Recovery (Learning)") OR (DE "Recovery (Disorders)")
AMED	(ZU "brain concussion") or (ZU "brain injuries traumatic")	No relevant thesaurus terms identified	(ZU "quality of life") OR (ZU "depression") or (ZU "depressive disorder") or (ZU "mood disorders") or (ZU "anxiety disorders")

Appendix B – Quality Assessment Ratings of Included Studies

Study	Selection bias	Study design	Confounders	Data collection methods	Withdrawal and drop-outs	Analyses	Global rating
Anderson & Fitzgerald (2018)	weak	moderate	moderate	moderate	n/a	strong	moderate
Bahraini, Monteith, Gerber, Forster, Hostetter & Brenner (2017)	moderate	moderate	strong	weak	n/a	strong	moderate
Hou & Moss-Morris (2012)	strong	moderate	moderate	strong	strong	strong	strong
Jones, Theadom, Barker-Collo, Broadbent & Feigin (2019)	weak	moderate	moderate	strong	weak	strong	weak
Rogan, Fortune & Prentice (2013)	weak	weak	moderate	strong	n/a	strong	weak

Snell, Siegert, Hay-Smith & Surgenor (2011)	moderate	moderate	strong	weak	n/a	strong	moderate
Snell, Hay-Smith, Surgenor & Siegert (2013)	moderate	moderate	strong	weak	strong	strong	moderate
Snell, Surgenor, Hay-Smith, Williman & Siegert (2015)	moderate	moderate	strong	moderate	strong	strong	strong
Snell, Martin, Macleod, Surgenor, Siegert, Hay-Smith et al (2018)	moderate	moderate	strong	moderate	n/a	strong	strong
Var Rajeswaran (2012)	moderate	weak	weak	moderate	n/a	weak	weak
Var & Rajeswaran (2013)	moderate	weak	weak	moderate	n/a	weak	weak
Whittaker, Kemp & House (2007)	moderate	moderate	weak	weak	moderate	strong	weak

Appendix C – EPHPP Quality Assessment Tool

QUALITY ASSESSMENT TOOL FOR QUANTITATIVE STUDIES

EPHPP
Effective Public Health Practice Project

COMPONENT RATINGS

A) SELECTION BIAS

(Q1) Are the individuals selected to participate in the study likely to be representative of the target population?

1 Very likely
2 Somewhat likely
3 Not likely
4 Can't tell

(Q2) What percentage of selected individuals agreed to participate?

1 80 - 100% agreement
2 60 – 79% agreement
3 less than 60% agreement
4 Not applicable
5 Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

B) STUDY DESIGN

Indicate the study design

1 Randomized controlled trial
2 Controlled clinical trial
3 Cohort analytic (two group pre + post)
4 Case-control
5 Cohort (one group pre + post (before and after))
6 Interrupted time series
7 Other specify _____
8 Can't tell

Was the study described as randomized? If NO, go to Component C.

No Yes

If Yes, was the method of randomization described? (See dictionary)

No Yes

If Yes, was the method appropriate? (See dictionary)

No Yes

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

1

C) CONFOUNDERS

(Q1) Were there important differences between groups prior to the intervention?

1 Yes
2 No
3 Can't tell

The following are examples of confounders:

1 Race
2 Sex
3 Marital status/family
4 Age
5 SES (income or class)
6 Education
7 Health status
8 Pre-intervention score on outcome measure

(Q2) If yes, indicate the percentage of relevant confounders that were controlled (either in the design (e.g. stratification, matching) or analysis)?

1 80 – 100% (most)
2 60 – 79% (some)
3 Less than 60% (few or none)
4 Can't Tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

D) BLINDING

(Q1) Was (were) the outcome assessor(s) aware of the intervention or exposure status of participants?

1 Yes
2 No
3 Can't tell

(Q2) Were the study participants aware of the research question?

1 Yes
2 No
3 Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

E) DATA COLLECTION METHODS

(Q1) Were data collection tools shown to be valid?

1 Yes
2 No
3 Can't tell

(Q2) Were data collection tools shown to be reliable?

1 Yes
2 No
3 Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

F) WITHDRAWALS AND DROP-OUTS

(Q1) Were withdrawals and drop-outs reported in terms of numbers and/or reasons per group?

1 Yes
2 No
3 Can't tell
4 Not Applicable (i.e. one time surveys or interviews)

(Q2) Indicate the percentage of participants completing the study. (If the percentage differs by groups, record the lowest).

1 80 -100%
2 60 - 79%
3 less than 60%
4 Can't tell
5 Not Applicable (i.e. Retrospective case-control)

RATE THIS SECTION	STRONG	MODERATE	WEAK	
See dictionary	1	2	3	Not Applicable

G) INTERVENTION INTEGRITY

(Q1) What percentage of participants received the allocated intervention or exposure of interest?

1 80 -100%
2 60 - 79%
3 less than 60%
4 Can't tell

(Q2) Was the consistency of the intervention measured?

1 Yes
2 No
3 Can't tell

(Q3) Is it likely that subjects received an unintended intervention (contamination or co-intervention) that may influence the results?

4 Yes
5 No
6 Can't tell

H) ANALYSES

(Q1) Indicate the unit of allocation (circle one)

community organization/institution practice/office individual

(Q2) Indicate the unit of analysis (circle one)

community organization/institution practice/office individual

(Q3) Are the statistical methods appropriate for the study design?

1 Yes
2 No
3 Can't tell

(Q4) Is the analysis performed by intervention allocation status (i.e. intention to treat) rather than the actual intervention received?

1 Yes
2 No
3 Can't tell

GLOBAL RATING

COMPONENT RATINGS
Please transcribe the information from the gray boxes on pages 1-4 onto this page. See dictionary on how to rate this section.

A	**SELECTION BIAS**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
B	**STUDY DESIGN**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
C	**CONFOUNDERS**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
D	**BLINDING**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
E	**DATA COLLECTION METHOD**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
F	**WITHDRAWALS AND DROPOUTS**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	Not Applicable

GLOBAL RATING FOR THIS PAPER (circle one):

1	STRONG	(no WEAK ratings)
2	MODERATE	(one WEAK rating)
3	WEAK	(two or more WEAK ratings)

With both reviewers discussing the ratings:

Is there a discrepancy between the two reviewers with respect to the component (A-F) ratings?

No Yes

If yes, indicate the reason for the discrepancy

1 Oversight
2 Differences in interpretation of criteria
3 Differences in interpretation of study

Final decision of both reviewers (circle one):

1 STRONG
2 MODERATE
3 WEAK

Section Two: Research Paper

Self-criticism, self-reassurance, injury perceptions and persistent post-concussion symptoms following traumatic brain injury

Word count: 7838 words (excluding tables, references and appendices)

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[1] see Additional Appendices - Appendix A for submission guidelines

Abstract

Persistent post-concussion symptoms (PPCS) affect a subset of individuals following traumatic brain injury (TBI) causing significant functional disability, even in those with mild injuries. Despite pre-injury psychological and individual personality factors being recognised as important within neuropsychological models of PPCS, self-criticism or self-reassurance have yet to be investigated in the PPCS literature. 41 participants between 3 and 12 months post-TBI of mild to moderate severity took part in this cross-sectional study. Self-report measures were used to collect data pertaining to current PPCS; depression; previously known predictors including injury perceptions and perceptions of cognitive functioning; and both self-criticism and self-reassurance as new variables for investigation. Both self-criticism and self-reassurance demonstrated moderate effect size correlations with PPCS and post-TBI depression. Self-criticism was an independent predictor of enduring PPCS and post-TBI depression, above and beyond previously known predictors. Self-reassurance did not demonstrate predictive ability for any of the outcomes investigated. Findings highlight that high levels of self-criticism in individuals following TBI may be a target for future intervention research both as a preventative approach to PPCS and also therapeutically for those with ongoing symptoms. Further research is necessary to replicate these findings across larger samples and to explore the nature of these relationships using more complex statistical methods.

Keywords: post-concussion, Traumatic brain injury, self-criticism, self-reassurance, perceptions

Introduction

Of the 1.4 million cases of TBI presenting to hospitals in the UK each year, mild severity traumatic brain injury (mTBI), accounts for approximately 80%, equating to over 1.1

million mTBI cases each year (1). The true prevalence of mTBI however, is difficult to decipher given that a number of people may not attend hospital for treatment following mTBI, particularly in cases with brief or no loss of consciousness. Varying approaches to the definition of mTBI complicates the issue further, with a variety of published classification systems having similar yet subtly different criteria (2,3). Moreover, there is variability in the range of injuries classified as mTBI from minor concussion to 'complicated mTBI' whereby injuries to the brain (i.e. bruising or bleeding) are observable on brain imaging.

Despite the varying classification systems, generally mTBI is defined based on three variables: Glasgow Coma Scale score (GCS; (4)) of 13-15; duration of loss or altered state of consciousness of less than 30 minutes and duration of post-traumatic amnesia (PTA) of less than 24 hours (5). Despite classification and diagnostic uncertainties, the incidence of mTBI has been considered a public health concern by the US Center for Disease Control (6) and remains an important area for continued research regarding aetiology and treatment.

'Post-concussion symptoms' are a common experience following mTBI. Symptoms usually span physical, cognitive and emotional domains and can include dizziness, headache, memory and concentration difficulties, sleep disturbance and irritability. Symptoms can be categorised as early onset (i.e. physical symptoms such as headache, dizziness and nausea) which are hypothesised to be a direct result of the neurological insult, and late onset (i.e. cognitive difficulties, irritability, fatigue etc) which are considered to be 'secondary' (7). For most people, symptoms resolve within a few weeks to months and pre-injury levels of functioning are resumed. However, for some people, symptoms remain and cause considerable functional disability which appears disproportionate to the severity of the initial mTBI. These ongoing symptoms are subsequently termed 'persistent post-concussion symptoms' (PPCS; (8)).

It is important to acknowledge at this point that the acronym 'PCS' was previously used (and is sometimes still referred to clinically) for the diagnostic term "post-concussion syndrome". While this diagnosis was included in both the Diagnostic and Statistical Manual of Mental Disorders fourth edition (DSM-IV; (9)) and the International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10; (10)), it has since been removed from the latest edition of the DSM (DSM-V). Instead, PPCS is categorised under "Major or Mild Neurocognitive Disorder due to Traumatic Brain Injury". This change follows years of debate surrounding the concept of PPCS as a syndrome and the usefulness of diagnostic labelling in PPCS has been questioned (8). Consequently, PPCS will be used to refer to 'persistent post-concussion symptoms' in this paper.

In their theoretical review, Silverberg and Iverson (11) concluded that pre-injury psychological factors are among the strongest predictors of the severity and course of PPCS. They also suggested that early post-concussion symptoms cause psychological distress and the individual's response to this distress determines their ongoing experience and ultimately the potential for developing PPCS. In a more recent review, Williams, Potter and Ryland (12) concluded that while careful formulation of both neurological and psychosocial factors are always important following mTBI, psychological factors specifically (such as self-appraisal of symptoms) have a significant role in the persistence of symptoms.

Following the increasing number of relevant factors to PPCS being identified, several integrative models have been developed over the years linking pre-, peri- and post-injury variables (11,13,14). In the early 1990s, Kay and colleagues (13) proposed that a complex interplay between neurological, physical, psychological, social and personality factors contribute to the development of PPCS. They posited that early cognitive symptoms following TBI (e.g., slower processing speed, reduced concentration) evoke a psychological response whereby the person may experience "failure, frustration and an inability to perform as usual"

(pp. 378). Anxiety ensues and leads to avoidance of situations which further contributes to the experience of depression. Both anxiety and depression exacerbate initial cognitive difficulties creating a vicious cycle. Kay and colleagues also purported that personality factors influence these processes through the initial reaction to symptoms and subjective cognitive appraisal, through vulnerable personality styles (e.g. being "an overachiever"; pp. 379) and also through the emotional response to the symptoms.

Similarly, in Silverberg and Iverson's biopsychosocial representation of PPCS, personality characteristics, such as perfectionism and anxiety sensitivity, are captured among the relevant pre-injury factors (11) in addition to post-injury illness behaviours and expectations. In their proposed, broader model of PCS, Hou and colleagues (14) also recognise the relevance of pre-injury factors including anxiety, depression and expectations and further note the separate cognitive, emotional and behavioural perpetuating factors of PPCS which include illness perceptions, anxiety and depression, and limiting behaviours (such as avoidance).

All three models described above acknowledge the importance of both subjective appraisals or 'injury perceptions' and premorbid personality factors for PPCS outcome. Symptom appraisals have been increasingly investigated within the TBI literature and have been shown to be implicated in PPCS (15–18). One specific type of appraisal that has demonstrated associations with PPCS is perceptions of cognitive functioning. In a sample of 140 veterans with TBI, Samuelson and colleagues found that perception of cognitive functioning (but not actual cognitive performance) mediated the relationship between PTSD diagnosis and functional outcomes with large effect size (19). Similarly, Spencer and colleagues reported a lack of correlation between objective and subjectively perceived cognitive functioning, noting that only perceived cognitive functioning was associated with emotional distress outcomes such as anxiety, depression and PTSD (20) following TBI. These

studies further highlight the importance of perceptions of cognitive abilities in PPCS recovery over and above actual cognitive ability.

In addition to perceptions of cognitive performance, Leventhal's common sense model (CSM) of illness behaviours (which was later developed into the self-regulatory model; SRM; (20,21)) is another model of perceptions/appraisals, taken from the health psychology literature, which has been increasingly applied to the TBI population. This model suggests that following an illness event, individuals create cognitive representations which include information such as the illness identity, expected duration, consequences, causes and controllability of symptoms, alongside an emotional response. Such cognitive and emotional representations then influence the person's approach to coping which is later appraised for its effectiveness.

Based on Leventhal's models described above, the prospective cohort study conducted by Hou and colleagues found that negative illness perceptions rated within the first few weeks post-TBI were a key predictor of PPCS at both three months and six months post-TBI (14). In a similar study, Snell and colleagues also evidenced that injury perceptions in the first few months post-TBI were significantly associated with PPCS outcome over time (22). Similar to the models of PPCS described above, the SRM suggests the importance of both injury beliefs and emotional responses following the onset of TBI. PPCS models go further in understanding what pre-existing factors might influence the cognitive and emotional representations a person creates, of which personality 'vulnerability' factors appear to be a key component.

While personality factors such as anxiety sensitivity (23) have been shown to be implicated in PPCS development, and personality factors more generally have largely been recognised as important (13,24), few personality traits have been empirically investigated. One specific personality factor that has not yet been investigated in PPCS research is self-criticism. Self-criticism has been repeatedly demonstrated as a transdiagnostic factor underpinning a

range of experiences of psychological distress including depression (25), social anxiety (26) and chronic pain (27), and has recently been applied to the wider brain injury population (28–30). Given that self-criticism has been shown to be an underpinning process in those experiencing anxiety, depression and chronic pain, and these are also common co-morbidities in PPCS, it makes sense that self-criticism may also be a factor in the development of PPCS. Pre-morbid mental health difficulties have also repeatedly demonstrated predictive ability for PPCS (31,32). As a common vulnerability factor for a range of mental health difficulties, it is hypothesised that self-criticism specifically may exacerbate distress following an illness event such as mTBI.

Considering Kay's model of PPCS (13), the experience of "failure, frustration and an inability to perform as usual" (pp. 378) is likely to be perceived as more disabling, and experienced as more distressing by those with higher levels of self-criticism, compared to those who are less self-critical. Based on Hou's model of PPCS (14), it is hypothesised that as a transdiagnostic process, self-criticism may act as both a predisposing factor, and also a perpetuating factor, connecting the cognitive and emotional variables.

In contrast to self-criticism, self-reassurance has also been found to be inversely associated with psychological distress (1) with evidence indicating a buffering effect against it (33). Self-reassurance can be described as the ability to be supportive and compassionate towards oneself when faced with setbacks and is not simply the opposite of self-criticism but a separate construct in itself (34). Indeed, fMRI evidence has highlighted that self-criticism and self-reassurance activate different networks within the brain: activity of the dorsolateral prefrontal cortex is associated with a tendency to be self-critical while the ventrolateral prefrontal cortex is positively correlated with high self-reassurance (35). In Wood's diathesis-stress paradigm (24), the risk of PPCS, construed by a variety of vulnerability factors (e.g. avoidance coping style, pre- and post-accident pressures etc) can be reduced by the presence

of certain protective factors. As already demonstrated in other populations (33,34), self-reassurance may be one such protective factor relevant to PPCS development.

To the author's knowledge, self-criticism and self-reassurance have not yet been investigated in relation to their relationship with PPCS. As such, this study will explore the relationships between self-criticism, self-reassurance and PPCS to determine if these new variables enhance current models of PPCS. These variables will be investigated alongside previously known predictors of PPCS and post-TBI depression including: injury perceptions (both generally and perceptions of cognitive functioning specifically); age (36); gender (37); and an individual's involvement in litigation (38–40). Specifically, the study aims to answer the following questions:

1. Is there a significant relationship between PPCS and:
    a) levels of self-criticism?
    b) levels of self-reassurance?
2. Is there a significant relationship between depression and:
    a) levels of self-criticism?
    b) levels of self-reassurance?
3. Does self-criticism and self-reassurance predict variance in PPCS above that predicted by demographics, litigation and injury perceptions?
4. Does self-criticism and self-reassurance predict variance in post-TBI depression above that predicted by demographics, litigation and injury perceptions?

Based on the research questions outlined above, it was hypothesised that higher scores for self-criticism and lower scores for self-reassurance would be associated with more severe PPCS. It was also hypothesised that self-criticism and self-reassurance would demonstrate predictive ability above demographic and litigation variables and also above previous predictor variables including injury perceptions and perceptions of cognitive functioning.

As a result of the COVID-19 pandemic, recruitment to this study was ended prematurely.

Methods

Design

This study employed a cross-sectional observational design using quantitative data collected from a series of self-report measures. Bivariate correlations and hierarchical multiple regression analyses were used to investigate the relationships between predictor and outcome variables in line with the research questions above. Three outcome variables were investigated; early onset PPCS (i.e., headache, dizziness and nausea), late-enduring PPCS (i.e., cognitive difficulties, irritability, fatigue etc) and depression. For each outcome, three separate regression models were examined as outlined below.

Model 1.

Step 1 – Demographic variables (including current age, age at time of injury, gender and litigation) that correlate with outcome

Step 2 – Self-criticism

Step 3 – Self-reassurance

Model 2.

Step 1 - Demographic variables (as above) that correlate with outcome

Step 2 – Injury perceptions

Step 3 – Self-criticism

Step 4 – Self-reassurance

Model 3.

Step 1 - Demographic variables (as above) that correlate with outcome

Step 2 – Perceptions of cognitive functioning

Step 3 – Self-criticism

Step 4 – Self-reassurance

Participants

An a priori power analysis suggested a total of 85 participants were required to detect a medium effect size (*f*=.15) at p<.05 and with 80% power using four predictor variables in a linear regression model. A model with six predictors would need 98 participants. However, as a result of the COVID-19 pandemic, recruitment ceased prematurely resulting in a smaller sample size. A total of 41 participants consented to take part and were included in the analysis. Participants were recruited across four different National Health Service (NHS) Trusts in the UK, three in the North West of England and one in the South of England. NHS services with specialist neuro-trauma pathways were targeted for recruitment in an attempt to ensure accurate injury data was collected. Eligible participants were English-speaking adult NHS patients (aged 18 and over) who had been admitted to hospital 3-12 months prior to participation due to sustaining a TBI. The 3-month lower limit was decided as clinically appropriate as this would allow enough time for post-concussion symptoms to be considered as 'persistent' (9). To be eligible for inclusion, participants were required to have been discharged home from an initial hospital admission without need for further specialist inpatient cognitive rehabilitation. This criterion ensured inclusion of those with mild to moderate TBI and excluded those with more

severe injuries who required further specialist neuro-rehabilitation. Participants were recruited between 1st October 2019 and 8th April 2020.

Measures

Injury and demographic data were collected from the participants directly and also from their medical records (with participants' consent). The injury data collected included date of injury; dates of admission and discharge from hospital; earliest GCS score; duration of loss of consciousness; duration of post-traumatic amnesia (PTA); and cause of injury. Demographic data collected included age at time of injury; current age; gender; employment status; level of education; partnership status; ethnicity; previous use of mental health services; and any other ongoing physical or mental health conditions. The presence of ongoing litigation was also collected as a relevant factor demonstrated within the PPCS literature (38–40).

Predictor Variables

The Forms of Self-Criticising/Attacking & Self-Reassuring Scale (FSCRS; (41)) was used as a measure of self-criticism and self-reassurance. The FSCRS is a 22-item self-report questionnaire with a 5-point Likert scale ranging from '0' ("not at all like me") to '4' ("extremely like me") and therefore total scores range from 0 to 88. The FSCRS was designed to measure two self-criticism constructs: inadequacy (e.g. "I am easily disappointed with myself"), and self-hatred (e.g. "I call myself names"); and also self-reassurance (e.g. "I find it easy to forgive myself"). A recent review of the factor structure of the FSCRS has suggested the combining of the two self-criticism constructs into a single measure resulting in a two-factor model (self-criticism and self-reassurance; (34)) which will be used in this study. The FSCRS has demonstrated strong internal consistency with Cronbach's alpha scores between .88 and .93 for the self-criticism scale and between .82 and .92 for the reassurance scale (34). The scale has also demonstrated adequate test-retest reliability (42) and has been used in recent research within the TBI population (30).

The Brief Illness Perceptions Questionnaire (BIPQ; (43)) was used as a measure of illness perceptions. The BIPQ consists of nine questions each measuring a domain of illness perception: consequences, timeline of recovery, personal control, treatment control, identity, coherence, concern, emotional representations and causes. Participants provide Likert scale ratings for each question, ranging from 0-10. Higher scores represent more negative perceptions of their TBI. The BIPQ has demonstrated strong internal consistency (α=.85; (44)) and good test-retest reliability (*r*=.72; (45) in health populations, and has also been used within research in the TBI population previously (14,46–48). In this study, the BIPQ was adapted to replace the word "illness" to "injury" in keeping with the patient population and in line with other studies using versions of the BIPQ in the TBI population (22,49,50). In addition, analysis of the BIPQ scale reliability also suggested that two out of the eight items (treatment control and coherence) performed differently to the other items and weakened the coherence of the scale. Review of the Cronbach's alpha values indicated that the measure would increase in reliability with these items removed. Consequently, and in line with use of the BIPQ in previous studies (14), a new BIPQ total score was computed based on the remaining six items with increased reliability (original BIPQ α=.911; new BIPQ α=.945). Using the adapted BIPQ measure, total scores ranged from 0 to 60.

The Cognitive Functioning questionnaire (CF-28; (51)) was used to assess participants' perceived current cognitive abilities. The CF-28 is a 28-item self-report questionnaire asking respondents to rate their perceived difficulty with regard to a range of cognitive skills on a 5-point Likert scale (e.g. "I had difficulty doing more than one thing at a time"). Total scores range from 28 to 140 with higher scores indicating better perceived cognitive functioning. High levels of internal reliability (α = .94) and test-retest reliability (*r* = .78) have been demonstrated for the CF-28 in samples of patients with various neurological problems (e.g. stroke, epilepsy, Parkinson's disease), but no data is available specific to TBI (51).

Outcome Variables

The Rivermead Post-concussion symptoms Questionnaire (RPQ; (52)) was used to assess PPCS. The RPQ is a 16-item list of common post-concussion symptoms experienced following a TBI. Respondents are asked to rate the presence of each symptom now (i.e. over the last 24 hours) compared to before the injury on a 5-point Likert scale (where 0 is not experienced at all and 4 is a severe problem). A higher score indicates more severe ongoing post-concussion symptoms. The RPQ has been commonly used within the PPCS research literature and is recommended in guidelines for PPCS assessment by the Ontario Neuro-foundation (53). Thompson and colleagues reported a cut-off score of 16 or more demonstrated 97% sensitivity and 87% specificity (54) in diagnosing PPCS from the RPQ. The total RPQ score has demonstrated strong reliability when assessing enduring symptoms (55). However, another study indicated that the RPQ is not representative of a single construct and instead, the RPQ should be split into early symptoms (RPQ3; based on the first three items of headache, dizziness and nausea/vomiting) and late-enduring symptoms (RPQ13; based on items 4-16 e.g. fatigue, irritability, difficulty concentrating) (56): this approach was therefore used in the current study. Total scores for the RPQ3 range from 0 to12 and total scores for the RPQ13 range from 0 to 52. Cronbach's alpha scores in previous studies (37) based on the use of the RPQ3 and RPQ13 demonstrate acceptable internal reliability of the RPQ3 (.750) and excellent internal reliability of the RPQ13 (.911). Test-retest reliabilities demonstrate coefficients of 0.89 and 0.72 for the RPQ13 and RPQ3 respectively.

Finally, the Patient Health Questionnaire (PHQ-9; (57)) was used to assess participants' current levels of depression. The PHQ-9 is a 9-item questionnaire assessing frequency of depression symptoms using a 4-point Likert scale, with each item ranging from 0 ("not at all") to 3 ("nearly every day"), giving a total score which ranges from 0-18. Higher scores indicate more severe levels of depression and cut-off scores are 0-4 for minimal or none, 5-9 for mild,

10-14 for moderate, 15-19 for moderately severe and more than 20 signifies severe depression. The PHQ-9 is widely used in clinical practice and has demonstrated excellent internal reliability (α=0.89; (58)) and test re-test reliability (*r*=0.87; (59)) within the TBI population.

Procedure

Early in the design of the study, patient representatives from one NHS trust were consulted and provided feedback regarding the length, layout and accessibility of the study materials. Following ethical approval, potential participants were identified either by the neuropsychology department (i.e. from waiting lists and current caseloads) or through routine follow-up clinics with neuro-rehabilitation consultants. If recruited through clinics, where participants were eligible to take part, either the treating clinician (or researcher, if present in clinics) provided details of the study and offered them the opportunity to become involved. Interested participants were provided with a study pack (containing information sheets, consent forms and the study questionnaires) and given the option of either completing the study pack immediately or taking it home with a prepaid envelope to post back to the service if they decided to take part at a later date. For those contacted from waiting lists, the same study pack was sent in the post along with a cover letter inviting them to take part. Following completion of the measures and receipt of a participant consent form, injury data was gathered from the participant's medical records.

Ethical Approval

The study was reviewed and granted ethical approval by the Health Research Authority Yorkshire & The Humber – Bradford Leeds Research Ethics Committee. Following this, approval was sought and granted by the Research and Development Department of each participating NHS trust.

Data Analysis

All self-report measures were scored according to the scale instructions. There were two or fewer missing items in total for each of the RPQ, BIPQ, FSCRS, and PHQ-9. As missing data was minimal, missing items were imputed using mean substitution.

Assumptions for statistical analyses were investigated using summary statistics for skewness and kurtosis alongside visual inspection of histograms and Q-Q plots. Summary statistics for skewness and kurtosis indicated a normally disturbed sample and so parametric correlations were conducted using *Pearson's r* correlation coefficients between demographic and study variables and each of the outcome measures. Cronbach's alphas for each measure were also calculated to assess the internal consistency within the sample.

Hierarchical multiple regression models were then used to explore the research questions. Assumptions of linearity, homoscedasticity of residuals and normality of error distributions were investigated through visual inspection of regression scatterplots (60). All assumptions required for regression appeared to be met. Several studies have indicated that small numbers of subjects per variable (SPV) are adequate for conducting linear regression analyses with the smallest reported as only two subjects per variable (61).

Three sets of hierarchical multiple regression models were constructed to investigate each outcome: RPQ3, RPQ13 and the PHQ-9, as presented in the design section above. Due to the limited sample size, separate regression models to include each of the previously known predictor variables separately were conducted in order to increase statistical power by reducing the number of variables within each model.

Results

Participant characteristics

42 participants consented to take part and returned completed study packs. However, one participant had not completed approximately 50% of the measures and was subsequently removed from the analysis. A summary of participant characteristics for the remaining 41

participants is included in Table 1. The mean age of participants at the time of participation in the study was 44.70 years (SD 17.90, range 18-84) and the mean age at the time of their injury was 44.06 years (SD 18.01). The mean time since injury was 7.67 months (SD 3.36). The participant sample was predominantly male (68%) and identified as white British/ white European (100%). Of the 41 participants, 54% were employed, 29% unemployed, 15% were retired and 2% were students. With regards to educational level, 9.8% of participants attended some secondary school, 19.5% completed secondary school, 31.2% attained G.C.S.E level qualifications, 17.1% attained A-level qualifications, 9.8% had completed an undergraduate degree and 9.8% of the sample had completed a post-graduate degree. The majority of participants described their partnership status as married/civil partnership/co-habiting (44%). 22% of the sample reported having accessed mental health services previously and 27% of the sample reported between one and four previous TBIs. 37% of the sample were already involved in a legal process regarding the most recent TBI with a further 10% planning to seek legal advice in the near future. Finally, 54% of the sample reported experiencing other co-morbidities which included both mental and physical health difficulties.

Injury data

Despite recruiting through clinical services, accurate acute injury data was difficult to obtain as ambulance records were often stored on separate electronic patient record systems which were not accessible by the treating team. Consequently, GCS scores, duration of LOC and duration of PTA were not obtainable for just over one third of participants (41% for GCS score and 32% for both duration of LOC and PTA). Of the available injury data collected, according to the Mayo TBI classification system (3), 4 participants (10%) were classified as having a possible TBI, 25 (63%) were classified as having a probable TBI, and 5 participants (12%) were classified as having a definite TBI. There was no injury data available for six participants and so were unable to be categorised. The majority of included TBIs resulted from

falls (34%), followed by road traffic collisions (RTC; 22%), assaults (20%) and other causes of injury (20%). The 'other' category of injury cause predominantly involved accidents in the work place.

[TABLE 1 ABOUT HERE]

Table 2 shows the means, standard deviations, ranges and Cronbach's alphas for each of the standardised measures included. 68% of participants reported an RPQ total score above the clinical cut-off of 16 indicating a probable PPCS diagnosis. Individual scores on the PHQ-9 indicated that 29% of the sample fell within the minimal range, 15% within the mild range, 15% within the moderate range, 12% in the moderately severe range and 29% within the severe range of depression. Each of the measures demonstrated excellent internal consistency within this sample with Cronbach's alpha scores of .84 and above.

[TABLE 2 ABOUT HERE]

Correlational analyses

Table 3 displays the correlation matrix for demographic and study variables using Spearman's rho correlation coefficients.

Demographic and litigation variables

As can be seen in Table 2, relationships between the demographic variables including age, gender, and time since injury, and involvement in litigation, plus all of the outcome variables (RPQ3, RPQ13 and PHQ9) were weak and not statistically significant.

[TABLE 3 ABOUT HERE]

Predictor variables

A significant positive correlation with a medium effect size was observed between the RPQ3 and the FSCRS-SC (ρ=.542, p<.01) and a significant negative correlation with a medium effect size was also found between the RPQ3 and the FSCRS-RS (ρ=-.432, p<.01). A significant positive correlation with large effect size was seen between the RPQ3 and the BIPQ

(ρ=.880, p<.01) and a significant negative correlation with a large effect size was also found between the RPQ3 and the CF-28 (ρ=-.804, p<.01). These results indicate that those reporting more early-onset PPCS do not only have more negative injury perceptions, and have more negative perceptions of their cognitive functioning as expected, but are also more self-critical and less self-reassuring.

A significant positive correlation with a medium effect size was observed between the RPQ13 and the FSCRS-SC (ρ=.641, p<.01) and a negative correlation with a medium effect size was also found between the RPQ13 and the FSCRS-RS (ρ=-.436, p<.01). Similarly to the RPQ3, significant correlations with large effect sizes were observed between the RPQ13 and the BIPQ (ρ=.840, p<.01) and the CF-28 (ρ=-.869, p<.01). Again these results demonstrate the previously known relationships with PPCS but also demonstrate that that those reporting higher levels of late-enduring PPCS are also more self-critical and less self-reassuring.

Depression was also investigated as an outcome variable using the PHQ-9. As expected, non-parametric correlations demonstrated a medium effect size correlation between the PHQ9 and the FSCRS-SC (ρ=.665, p<.01) and a negative correlation with a medium effect size with the FSCRS-RS (ρ=-.516, p<.01). Significant correlations with large effect sizes were also demonstrated between the PHQ9 and the BIPQ (ρ=.830, p<.01) and the CF-28 (ρ=-.890 p<.01) indicating that those with more negative injury perceptions and those who rated poorer cognitive functioning also experienced more symptoms of depression.

Hierarchical Multiple Regression

Given that none of the demographic variables or litigation-seeking were significantly correlated with the outcomes, steps involving these variables in the regression models were omitted.

Early post-concussion symptoms

Tables 4a-c report the results of the regression analyses for early PPCS as measured by the RPQ3.

[TABLE 4a-c ABOUT HERE]

The regression model for early PPCS indicated that self-criticism (step 1) accounted for 32.7% of the variance (p<.001) and self-reassurance (added at step 2) contributed a further 4.5% (p=.107) although this was not significant. Together, this model explained 37.2% of the total variance in early PPCS scores (Adj R^2=.339), although self-criticism was the only significant independent predictor in the final model (β=.418, p=.012).

The second regression model for early PPCS included illness perceptions in step one, self-criticism in step two and self-reassurance in step three. Within this model, illness perceptions accounted for 74.9% of the total variance (p<.001), self-criticism accounted for an additional 3.6% (p=.015) and self-reassurance contributed a further 1.1%, although this was not significant (p=.168). The model explained 79.6% of the variance in early PPCS scores (Adj R^2=.779), but only illness perceptions was a significant independent predictor in the final model (β=.746, p<.001).

The third regression model for early PPCS included perceptions of cognitive functioning as step one; self-criticism as step two and self-reassurance as step three. Within this model, perceptions of cognitive functioning accounted for 65.6% of the total variance (p<.001); self-criticism accounted for an additional 1.2% although was not significant (p=.241); and self-reassurance contributed only a further 0.2% which was also not significant (p=.619). The model explained 67% of the variance in early PPCS scores (Adj R^2=.644). Perceptions of cognitive functioning alone was a significant independent predictor in the final model (β=-.710, p<.001).

Overall, self-criticism and self-reassurance did not make any further contributions to predicting early PPCS above previously known predictors.

Late-enduring post-concussion symptoms

Tables 5a-c report the results of the regression analyses for late PPCS as measured by the RPQ13.

[TABLE 5a-c ABOUT HERE]

The first regression model for late PPCS indicated that self-criticism at step one accounted 43.4% ($p<.001$) of the variance and self-reassurance added at step two only contributed a further 0.6% which was not significant ($p=.518$). Together, this model explained 44% of the total variance in late PPCS scores (Adj. $R^2=.411$), and self-criticism was the only significant independent predictor in the final model ($\beta=.602$, $p<.001$).

The second regression model for late-PPCS indicated that illness perceptions at step 1 accounted for 72.9% of the variance ($p<.001$); self-criticism (added at step 2) contributed a further 8.7% ($p<.001$) and self-reassurance (at step 3) did not contribute anything further ($p=.768$). Together, these variables explained 81.7% of the variance in depression scores (Adj $R^2=.802$); this time both illness perceptions ($\beta=.703$, $p<.001$) and self-criticism ($\beta=.347$, $p=.001$) were significant independent predictors in the final model.

The third regression model for late PPCS included perceptions of cognitive functioning as step one, self-criticism as step two and self-reassurance as step three. Within this model, perceptions of cognitive functioning accounted for 74.7% of the total variance ($p<.001$), self-criticism significantly accounted for a further 3.2% ($p=.024$) and self-reassurance contributed only a further 0.9% which was not significant ($p=.231$). This model explained a total of 78.7%

of the variance in late PPCS scores (Adj R^2=.77). Both perceptions of cognitive functioning (β=-.765, p<.001) and self-criticism (β=.273, p=.011) were significant independent predictors in the final model.

These results suggest that self-criticism, but not self-reassurance, makes a significant independent contribution to the prediction of late-enduring PPCS above previously known predictors.

Depression following TBI

Tables 6a-c report the results of the regression analyses for depression as measured by the PHQ-9.

[TABLE 6a-c ABOUT HERE]

The initial regression model for depression as the outcome indicated that self-criticism added at step 1 accounted 45.3% of the variance (p<.001) and self-reassurance at step 2 contributed an additional 4.7% which did not quite reach significance (p=.066). Together, this model explained 50% of the total variance in depression scores (Adj. R^2=.474). Only self-criticism was a significant independent predictor in the final model (β=.516, p=.001) although self-reassurance approached significance (β=-.265, p=.066).

The second regression model for depression indicated that illness perceptions accounted for 69% of the variance in PHQ9 scores at step 1 (p<.001). Self-criticism significantly increased the explanatory power of the model, contributing a further 10.5% of explained variance at step 2 (p<.001) and while self-reassurance explained an additional 1.5% at step 3, this did not quite reach significance (p=.091). Together, these variables explained 81% of the variance in depression scores (Adj. R^2=.795). Only illness perceptions (β=.638,

p<.001) and self-criticism (*β*=.285, *p*=.004) were significant independent predictors in the final model.

The third and final regression model for depression included perceptions of cognitive functioning as step one, self-criticism as step two and self-reassurance as step three. Within this model, perceptions of cognitive functioning accounted for 81.4% of the total variance (p<.001); self-criticism accounted for an additional 2.9% (p=.012) and self-reassurance contributed only a further, non-significant 0.2% (p=.540). This model explained a total of 84.5% of the variance in depression scores (Adj. R^2=.832). Both perceptions of cognitive functioning (*β*=-.762, *p*<.001) and self-criticism (*β*=.189, *p*=.038) were significant independent predictors in the final model.

Again these results suggest that self-criticism, but not self-reassurance, makes a significant independent contribution to the prediction of post-TBI depression above previously known predictors.

Discussion

This study investigated whether self-criticism and self-reassurance made significant contributions to current models of PPCS above previously known predictors. These relationships are important to understand in the context of PPCS whereby similar psychological factors have been repeatedly hypothesised to be key determinants of recovery outcomes, yet empirical investigation particularly of self-criticism and self-reassurance in this population, have not been conducted. As a result of the COVID-19 pandemic during the recruitment phase of this study, data collection was limited.

This study has contributed new findings to the TBI research literature, demonstrating that individuals who score higher on measures of self-criticism also report more severe PPCS with medium effect size correlations for both early-onset and late-enduring symptoms. Using

multiple regression analyses, this study also demonstrated that self-criticism provides a significant contribution to the variance in both early and late-enduring PPCS severity, but self-reassurance did not. When illness perceptions were entered into the model as a previously known predictor of PPCS outcome, self-criticism demonstrated independent predictive ability for the late-enduring symptoms only, not for early-onset symptoms. Self-reassurance did not contribute to either model. Similarly, when perceptions of cognitive functioning were entered into the model, self-criticism was independently predictive of late-enduring PPCS and not early symptoms. Again, self-reassurance independently predicted neither. These findings support the position that self-criticism may be more involved in enduring PPCS as opposed to the experience of early physiological symptoms. In line with neuropsychological models of PPCS, which indicate the importance of personality variables (e.g. anxiety sensitivity, or perfectionism) in mTBI recovery (11,13,14), self-criticism appears to be another potentially important vulnerability factor in the trajectory of recovery, such that those who are high in self-criticism are more likely to experience worse PPCS outcome.

According to Kay and colleagues' model (13), the relationship between psychological factors and functional outcome is mediated by subjective cognitive deficits. Within the present study, medium effect size correlations were found between self-criticism and perceptions of cognitive functioning, and large effect size correlations were found between perceptions of cognitive functioning and all three outcome variables i.e. early-onset PPCS, late-enduring PPCS and depression. Consequently, given a larger sample size achieving adequate statistical power, a mediation analysis may have proven useful in exploring the relationships between these variables, e.g. whether subjective cognitive deficits mediate the relationship between self-criticism and symptoms (or depression), in line with this model. Such findings may evidence the utility in providing objective feedback on cognitive performance as part of a therapeutic intervention. Providing psychoeducation about the function of negative thoughts and how they

can be distracting and impede cognitive performance may also be useful alongside supporting the development of a more compassionate response to cognitive errors.

As expected, and in line with previous research, significant relationships (with a medium effect size) were found between both self-criticism and self-reassurance with depression (25). When considering self-criticism and self-reassurance together in a regression model, self-criticism was found to be an independent predictor of depression in the current TBI sample, explaining 45.3% of the variance in scores on the PHQ9. Self-reassurance did not quite reach significance as an independent predictor, although a significant result may have been reached in a larger sample size. When previous predictors were added into the model, self-criticism remained a significant predictor above both previously known predictors, highlighting that self-criticism is an important variable in predicting the experience of depression following mild to moderate TBI. Again, self-reassurance did not reach significance.

The lack of significant predictive ability of self-reassurance upon depression contrasts with previous findings wherein both self-criticism and self-reassurance were predictive of depression scores in a university sample (33). This study also demonstrated a moderating effect of self-reassurance such that for those with higher levels of self-reassurance, the relationship between self-criticism and depression was weaker. Such a moderation effect would be interesting to explore in a larger sample of those with PPCS, as it would enable an exploration of whether self-reassurance serves as a protective factor for PPCS development in accordance with Wood's diathesis stress paradigm of PPCS development (24). Further empirical investigation confirming or disproving this relationship would also be useful clinically, providing evidence for the provision of early intervention, such as self-talk strategies emphasising self-reassurance, for those identified as more at risk of developing PPCS.

Strengths and limitations

Recruitment through clinical services supporting the collation of accurate injury data was a clear strength of this study's recruitment methodology, increasing confidence in the reliability of the data and participant sample. Unfortunately, this recruitment approach also came at a cost of being more labour intensive and this, combined with needing to cease data collection prematurely due to the COVID-19 pandemic, resulted in a smaller sample being recruited. Nevertheless, large effect sizes meant that several relationships still achieved significance despite the small sample size. The sample size in this study limited both the statistical methodology employed, and also the reliability and generalisability of findings. As pilot work, statistical adjustments for multiple testing were not made and p-values were set at $p<.05$. This should be considered during interpretation of the findings reported.

The cross-sectional design of this study also limits the inference of causality between the variables investigated. Particularly in cases of PPCS, where the relationships between variables (including those investigated in this study) are likely to both influence and be influenced by each other, more complex methodology, including longitudinal studies and more complex statistical analyses are required with larger sample sizes. Nonetheless, as the first to investigate self-criticism within this population, this study contributes much to the PPCS literature and it is hoped that further research into these relationships will be inspired.

A further limitation of this study was the measurement of outcome through self-report alone. Several studies have demonstrated reporting biases within this particular patient group (63–65) and it is therefore possible that the high levels of correlation between variables may be, at least in part, explained by a bias in reporting. High levels of comorbidity demonstrated in the literature between PPCS and depression may also account for high correlations found between variables, given that large effect sizes were found between the PHQ9 and both the RPQ3 and RPQ13. Herrmann and colleagues (66) investigated PPCS reporting (using the RPQ) in individuals with and without depression following mild to moderate TBI within the last year

using factor analysis, and found that those experiencing depression rated more PPCS than those who were not. The evolving and dynamic nature of PPCS means that these variables are often difficult to untangle for empirical investigation.

It is interesting to note that the study sample was 100% white British/white European despite recruiting from various NHS trusts across a spread of geographical locations within the UK. Not only does this highlight that the sample may not be representative of the wider mTBI population, but also brings into question the accessibility of NHS services to ethnic minority groups. Including only English-speaking participants in the study (due to a lack of validation of the measures in other languages) may also have contributed to a skew in the ethnicity of the sample. The inclusion criteria employed in this study (e.g. only NHS patients who had been admitted and then discharged home) may also limit the generalisability of findings (although this is common in mTBI research (67)), as a proportion of individuals (e.g. those who attended A&E but were not admitted) are unlikely to have been represented in this study.

Clinical implications and future research

Findings from this study have important clinical implications including an increased understanding of psychological factors that are amenable to intervention following mTBI. Given that individuals who have sustained an mTBI are three times more likely to experience depression than those who have not had an mTBI (68), factors known to influence depression, such as self-criticism, are important to investigate within this population.

At present, a unified approach to the treatment of PPCS is lacking. Some studies have reported on the preventative effects of psychological intervention within the first few weeks of mTBI, reducing individuals' negative expectations and perceptions of recovery (69–71). Wade and colleagues (71) for example, found a significant reduction in the emergence of PPCS following early psychological intervention focused on information and advice giving. Nevertheless, for those who do go on to develop PPCS, the research literature on effective

psychological interventions remains in its infancy. As the most researched psychological interventions, several studies evidence positive effects following cognitive behavioural treatment and cognitive rehabilitation strategies (70,72,73). However, the standardisation of treatment approach varies considerably across studies, making conclusions difficult to draw. A recent Cochrane review of treatments for PPCS concluded that, while some evidence exists for the effectiveness of CBT, cognitive rehabilitation and psychoeducation, findings are limited by a lack of high quality evidence (74).

Limitations of CBT have been noted across the broader mental health research literature as challenging thoughts is not always a useful approach in reducing distress, particularly in those who demonstrate high levels of self-criticism (75). This is particularly relevant within the mTBI population whereby changes in pre- to post-TBI functioning may be prominent and are likely to fuel self-criticism and subsequent emotional distress (29). Indeed compassion focussed therapy (CFT; (75)), which specifically aims to foster a more compassionate response to self-criticism, has demonstrated increasing utility in reducing distress in the broader acquired brain injury population, albeit with more severely injured samples (29,30).

While recovery from mTBI and PPCS can be considered as distinct from more severe forms of TBI (5), a number of commonalities are evident including the importance of the psychological response in recovery outcomes as well as a "shaken sense of self" ((13), pp.378). Gracey, Longworth and Psaila (76) propose a transdiagnostic cognitive behavioural model of emotional adjustment following brain injury, which centres around subjective experiences of threats to self: including self-criticism as an internally directed threat. Whilst it concentrates on acquired brain injury more generally, the model eloquently describes the complex interplay between pre- and post-injury factors, most of which could potentially be applied to mTBI and the experience of PPCS. With accumulating post-injury experiences of threats to self (such as those described in Kay's model (13) as failures in performance compared to pre-injury

abilities) individuals employ often unhelpful coping strategies in an attempt to minimise the pre- to post-injury self-discrepancies. One such example is avoidance, which, in turn, leads to withdrawal from social activities and the risk for emotional distress increases. Findings from the current study are consistent with this model, as self-criticism can be considered as a form of 'threat to self', increasing distress by emphasising pre- to post-injury discrepancies.

The relationship between self-criticism and specifically late-enduring PPCS suggest that self-criticism may be an important target for both preventative interventions following TBI and also in those seeking support for prolonged symptoms. Early intervention might involve an increased emphasis on normalising symptoms and outlining the contributory effect self-criticism has on symptoms. Third-wave CBT approaches such as Acceptance and Commitment Therapy (ACT; (77)) or CFT may prove fruitful in the prevention and treatment of PPCS by reducing the emotional distress caused by self-criticism through the development of skills in acceptance and self-compassion. Building a compassionate response to self-criticism is also supported by Gracey and colleagues' transdiagnostic model, described above, as an important intervention for emotional adjustment following brain injury (76) which may, in turn, lead to a reduction in PPCS. While ACT has not been empirically trialed for PPCS, a number of therapeutic tools and metaphors drawn from this approach have been found useful in clinical practice (78).

As pilot work and the first (to the author's knowledge) to investigate relationships between PPCS and self-criticism and self-reassurance, it is hoped that findings from this study can prompt further investigation into the role of self-criticism in PPCS. Careful consideration of potential recruitment biases is advised in order to increase validity and generalisability of findings. Longitudinal studies would be a useful methodological approach, investigating whether high levels of self-criticism early post-injury are predictive of later PPCS development. Given the complex interplay between self-criticism; perceptions of cognitive

functioning and symptoms of depression and PPCS, in addition to a number of other psychological and non-psychological variables outlined in the neuropsychological models noted previously (13,14,76), more complex statistical models might also prove useful in uncovering the nature of these relationships. For example, based on Kay's model of PPCS (13), a moderation model investigating whether self-criticism moderates the relationship between perceptions of functioning and distress may be indicated. Also, as indicated above, a moderating effect of self-reassurance on the relationship between self-criticism and depression also seems plausible and in keeping with the notion of vulnerability and protective factors in PPCS development (11,13,14,23) and would be a useful focus of future empirical investigation.

Conclusions

Findings from this study indicate that individuals with high levels of self-criticism and lower levels of self-reassurance report more severe PPCS. Self-criticism, but not self-reassurance, made a significant independent contribution to explaining the variance in both enduring PPCS severity and also symptoms of depression in individuals 3-12 months post-TBI above previously known predictors: injury perceptions and perceptions of cognitive functioning. Further investigation into the role of self-criticism in PPCS development is important to the advancement of effective interventions for those experiencing PPCS.

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Tables and Figures

Table 1 – Demographic and clinical characteristics of participants

Variable	N	%	Mean (SD)	Range
Gender				
Male	28	68.29		
Female	13	31.71		
Current age			44.70 (17.90)	18 - 84
Age at time of injury			44.06 (18.01)	17 - 84
Time since injury (months)			7.67 (3.36)	3 - 12
Employment Status				
Full-time employed	15	36.59		
Part-time employed	6	14.63		
Self-employed	1	2.43		
Unemployed – seeking employment	2	4.88		
Unemployed – not seeking employment	10	24.39		
Other	7	17.07		
Level of Education				
Attended some secondary school	4	9.76		
Completed secondary school	8	19.51		
G.C.S.E. qualifications	14	34.15		
A-Level qualifications	7	17.07		
Undergraduate degree	4	9.76		
Postgraduate degree	4	9.76		
Partnership Status				
Married/Civil partnership/ Co-habiting	18	43.90		
Divorced / separated	4	9.76		
Single	16	39.02		
Widow(er)	1	2.44		
Other	2	4.88		
Ethnicity				
White British / European	41	100		
History of MH difficulties				
Yes	9	21.95		
No	30	73.17		
Prefer not to say	2	4.88		
History of prior TBI				
Yes	11	26.83		
No	30	73.17		
If yes, how many			2 (1.18)	1 - 4

Legal process		
Yes	15	36.59
No	21	51.22
Planning to	4	9.76
Prefer not to say	1	2.44
Other mental/physical health problems		
Yes	22	53.66
No	19	46.34
TBI severity classification		
Possible	4	9.75
Probable (mild)	26	63.41
Definite (mod-severe)	5	12.19
Unknown/no data	6	14.63
Cause of injury		
Fall	14	34.15
RTC	9	21.95
Assault	8	19.51
Other	8	19.51
unknown	2	4.88

Table 2 - Descriptive Statistics and Internal Consistency for Standardised Measures

Measure	Mean (SD)	Range	Cronbach's alpha
RPQ			
RPQ3	4.32 (3.85)	0-12	**.85**
RPQ13	24.12 (16.29)	1-49	**.96**
FSCRS			
Self-criticism	22.68 (12.94)	1-45	**.93**
Reassuring self	17.61 (6.66)	4-31	**.84**
BIPQ	34.81 (18.87)	0-60	**.95**
CF-28	91.463 (35.283)	34-140	**.99**
PHQ9	13.02 (9.47)	0-29	**.94**

Note. All values rounded to two decimal places; SD = Standard deviation;

Table 3 – Pearson's r correlations between study variables

	1. Gender (0=male, 1=female)	2. Current age	3. Time since injury	4. Litigation (0=no, 1=yes)	5. RPQ3	6. RPQ13	7. FSCRS-SC	8. FSCRS-RS	9. PHQ9	10. BIPQ	11. CF-28
1.	-	-.113	-.021	.232	-.178	-.254	-.269	.111	-.250	-.156	.263
2.	-	-	-.369*	-.323*	-.129	-.240	-.141	-.118	-.093	-.136	.173
3.	-	-	-	.242	.143	.140	.091	-.123	.210	.252	-.338*
4.	-	-	-	-	.237	.189	-.025	-.089	.272	.295	-.151
5.	-	-	-	-	-	.877**	.572**	-.507**	.854**	.865**	-.810**
6.	-	-	-	-	-	-	.659**	-.451**	.907**	**.**854**	-.864**
7.	-	-	-	-	-	-	-	-.587**	.673**	.466**	-.596**
8.	-	-	-	-	-	-	-	-	-.571 **	-.389*	.535**
9.	-	-	-	-	-	-	-	-	-	.831**	-.902**
10.	-	-	-	-	-	-	-	-	-	-	-.802**

*Note. * = significant at the 0.05 level; ** = significant at the 0.01 level. All two-tailed. RPQ = Rivermead Post-concussion Questionnaire; FSCRS-SC = The Forms of Self-Criticising/Attacking & Self-Reassuring Scale – Self-Criticism scale; FSCRS-RS - The Forms of Self-Criticising/Attacking & Self-Reassuring Scale – Reassuring Scale; PHQ-9 = The Patient Health Questionnaire; BIPQ = The Brief Illness Perception Questionnaire; CF-28 = Cognitive Functioning 28-item questionnaire.*

Table 4a – Results of multiple regression model 1 for RPQ3

	B	SE	*Beta*	*t*	*p*	*R2*	Adj *R2*	*R2 change*	*F*
Step 1 – Self-criticism						.327	.310	.327**	18.939**
FSCRS-SC	.170	.039	.572	4.352	<.001**				
Step 2 – self-reassurance						.372	.339	.045	11.252**
FSCRS-SC	.124	.047	.418	2.633	.012*				
FSCRS-RS	-.152	.092	-.262	-1.651	.107				

Note. * = significant at the 0.05 level; ** = significant at the 0.01 level.

Table 4b – Results of multiple regression model 2 for RPQ3

	B	SE	*Beta*	*t*	*p*	*R2*	Adj *R2*	*R2 change*	*F*
Step 1 – illness perceptions						.749	.742	.749**	116.190**
BIPQ	.177	.016	.865	10.779	<.001**				
Step 2 – self-criticism						.785	.774	.036**	69.404**

BIPQ	.156	.017	.765	9.001	<.001**				
FSCRS-SC	.064	.025	.216	2.536	.015*				
Step 3 – self-reassurance						.796	.779	.011	48.120**
BIPQ	.152	.017	.746	8.770	<.001**				
FSCRS-SC	.044	.029	.148	1.529	.135				
FSCRS-RS	-.076	.054	-.131	-1.407	.168				

Note. * = significant at the 0.05 level; ** = significant at the 0.01 level.

Table 4c – Results of multiple regression model 3 for RPQ3

	B	SE	*Beta*	*t*	*p*	*R2*	Adj *R2*	*R2 change*	*F*
Step 1 – perception of cognitive functioning						.656	.647	.656**	74.295**
CF-28	-.088	.010	-.810	-8.619	<.001**				
Step 2 – self-criticism						.668	.651	.012	38.258**
CF-28	-.079	.013	-.727	-6.252	<.001**				
FSCRS-SC	.041	.035	.139	1.192	.241				
Step 3 – self-reassurance						.670	.644	.002	25.087**
CF-28	-.077	.013	-.710	-5.788	<.001**				
FSCRS-SC	.034	.038	.113	.886	.381				

FSCRS-RS	-.035	.070	-.061	-.501	.619

Note. * = significant at the 0.05 level; ** = significant at the 0.01 level.

Table 5a – Results of multiple regression model 1 for RPQ13

	B	SE	*Beta*	*t*	*p*	*R2*	Adj *R2*	*R2 change*	*F*
Step 1 – Self-criticism						.434	.420	.434**	29.930**
FSCRS-SC	.828	.151	.659	5.471	<.001**				
Step 2 – self-reassurance						.440	.411	.006	14.957**
FSCRS-SC	.756	.188	.602	4.015	<.001**				
FSCRS-RS	-.239	.366	-.098	-.652	.518				

Note. * = significant at the 0.05 level; ** = significant at the 0.01 level.

Table 5b – Results of multiple regression model 2 for RPQ13

	B	SE	*Beta*	*t*	*p*	*R2*	Adj *R2*	*R2 change*	*F*
Step 1 – illness perceptions						.729	.723	.729**	105.173**
BIPQ	.736	.072	.854	10.255	<.001**				
Step 2 – self-criticism						.817	.807	.087**	84.606**
BIPQ	.602	.068	.699	8.902	<.001**				
FSCRS-SC	.419	.099	.334	4.249	<.001**				

Step 3 – self-reassurance						.817	.802	.000	55.080**
BIPQ	.606	.069	.703	8.727	<.001**				
FSCRS-SC	.436	.115	.347	3.789	.001**				
FSCRS-RS	.064	.215	.026	.297	.768				

Note. * = significant at the 0.05 level; ** = significant at the 0.01 level.

Table 5c – Results of multiple regression model 3 for RPQ13

	B	SE	*Beta*	*t*	*P*	*R2*	Adj *R2*	*R2 change*	*F*
Step 1 – perception of cognitive functioning						.747	.740	.747**	114.871**
CF-28	-.398	.037	-.864	-10.718	<.001**				
Step 2 – self-criticism						.779	.767	.032*	66.912**
CF-28	-.337	.044	-.731	-7.695	<.001**				
FSCRS-SC	.281	.119	.224	2.356	.024*				
Step 3 – self-reassurance						.787	.770	.009	45.674**
CF-28	-.353	.045	-.765	-7.770	<.001**				
FSCRS-SC	.343	.129	.273	2.660	.011*				
FSCRS-RS	.291	.239	.119	1.219	.231				

Note. * = significant at the 0.05 level; ** = significant at the 0.01 level.

Table 6a – Results of multiple regression model 1 for PHQ9

	B	SE	*Beta*	*t*	*p*	*R2*	Adj *R2*	*R2 change*	*F*
Step 1 – Self-criticism						.453	.439	.453**	32.321**
FSCRS-SC	.493	.087	.673	5.685	<.001**				
Step 2 – self-reassurance						.500	.474	.047	19.015**
FSCRS-SC	.378	.104	.516	3.645	.001**				
FSCRS-RS	-.381	.202	-.268	-1.891	.066				

Note. * = significant at the 0.05 level; ** = significant at the 0.01 level.

Table 6b – Results of multiple regression model 2 for PHQ9

	B	SE	*Beta*	*t*	*p*	*R2*	Adj *R2*	*R2 change*	*F*
Step 1 – illness perceptions						.690	.683	.690**	86.989**
BIPQ	.417	.045	.831	9.3327	<.001**				
Step 2 – self-criticism						.795	.784	.105**	73.714**
BIPQ	.332	.042	.661	7.962	<.001**				
FSCRS-SC	.267	.061	.365	4.405	<.001**				
Step 3 – self-reassurance						.810	.795	.015	52.743**
BIPQ	.320	.041	.638	7.783	<.001**				
FSCRS-SC	.209	.068	.285	3.058	.004**				

FSCRS-RS	-.221	.127	-.155	-1.735	.091				

Note. * = significant at the 0.05 level; ** = significant at the 0.01 level.

Table 6c – Results of multiple regression model 3 for PHQ9

	B	SE	*Beta*	*t*	*p*	*R2*	Adj *R2*	*R2 change*	*F*
Step 1 – perception of cognitive functioning						.814	.810	.814**	171.154**
CF-28	-.242	.019	-.902	-13.083	<.001**				
Step 2 – self-criticism						.843	.835	.029*	101.998**
CF-28	-.209	.021	-.777	-9.712	<.001**				
FSCRS-SC	.154	.059	.210	2.629	.012*				
Step 3 – self-reassurance						.845	.832	.002	67.023**
CF-28	-.205	.023	-.762	-9.055	<.001**				
FSCRS-SC	.138	.064	.189	2.151	.038*				
FSCRS-RS	-.074	.119	-.052	-.619	.540				

Note. * = significant at the 0.05 level; ** = significant at the 0.01 level.

Section Three: Critical Appraisal

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Sections one and two of this thesis focussed on gaining further insights into factors that influence recovery following TBI, particularly in relation to persistent post-concussion symptoms (PPCS). This paper will summarise the main findings of those two sections: the systematic literature review and the empirical paper, before discussing some of the key decision points, challenges, and opportunities for improvement based on the strengths and limitations of this thesis.

Main findings

Systematic Literature Review

The systematic literature review examined the relationships between injury perceptions following traumatic brain injury (TBI) and outcome including PPCS, psychological distress and quality of life (QoL) by synthesizing information from 12 quantitative research papers. Findings of the review indicate that the attribution of more symptoms to the TBI; a perception that symptoms will last a long time; a perception of greater negative consequences of the TBI and a stronger emotional reaction to it are more likely to be associated with increased reporting of PPCS. Slight differences were found for QoL outcomes insofar as the attribution of symptoms was not significantly associated with injury perceptions, but increased levels of concern and less perceived personal control were. Findings emphasise the importance of an awareness of injury perceptions across professions supporting individuals in the early days post-TBI and it is suggested that clinical psychologists may have a role in the multi-disciplinary team in acute care regarding this. Interventions aimed at addressing injury perceptions in the early weeks and months post-TBI are likely to be efficacious for symptomatic outcome, but also for broader QoL and psychological well-being over the longer term.

Empirical paper

The main research paper was underpinned by theoretical models and research (1–4) highlighting the importance of psychological and personality factors in persistent post-concussion symptoms (PPCS) and depression following mild to moderate TBI. The potential for self-criticism and self-reassurance to be important personality variables was discussed also, variables which have not been previously explored in this group. These variables were investigated alongside other previously known predictors, including injury perceptions and also perceptions of cognitive functioning, using correlation and regression models. Significant correlations with moderate effect size were found between both self-criticism and self-reassurance and each of the outcomes investigated early onset PPCS, late enduring PPCS and depression. Regression analyses demonstrated that self-criticism was an independent predictor of late enduring symptoms and post-TBI depression above each of the previously known predictors. Self-reassurance did not demonstrate predictive ability, in addition to self-criticism alone and also previously known predictors. In the main paper, clinical implications are discussed including the potential usefulness of targeting self-criticism both in the early days post-TBI as a preventative approach to PPCS, but also for those referred much later in their recovery journey for PPCS. Third-wave cognitive behavioural therapy approaches may prove efficacious in this respect, increasing individuals' capacity for self-compassion (5,6).

Decision-making, challenges and opportunities for improvement

Systematic literature review

Developing a research question and defining search terms

Due to a clinical interest in PPCS, initial scoping searches were focused on injury perception studies that reported on participants experiencing PPCS i.e. focused predominantly on symptoms. However, through more in-depth reading into the subject area and uncovering the links between injury perceptions, PPCS, psychological distress and QoL, it was decided that the search terms would be expanded to include these as outcomes too. While the papers

focusing on psychological distress and QoL included in the review were found during initial scoping searches, it was expected that more papers on these topics would exist and be found through systematic searching. Unfortunately, no further studies were identified and it appears that these outcomes are not very well-researched with regards to the TBI population. A discussion took place with the research supervisors regarding whether it was appropriate to keep psychological distress and QoL outcomes in the review given the limited number of studies found. As these appeared to be important variables in the context of injury perceptions and also in relation to the TBI population, it was agreed that keeping them in would be both in keeping with the process and purpose of systematic literature reviews, but also an important acknowledgement of the lack of empirical research in this area. Publication of the literature review will hopefully inspire further research in the role of injury perceptions in QoL and psychological distress outcomes in the TBI population.

Another important decision made during this stage was the exclusion of functional recovery as an outcome. Several studies were found during scoping searches highlighting specific aspects of functional recovery such as return to work. Given that functional recovery can be defined by a multitude of variables such as return to work, social engagement, community participation etc., it was difficult to determine a discreet category of 'functional recovery'. Consequently, it was decided that this would not be included as an outcome within the review.

However, following the synthesis of results and finding that a number of papers defined post-concussion symptom outcome based on a combination of symptomatic and functional outcomes, the inclusion of functional recovery in the search strategy may actually have been useful in investigating injury perceptions and PCS outcome more broadly. Nevertheless, the outcomes investigated in the review appear to be more homogenous and in keeping with a psychological perspective of TBI outcome, with psychological distress and psychological QoL

outcomes being investigated alongside PPCS, which is believed to be underpinned largely by psychological processes.

Further to the above, several discussions with the university librarians and research supervisors regarding the quality and appropriateness of search terms were held given the complexities noted above. As is expected with all reviews of the literature, there always remains some doubt as to whether all of the relevant articles were captured.

Synthesis of findings

The synthesis of results from each of the included studies was challenging for a number of reasons. The inclusion of studies employing a range of methodologies, some correlational and other using group comparisons, resulted in few studies being directly comparable. Differences in study variables such as the use of measures and also differences in sample variables, such as time since injury, all contributed to difficulties in synthesising findings in a coherent and meaningful way. The division of the main results section into each of the outcomes investigated (PCS, QoL and psychological distress) appeared to be the most coherent approach to structuring this section, with further sub-divisions into each of the injury perception subscales for the largest section investigating PCS outcomes.

Future Directions

The majority of included studies related to mTBI and PPCS despite the search being inclusive of all injury severities. The limited number of studies available which included individuals with moderate to severe TBI highlights the need for more research into injury perceptions with more severe injuries. However, this may be a more complex endeavor, since with increasing severity TBI comes an increasing likelihood of cognitive impairment and possible difficulties with insight and awareness. This makes research on injury perceptions more difficult and potentially less meaningful as the development of injury perceptions is predominantly a cognitive process requiring an awareness that one has experienced an injury

alongside an ability to think abstractly about future expectations, possible consequences etc. Nevertheless, the categorization of a TBI as severe and the possible consequences of such injury should not automatically rule out the investigation of injury perceptions in this group.

Interestingly, in the study by Twiddy and colleagues (7), injury perceptions were assessed in both individuals who had suffered a stroke and their carers. They reported that patient distress three months post-stroke was associated with injury perceptions of the carer and the discrepancy between the injury perceptions of patients and carers was also associated with both patient distress and carer distress. These findings underline the importance of more systemic understandings of a person's experience following an acquired brain injury, whether that be a result of a stroke or a TBI. It is widely recognised that a TBI can impact a whole family, not just the individual who acquired the injury, (8) and thus the influence of the support network around a person following TBI cannot be underestimated. Consequently, research exploring the injury perceptions of both individuals following TBI and their carers may lead to useful insights and opportunities for intervention.

In addition to the above, it is important to recognise the evolving nature of injury perceptions following TBI within recommendations for future research. In their cluster analysis exploration, Snell and colleagues (9) also assessed change in PCS within three months post-TBI and six months later across the three cluster groups: low, medium and high adapters. They found significant differences in the change scores between the 'low adapters' (those endorsing stronger negative injury perceptions) than both the medium and high adapters. This highlights that those with more negative injury perceptions are more likely to experience persisting symptoms and poor outcome over time compared to those with more positive injury perceptions who experience larger reductions in RPQ scores. These findings not only underscore the changing nature of injury perceptions through natural recovery but also indicate the potential reinforcing nature of injury perceptions such that those with more negative

perceptions experience worse PPCS which, in turn, reinforces those same negative perceptions. The provision of early intervention following TBI becomes even more important in this context as a preventative approach to PPCS, reducing the risk of later depression and improving the likelihood of greater QoL.

Empirical paper

Recruitment

Recruiting through clinical services was both a strength and a challenge of this study. Having access to clinical data of participants (following consent) enabled, in theory, the accurate collation of injury data, which could enable accurate description of the sample. However, in reality, accurate injury data, such as earliest Glasgow Coma Scale (GCS) score, was difficult to collate as they were often recorded in ambulance or accident and emergency (A&E) records from one NHS trust, but not provided with the referral information to the separate NHS trust conducting the neuro-trauma follow-up clinics. With regards to recruitment from neuropsychology services, early injury information was often not made available either and was difficult to obtain. Similar studies with individuals who have suffered a TBI and who do report on clinical injury data are usually conducted by clinicians working in the service and therefore have easier access to this information for eligible participants. However, this was more difficult as an independent researcher as it risked putting additional and undue burden on the clinicians who kindly offered to support recruitment to this study. Including A&E services in the recruitment phase may help to increase access of accurate early injury data in the future.

Furthermore, as a result of care pathways and routes of referral, by the time individuals with PPCS had been referred to a neuropsychology team and screened for inclusion in this study, they were often more than 12 months post-TBI and therefore no longer eligible. Neuro-trauma pathways and follow-up clinics were more fruitful although tended to review patients with more severe injuries and those who underwent neuro-surgery as a result of their TBI. As

the researcher was required to attend the neuro-trauma clinics to recruit in person, this approach proved extremely time intensive also, particularly when attending two (sometimes three) clinics per week across NHS trusts in the North West, in addition to maintaining other work commitments (e.g. clinical placement). Surgery data was not collected in this study although a number of participants had undergone neurosurgical procedures during their acute admission to hospital. Given that surgical intervention has been shown to influence clinical outcomes following TBI (10), this may be a useful variable to consider in future research.

The inclusion criteria for time since injury was limited to 12 months (as opposed to having no upper limit) in an attempt to increase the homogeneity sample. However, this reduced the number of individuals who were eligible to participate. In hindsight, it may have been beneficial to widen the inclusion criteria to 24 months and indeed this was discussed as a possible amendment to the project after several months of data collection. Conversely, extending the 'time since injury' inclusion criteria may have led to a more heterogenous sample. Whilst a slow pace of recruitment would not usually have presented a significant problem, and the data collection phase was indeed several months in duration, the time restrictions of the thesis project (reduced further by the COVID-19 pandemic) and limitations on the researcher's time in attending clinics in person meant that only a small sample size was recruited at the time data collection ended.

The COVID-19 pandemic of 2020 resulted in the premature ending of the data collection phase for several reasons. The neuro-trauma clinics and outpatient department services transitioned to remote working which prevented the researcher from attending clinics for recruitment of participants. Non-essential research was also put on hold by the NHS trusts in order to focus resources on the pandemic and prioritise COVID-19-related research only. Moreover, it was assumed that the potential psychological impact of the COVID-19 pandemic, and subsequent enforced lockdown procedures, may have resulted in a skewed dataset from

pre- to post- pandemic onset: for instance, as people may have reported increasing symptoms of depression as a result of lockdown. Subsequently, through discussion in research supervision, it was agreed that data collection should cease.

Choice of measures

A number of key decisions were made with respect to the choice of measures used to assess each of the study variables. Firstly, deciding upon measure for self-criticism was important to consider given that self-criticism can be conceptualized in a number of different ways: as a personality trait, a response to a difficult situation, a habitual cognitive style and a mood regulation strategy (11). The decision to conceptualise self-criticism as both a personality trait and a response to a situation was made based on a combination of the consideration of current models of PPCS (1,12) and clinical experience of individuals presenting with PPCS and high levels of self-criticism. Consequently, the Attitude To Self scale (ATS; (13)) and the Forms of Self-criticising/attacking and Reassuring Scale (FSCRS; (14)) were chosen in accordance with a recent review of self-criticism measures (11).

A further decision point in the choice of measures used was the decision to present results from the FSCRS only. Three participants completed less than 50% of the items on the ATS and thus, if used, would further limit the sample size in an already small total sample. Also, given that there was a scarcity of research studies that had used the ATS, and this being only a 10-item scale with three separate subscales, there was less confidence that it was a comprehensive measure of self-criticism compared to the FSCRS.

Use of the Rivermead post-concussion symptoms questionnaire (RPQ; (15)) also created an important decision point relating to both the study design and the analyses conducted. The RPQ has been used both clinically, and in research, to establish individuals as having PPCS or not. As reported in the methods section of the empirical paper, a cut-off score of 16 demonstrates 97% sensitivity and 87% specificity in diagnosing PPCS (16). As such, the

RPQ could have been, and indeed was planned to be, used as a method of dichotomizing participants into two groups in order to compare variables, such as self-criticism, between groups in line with similar research (17). However, dichotomizing a continuous measure can lead to a reduction in power which was already a concern during data analysis given the small sample size.

In addition to the above, when used as a continuous variable, there are a number of ways the RPQ can be sub-categorised. One approach (and the one used in the empirical paper) is to divide the RPQ into early-onset physiological symptoms i.e. headache, dizziness and nausea/vomiting (based on the RPQ items 1-3), and late enduring symptoms (based on the RPQ items 4-16) which are considered more typical of enduring symptoms i.e. difficulties concentrating, fatigue etc. Eyres and colleagues (18) studied the construct validity of the RPQ and highlighted how the RPQ is not unidimensional: instead, they advocate for the use of the RPQ3 and RPQ13 as these subscales demonstrate good psychometric properties.

In contrast, some studies (19,20) use a different approach to sub-categorising the RPQ, instead dividing the continuous measure into three categories: cognitive, emotional and somatic. A factor analysis by Potter and colleagues (21) demonstrated that these three constructs do exist but with co-variance between them. These findings, in combination with the aims of this study investigating factors involved specifically in the *persistence* of PCS, contributed to the decision to use the RPQ3 and RPQ13 division.

Finally, the Brief Illness Perception Questionnaire (BIPQ; (22)) was used as a measure of injury perceptions: a previously known predictor of PPCS. However, despite the literature review investigating each of the individual subscales of the BIPQ (and Illness Perception Questionnaire-Revised (23)), a total score was used in the empirical paper. Similar to another study investigating the association between the BIPQ and the RPQ (24), the total score was computed following exploration of the reliability of the measure given that several subscales

(including the coherence and treatment control subscales) would increase the reliability of the measure if deleted. Interestingly, the systematic literature review also suggested that the coherence and treatment control subscales demonstrated much weaker associations with PCS outcomes. The decision to use the BIPQ as a total score was also influenced by the notion that illness perceptions were not the main focus of the empirical paper, but were included as previously known predictors. The word limitations of the empirical paper fulfilled as part of the thesis project also limited further exploration of the individual domains of the BIPQ. Exploration of the individual BIPQ items with the outcomes (i.e. RPQ3, RPQ13 and PHQ) could be presented in a future research paper.

Complexity of relationships between study variables

One of the biggest challenges in investigating specific variables within research in this field is the knowledge that relationships between these and many other variables not measured are much more complex. Most notably, there is much uncertainty regarding PPCS as unique to mTBI following evidence highlighting that PPCS is present in other populations such as those experiencing orthopedic injury without brain injury (25), depression (26), chronic pain (27,28) involvement in litigation processes (29) and even healthy controls (30–32). High correlations between PPCS and symptoms of depression also bring into question the separateness of PPCS from psychological distress. However, this study aimed to understand the influence of self-criticism on PPCS, although it is likely to be contributable, in part, to depression also which is difficult to disentangle from PPCS. A number of sensitivity analyses were conducted including backwards regression and alternating the order of variable entry of self-criticism and self-reassurance into the regression model. Consistency in the findings across these analyses and the strengths of these relationships demonstrated with the current sample size, increases confidence in the conclusion that self-criticism is an important predictor variable in PPCS and is worthy of further empirical investigation.

As stated in the discussion section of the empirical paper, more complex models, including mediation and moderation relationships could be more likely to be representative of the influence of self-criticism on PPCS on a variety of other variables. For example, it is reasonable to suggest that if a person is more self-critical, then they are more likely to rate their cognitive abilities more negatively which may in turn influence PPCS reporting on a measure such as the RPQ. Indeed, a post-hoc mediation analysis on the current dataset revealed that, despite the small sample size, there was a significant indirect effect of self-criticism on PPCS through perceptions of cognitive functioning (the direct path also remained significant).

Furthermore, neuropsychological models of PPCS (1) suggest that self-criticism may be a moderator of the relationship between perceptions of cognitive functioning and depression such that those who are high in self-criticism have a stronger relationship between their perception of cognitive functioning and depression. This would be an interesting hypothesis to explore in future research with individuals experiencing PPCS.

Research investigation demonstrating the buffering effect of self-reassurance (33) might also indicate that self-reassurance moderates the relationship between self-criticism and depression. Unfortunately, there were not enough participants recruited to the study to statistically investigate these relationships, but these could be investigated in the future with larger samples. Further investigation into protective factors with regards to the development of PPCS may also be useful as the identification of protective factors is a key component of psychological formulation in clinical practice (34).

Personal reflections

Clinical experience of working with individuals experiencing PPCS, and particularly those with more severe PPCS presenting as highly self-critical, led to the author's interest in this topic area specifically. Neuropsychological formulation within this group often highlights a hypervigilance to cognitive errors (particularly memory), often attributing normal episodes

of forgetting to cognitive impairment or personal incompetence instead. Understandably, an increasing awareness of forgetting often leads to anxiety which further impedes memory performance (35). Such experiences appear to fuel a shift in identity from conscientious and able, to forgetful and mistake-prone. The researcher hypothesises that this pre- to post-TBI discrepancy in self-appraisal is perhaps more likely to exacerbate self-criticism and lead to psychological distress (increasing the likelihood of cognitive errors) as highlighted in other literature involving individuals with ABI (36,37). However, given that individuals presenting with PPCS have often experienced a milder injury, and are expected, both by themselves and others, to have completely recovered, this may lead the person to believe that their cognitive difficulties are 'unjustified', further increasing the likelihood of self-criticism.

It was interesting being invited to sit in on neuro-trauma clinics with predominantly medically orientated consultants during recruitment of participants to this study. For the people consenting to take part in the study and offering to complete the study packs immediately following the consultation, discussions with the researcher highlighted a general lack of understanding of, or education about, the psychological influences of PPCS by patients and families. A number of participants described finding the measures interesting to complete as they had not considered the relevance of these factors (how self-critical they are / their beliefs about the injury etc) to their experience of PPCS. This brought attention to the importance of psychological input during the early weeks to months post-TBI.

Conclusions

Overall, the two papers contributing to this thesis have provided unique contributions to the TBI research literature and have been successful in gaining further insights into changeable psychological factors that influence outcome and recovery. The systematic literature review contributed new findings to the research on illness perceptions, highlighting the specific injury perceptions that appear to be pertinent to the TBI population. This paper

complimented the empirical paper which also included injury perceptions as a previously known predictor of PPCS and depression outcomes following TBI. The empirical paper was successful in evidencing significant relationships between self-criticism and self-reassurance with PPCS and depression post-TBI. More notably, regression analyses revealed that self-criticism was an independent predictor of both late enduring PPCS and post-TBI depression, suggesting the potential for targeting self-criticism as an intervention post-TBI. The author's keen interest in this specific area of clinical neuropsychology will inspire future research and a motivation to develop services with the aim of better identifying and supporting those at risk of poor outcome following TBI.

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Section Four: Ethics Documentation

Self-criticism, self-reassurance, injury perceptions and persistent post-concussion symptoms following traumatic brain injury: A pilot study

Word Count: 6972 (excluding references, tables and appendices)

Lindsay Prescott

Doctorate in Clinical Psychology

Division of Health Research, Lancaster University

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1. Integrated Research Application (IRAS) approved application form

IRAS Form | Reference: 19/YH/0311 | IRAS Version 5.13

Welcome to the Integrated Research Application System

IRAS Project Filter

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

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

Please enter a short title for this project (maximum 70 characters)
Self-criticism and persistent post-concussion symptoms after TBI

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

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

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

( ) Other study

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

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

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

[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 applications do you require?

☑ IRAS Form
☐ Confidentiality Advisory Group (CAG)
☐ Her Majesty's Prison and Probation Service (HMPPS)

Most research projects require review by a REC within the UK Health Departments' Research Ethics Service. Is your study exempt from REC review?

○ Yes ◉ No

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

◉ Yes ○ No

5a. Are all the research costs and infrastructure costs (funding for the support and facilities needed to carry out research e.g. NHS Support costs) for this study provided by a NIHR Biomedical Research Centre, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC), NIHR Patient Safety Translational Research Centre or Medtech and In Vitro Diagnostic Cooperative in all study sites?

Please see information button for further details.

○ Yes ◉ No

Please see information button for further details.

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 Portfolio?

Please see information button for further details.

○ Yes ◉ No

The NIHR Clinical Research Network provides researchers with the practical support they need to make clinical studies happen in the NHS e.g. by providing access to the people and facilities needed to carry out research "on the ground".

If you select yes to this question, you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form (PAF) immediately after completing this project filter question and before submitting other applications. Failing to complete the PAF ahead of other applications e.g. HRA Approval, may mean that you will be unable to access NIHR CRN Support for your study.

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

○ Yes ◉ No

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

○ Yes ◉ No

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

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

○ Yes ◉ No

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

◉ Yes ○ No

Please describe briefly the involvement of the student(s):
This research will form the thesis submitted for a doctorate in clinical psychology (DClinPsy) awarded by Lancaster University.

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

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

IRAS Form (project information)

Please refer to the E-Submission and Checklist tabs for instructions on submitting this application.

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)
Self-criticism and persistent post-concussion symptoms after TBI

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

REC Name:
Yorkshire & The Humber - Bradford Leeds Research Ethics Committee

REC Reference Number: 19/YH/0311

Submission date: 07/08/2019

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

The role of self-criticism in the experience of persistent post-concussion symptoms following traumatic brain injury

A2-1. Educational projects

Name and contact details of student(s):

Student 1

	Title	Forename/Initials	Surname
	Miss	Lindsay	Prescott
Address	C34 Furness		
	Lancaster University		
	Lancaster		
Post Code	LA1 4YT		
E-mail	l.prescott@lancaster.ac.uk		
Telephone	07508375657		
Fax	0		

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	Fiona	Eccles
Address	C34 Furness		
	Lancaster University		
	Bailrigg		
Post Code	LA1 4YT		
E-mail	f.eccles@lancaster.ac.uk		
Telephone	01524592807		
Fax	0		

Academic supervisor 2

	Title	Forename/Initials	Surname
	Dr	Will	Curvis
Address	C34 Furness		
	Lancaster University		
	Bailrigg		
Post Code	LA1 4YT		
E-mail	w.curvis@lancaster.ac.uk		
Telephone	01524593095		
Fax	0		

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 Miss Lindsay Prescott	☑ Dr Fiona Eccles ☑ Dr Will Curvis

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

A3-1. Chief Investigator:

	Title	Forename/Initials	Surname
	Miss	Lindsay	Prescott
Post	Trainee Clinical Psychologist		
Qualifications	BSc		
ORCID ID			
Employer	Lancashire Care NHS Foundation Trust		
Work Address	C34 Furness Lancaster University Bailrigg		
Post Code	LA1 4YT		
Work E-mail	l.prescott@lancaster.ac.uk		
* Personal E-mail	linzi_prescott@hotmail.com		
Work Telephone	07508375657		
* Personal Telephone/Mobile	07837746569		
Fax	0		

** 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 HRA/R&D reviewers that is sent to the CI.

	Title	Forename/Initials	Surname
	Mrs	Becky	Gordon
Address	Head of Research Quality & Policy Lancaster University Bailrigg		
Post Code	LA1 4YT		
E-mail	sponsorship@lancaster.ac.uk		
Telephone	01524592981		
Fax	0		

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):	n/a
Sponsor's/protocol number:	n/a
Protocol Version:	0.1
Protocol Date:	03/07/2019
Funder's reference number (enter the reference number or state not applicable):	n/a
Project website:	n/a

Additional reference number(s):

Ref.Number Description	Reference Number
n/a	n/a

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.

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

○ Yes ◉ No

Please give brief details and reference numbers.
n/a

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 Health Research Authority (HRA) website following the ethical review. Please refer to the question specific guidance for this question.*

Post-concussion symptoms (PCS) are a common experience following traumatic brain injury (TBI) and includes the experience of headaches, dizziness, irritability and memory difficulties. In most cases these symptoms resolve within three months although for some, symptoms remain and become persistent (PPCS).Many factors have been shown to contribute to the likelihood of someone developing PPCS including both injury related and non-injury related factors. In a recent review of the evidence base, Silverberg and Iverson (2011) concluded that psychological factors have as much a causal role in the development and maintenance of PPCS as neurobiological factors and gaining a better understanding of these is important for reducing the risks of PPCS.

Some psychological factors involved in PPCS have been investigated and generally focus on an individual's understanding of their symptoms and expectations for recovery. This has formed the basis for some preventative treatment approaches aimed at normalising the experience of PCS symptoms and providing education. However, for those who still go on to experience PPCS, the evidence for effective treatment is limited.

In other areas of health psychology, studies have looked at self-criticism as an underlying psychological process that influences many forms of distress including the experience of somatic symptoms such as chronic pain. However, the role of self-criticism in the maintenance of PPCS has not yet been investigated.

This study will aim to assess whether there are differences in the levels of self-criticism in those with PPCS compared to those who have had a TBI but whose symptoms have resolved. This study will also investigate whether an individual's self-appraisal of their cognitive functioning and their illness perceptions also plays a role in PPCS and if these variables, together with self-criticism, predict whether a person experiences PPCS or not.

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, HRA, 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.

Due to the nature of the methodological design, recruitment of participants may present difficulties. Recruiting directly from services, whereby participant demographics and injury data can be accurately collected, was considered as the most preferred option as opposed to online recruitment. However, should direct recruitment from services become problematic, the study may then be disseminated wider to include third sector organisations using a weblink for the study. In such cases, participant injury data will rely on self-report rather than clinical data. Should this alternative recruitment strategy be required an amendment will be sought.

An ethical issue raised during the design stage was the sensitivity of the information being collected from participants

that may result in emotional distress. All participants will be provided with contact details for additional emotional support in the information sheet should they need it, including those reporting no ongoing symptoms. As participants will be recruited directly from services, they will be in contact with services during the recruitment phase. As such, it is likely that participants experiencing ongoing difficulties will remain open to the service and so any concerns raised regarding risk to participants' during the study can also be highlighted to the relevant clinical team. Should participants require additional support following the study if they are no longer open to the NHS service, as per clinical practice, participants are directed to their GP.

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
- ☑ Cross-sectional study
- ☐ Database analysis
- ☐ Epidemiology
- ☐ Feasibility/ pilot study
- ☐ Laboratory study
- ☐ Metanalysis
- ☐ Qualitative research
- ☑ Questionnaire, interview or observation study
- ☐ Randomised controlled trial
- ☐ Other (please specify)

n/a

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

1. Does self-criticism, self-appraisals of cognitive functioning and illness perceptions predict PPCS?

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

2. Does self-criticism, self-appraisals of cognitive functioning and illness perceptions predict depression after TBI?

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

Self-criticism has been increasingly researched as a transdiagnostic process underlying many experiences of psychological distress (Gilbert, 2000) including depression (Gilbert, 2009b), chronic pain (Penlington, 2018) and has recently been applied to the wider brain injury population (Ashworth, 2014; Ashworth, Clarke, Jones, Jennings & Longworth, 2015). A self-critical intrapersonal style may well be an important factor in the maintenance of PPCS and uncovering this may provide a key focus of future treatment. Prevention studies demonstrate the importance of patients receiving positive messages and expectations regarding recovery following TBI. However, it makes sense that the small group of individuals who go on to develop PPCS are naturally more self-critical in their intrapersonal style, influencing more negative appraisals of their symptoms, increasing distress and thus exacerbating a self-critical style. This increasing psychological distress is hypothesised to influence the experience of PPCS.

The role of self-criticism and its impact on the development or maintenance of PPCS has not yet been investigated in the research literature and will therefore be the focus of this study. This will be investigated alongside measures of self-appraisal of cognitive functioning and illness perceptions. While these two variables have been linked to the experience of PPCS in the literature already, empirical studies remain scarce. As such, this study aims to confirm and build upon previous literature by investigating whether these three variables together can predict PPCS.

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.*

Design:
This study will take a quantitative methodological approach using an independent measures cross-sectional design. For research question 1, participants will be categorised into two groups; PPCS and non-PPCS, depending on whether their scores on a measure of PCS meets the threshold for diagnosis or not. Research question 1 will use multi-variate logistic regression with all three predictor variables included in the model. If relevant, demographic and injury data will be controlled for. In order to answer research question 2 linear multiple regression will be used in order to see if the three variables; self-criticism, appraisal of cognitive functioning and illness perceptions, are predictive of depression.

Participants:
Participants eligible for inclusion in the study will i) be aged 18 years old and over, ii) be between 3- and 12-months post-injury iii) have been admitted to an adult inpatient hospital ward due to traumatic head injury and subsequently discharged home (rather than to a specialist inpatient rehabilitation unit) and iv) be able to understand and complete questionnaires in the English language.

These inclusion criteria would ensure participants' injuries are of a milder severity (compared to those who require further specialist neuro-rehabilitation) and would be able to consent to taking part in the study. While injury demographic and injury data will not be used as an inclusion criterion, it will be used to described and situate the sample. The 3-month lower limit is clinically appropriate as this is the lower time limit for PCS to be categorised as 'persistent'.

Patients who have sustained a brain injury due to other non-traumatic causes (e.g. stroke, infection etc) will not be included in the study. Those who are unable to complete questionnaires in the English language will also be excluded due to the resource limitations of the study and the measures used not being validated in other languages.

Recruitment & Data Collection:
Participants will be recruited from several major trauma sites and community/outpatient neuropsychology services locally and nationally. Clinicians from each NHS trust will identify potential routes to recruit appropriate participants through a combination of reviews of clinician caseloads, reviews of waiting lists for treatment of follow-up and also a review of databases containing participants who have consented to be contacted about research.

Potential patients will be screened for eligibility by a clinician within each NHS trust based on the inclusion and exclusion criteria above. Patients identified as eligible to take part in the study will be sent a study pack containing the cover letter, information sheet, consent form and questionnaires. Study packs will be provided to each NHS trust by the lead researcher. Dissemination of the study pack will depend on the recruitment route, for example in some cases the clinician may send the study pack to potential participants in the post prior to an upcoming appointment, allowing them to consider a review the materials before deciding whether to take part. Alternatively, participants may be given the study pack in person by the clinician when they attend for an appointment. The lead researcher may also attend relevant clinics held in each NHS trust and disseminate the study packs in person.

The study questionnaires include 6 validated questionnaires and a study demographic questionnaire. The demographic questionnaire will gather information pertaining to: age at time of injury, current age, gender, employment status, level of education, partnership status, ethnicity, previous use of mental health services, presence of ongoing litigation, any other ongoing medical conditions including the presence of orthopaedic injury and/or pain and a list of currently prescribed medications. Previous use of mental health services and the presence of ongoing litigation are important variables to consider in the analysis given previous research highlighting their potential role in the persistence of PCS (Lishman, 1988; Binder & Rohling, 1996). Gathering information about any ongoing pain, medical conditions and a list of current medications are also important variables to consider as they too can impact on the presence of PPCS. The side effects of certain medications can mirror some of the symptoms of PPCS and so it would be important to consider this during the analysis.

As part of the consent process, participants will be asked to consent to their injury data being collected from the service and shared with the research team. All participants will be allocated a unique ID by the clinician within each relevant NHS trust which will enable the clinical data to be added to the participant's data set while maintaining participant anonymity.

No further involvement required from participants.

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

Give details of involvement, or if none please justify the absence of involvement.
Service users from Salford Royal NHS Foundation Trust have been involved in the review of study materials, contributing to the design and usability for participants. Clinicians working in the area have also been involved in the design and planning of the study to ensure its relevance and usefulness to clinical practice.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A15. What is the sample group or cohort to be studied in this research?

Select all that apply:

- [ ] Blood
- [ ] Cancer
- [ ] Cardiovascular
- [ ] Congenital Disorders
- [ ] Dementias and Neurodegenerative Diseases
- [ ] Diabetes
- [ ] Ear
- [ ] Eye
- [ ] Generic Health Relevance
- [ ] Infection
- [ ] Inflammatory and Immune System
- [ ] Injuries and Accidents
- [x] Mental Health
- [ ] Metabolic and Endocrine
- [ ] Musculoskeletal
- [x] Neurological
- [ ] Oral and Gastrointestinal
- [ ] Paediatrics
- [ ] Renal and Urogenital
- [ ] Reproductive Health and Childbirth
- [ ] Respiratory
- [ ] Skin
- [ ] Stroke

Gender:	Male and female participants
Lower age limit: 18	Years
Upper age limit:	No upper age limit

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

- Aged 18 years or older
- Sustained a traumatic brain injury resulting in admission to hospital
- Discharged home from hospital without further inpatient neuro-rehabilitation
- Between 3 and 12 months post-injury
- Be able to understand and complete measures in the English language

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

Patients who have sustained a brain injury due to other non-traumatic causes (e.g. stroke, infection etc) will not be included in the study. Those who are unable to complete questionnaires in the English language will also be excluded due to the resource limitations of the study and also due to the questionnaires not being currently available in other languages.

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
Recruitment - Review of waiting lists/follow-up patients and database of patients who have consented to be contacted for research.	1	0	30mins	Clinician at outpatient clinic/hospital site.
Seeking consent	1	0	5 minutes	Clinician at outpatient clinic/hospital site or via post
Dissemination/collection of questionnaires	1	0	5 minutes	Clinician at outpatient clinic/hospital site or at patients own home.
Retrieval of clinical data from patient records	1	0	10 minutes	Clinician at outpatient clinic/hospital site (lead researcher at Salford Royal NHS Foundation Trust)

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

The length of time in the study will depend on how long it takes participants to return the measures. It is estimated that study participation will last between 1 hour to 2 weeks.

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.

There are no significant risks identified with participating in this study. However, it is possible that the sensitivity of the

information being collated from participants may result in emotional distress. All participants will be provided with contact details for additional emotional support in the information sheet should they need it, including those reporting no ongoing symptoms. Participants are made aware that their participation is voluntary and they can withdraw from the study at any time prior to the measures being returned to the research team. At this point the data will be anonymous and therefore difficult to separate from the data set. As participants will be recruited directly from services, they will be in contact with services during the recruitment phase. As such, it is likely that participants experiencing ongoing difficulties will remain open to the service and so any concerns raised regarding risk to participants' during the study can also be highlighted to the relevant clinical team. Should participants require additional support following the study if they are no longer open to the NHS service, as per clinical practice, participants are directed to their GP.

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:

As previous question: There are no significant risks identified with participating in this study. However, it is possible that the sensitivity of the information being collated from participants may result in emotional distress. All participants will be provided with contact details for additional emotional support in the information sheet should they need it, including those reporting no ongoing symptoms. Participants are made aware that their participation is voluntary, and they can withdraw from the study at any time prior to the measures being returned to the research team. At this point the data will be anonymous and therefore difficult to separate from the data set. As participants will be recruited directly from services, they will be in contact with services during the recruitment phase. As such, it is likely that participants experiencing ongoing difficulties will remain open to the service and so any concerns raised regarding risk to participants' during the study can also be highlighted to the relevant clinical team. Should participants require additional support following the study if they are no longer open to the NHS service, as per clinical practice, participants are directed to their GP.

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

No benefit.

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

There are no identified risks to researchers and no lone -working is required as part of the study. Clinicians involved in the study will follow the relevant trusts' guidelines related to seeing patients.

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).*

Clinicians from each NHS trust will identify potential routes to recruit appropriate participants through a combination of reviews of clinician caseloads, reviews of waiting lists for treatment of follow-up and also a review of databases containing participants who have consented to be contacted about research. Clinicians will identify whether patients meet the inclusion criteria to partake in the study.

Patients identified as eligible to take part in the study will be sent a study pack containing the cover letter, information sheet, consent form and questionnaires (see "Materials" section). Dissemination of the study pack will depend on the recruitment route, for example in some cases the study pack may be sent to potential participants in the post prior to an upcoming appointment, allowing them to consider a review the materials before deciding whether to take part. Alternatively, participants may be given the study pack in person by the clinician when they attend for an appointment. As part of the consent process, participants will be asked to consent to their injury data being collected from the service and shared with the research team. All participants will be allocated a unique ID by the clinician within each

relevant NHS trust which will enable the clinical data (collected using the TBI Information sheet) to be added to the participant's data set while maintaining participant anonymity.

Following the completion of the measures by the participant the clinical data will be securely transferred from the relevant clinician to the lead researcher. This may take several forms depending on the processes of data security within each trust but may include: email encryption, upload of data to a secure cloud service, telephone call whereby data from the clinician can be entered directly into the database by the lead researcher or collection of data in person by the lead researcher. In the latter case, the lead researcher will transport the data securely, enter the data into the database at the earliest opportunity and then delete the hardcopies. As an NHS employee (at Lancashire Care NHS Foundation Trust) and honorary researcher at SRFT (the lead trust and field supervisor's place of work), clinical data will be extracted from Trust databases/clinical records by the lead researcher for this site only. In all cases, data will be kept secure and unique ID's will be used in place of any identifiable data.

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:

Clinicians from each service in each NHS trust will identify potential routes to recruit appropriate participants through a combination of reviews of clinician caseloads, reviews of waiting lists for treatment of follow-up and also a review of databases containing participants who have consented to be contacted about research. Clinicians will identify whether patients meet the inclusion criteria to partake in the study. The lead researcher can maintain regular contact with clinicians to offer guidance relating to inclusion criteria and study participation.

A27-3. Describe what measures will be taken to ensure there is no breach of any duty of confidentiality owed to patients, service users or any other person in the process of identifying potential participants.*Indicate what steps have been or will be taken to inform patients and service users of the potential use of their records for this purpose. Describe the arrangements to ensure that the wishes of patients and service users regarding access to their records are respected. Please consult the guidance notes on this topic.*

Only clinicians within each service who already have access to patient data as part of routine clinical practice will be able to screen waiting lists/clinician case loads, patient databases and reviews of follow-up patients.

As part of the consent process, participants will be asked to consent to their injury data being collected from the service and shared with the research team. The data collected will be pre-defined and specific to the TBI only. No further personal data will be gathered from patient record systems. All participants will be allocated a unique ID by the clinician which will enable the clinical data to be attached to the participant's questionnaire data set, while maintaining participant anonymity. While hardcopies of the consent form will contain the participants' name, no identifiable information will be logged in the data set. Each participants' unique ID will be used in place of participants name on all measures used in the study.

A27-4. Will researchers or individuals other than the direct care team have access to identifiable personal information of any potential participants?

(•) Yes ( ) No

A27-5. Has prior consent been obtained or will it be obtained for access to identifiable personal information?

(•) Yes ( ) No

If Yes, please give details below.

As part of the consent process, participants will be asked to consent to their injury data being collected from the service and shared with the research team. A completed consent form for each participant will be required prior to their injury data being transferred to the research team.

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

○ Yes ◉ No

A29. How and by whom will potential participants first be approached?

Clinicians from each service in each NHS trust will identify potential routes to recruit appropriate participants through a combination of reviews of clinician caseloads, reviews of waiting lists for treatment of follow-up and also a review of databases containing participants who have consented to be contacted about research. Clinicians will identify whether patients meet the inclusion criteria to partake in the study. Patients identified as eligible to take part in the study will be sent a study pack containing the cover letter, information sheet, consent form and questionnaires (see "Materials" section). Dissemination of the study pack will depend on the recruitment route, for example in some cases the study pack may be sent to potential participants in the post prior to an upcoming appointment, allowing them to consider a review the materials before deciding whether to take part. Alternatively, participants may be given the study pack in person by the clinician when they attend for an appointment.

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.

An information sheet and consent form will be used alongside a cover letter for each host trust in order to ensure informed consent is gathered. A completed consent form for each participant will be required prior to their data being added to the dataset.

If you are not obtaining consent, please explain why not.

n/a

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?

Participants can be recruited into the study at any time during the data collection phase. Participants who would like to take the study information home to further consider whether they would like to take part will be given an estimate of the remaining time for data collection.

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)*

As an inclusion criterion of the study, participants will be able to understand and complete measures in the English language. Due to the resource limitations of the study, translation and interpretation services cannot be supported but most importantly, the measures to be used have not been validated in other languages and could therefore be invalid if translated into other languages.

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:

n/a

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
- ☐ Access to social care records by those outside the direct social care 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
- ☑ 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
- ☐ Storage of personal data on any of the following:
  - ☑ Manual files (includes paper or film)
  - ☑ NHS computers
  - ☐ Social Care Service computers
  - ☐ Home or other personal computers
  - ☑ University computers
  - ☐ Private company computers
  - ☐ Laptop computers

Further details:

Relevant clinicians in each service will access patient medical records to retrieve specific information which will be given to researcher. Participants are asked to consent to this in order to participate. This is the case in all Trusts except Salford Royal NHS Foundation Trust where the clinical data will be extracted from Trust databases/clinical records by the lead researcher. At all other sites, the data will be extracted by a clinician and passed to the lead researcher as outlined above.

Electronic transfer of participant information will be conducted securely as per data protection processes. A unique ID will be allocated to each participant's data set to ensure confidentiality.

Use of personal addresses or emails will only be used if instigated by the participants in order to request a copy of the final study write up. Any personal details will be destroyed once a copy of the study has been sent.

A37. Please describe the physical security arrangements for storage of personal data during the study?

Completed hardcopies of the questionnaire packs will be kept securely at the host trust until collected at the earliest opportunity by the lead researcher. Completed questionnaire packs will be kept in a locked cabinet within a secure office space. At the earliest opportunity, the lead researcher will scan the completed documents in electronically and save them to the university's secure server. The hardcopies will then be destroyed. In all cases, data will be kept secure and unique IDs will be used in place of any identifiable data.

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.*

During the data collection phase, the Data Protection Act, GDPR principles and NHS Code of Confidentiality will be followed at all times. The process described above (question A37) will be followed during the study to maintain confidentiality.
Following the study, as per University policy, the study dataset (including digital copies of the consent forms) will be stored on the University's secure server or a secure cloud service with the same security credentials and held for 10 years. Copies of the completed questionnaires will be deleted from the system once the lead researcher has completed their viva. Following the completion of the study, the data will be kept securely by the research coordinator of the Lancaster University Doctorate in Clinical Psychology and will remain under the custodianship of Fiona Eccles (research supervisor). After 10 years, the data custodian will arrange for the data to be deleted from the system.

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.*

Initially, only clinicians within the host trust will have access to participants personal data. As part of the consent process, participants will be asked to consent to their injury data being collected from the service and shared with the research team. However, as an NHS employee (at Lancashire Care NHS Foundation Trust) and honorary researcher at Salford Royal NHS Foundation Trust (the lead trust and field supervisor's place of work), clinical data will be extracted from Trust databases/clinical records by the lead researcher. At all other sites, the data will be extracted by a clinician and passed to the lead researcher as outlined above.

All participants will be allocated a unique ID by the clinician which will enable the clinical data to be attached to the participant's data set, while maintaining participant anonymity. While hardcopies of the consent form will contain the participants' name, no identifiable information will be logged on the database. Each participants' unique ID will be used in place of participants name on all measures used in the study.

Storage and use of data after the end of the study

A41. Where will the data generated by the study be analysed and by whom?

The data will be analysed on secure university servers by the lead researcher and the research team.

A42. Who will have control of and act as the custodian for the data generated by the study?

	Title	Forename/Initials	Surname
	Dr	Fiona	Eccles
Post	Lecturer in Health Research		
Qualifications	DClinPsy		
Work Address	C34 Furness		
	Lancaster University		
	Bailrigg		
Post Code	LA1 4YT		
Work Email	f.eccles@lancaster.ac.uk		
Work Telephone	01524592807		
Fax	0		

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:
As per University policy, the study dataset (including digital copies of the consent forms which may include participants' names) will be stored on the University's secure server or a secure cloud service with the same security credentials and held for 10 years. The completed questionnaires will be destroyed once the lead researcher has completed their viva. Following the completion of the study, the data will be kept securely by the research coordinator of the Lancaster University Doctorate in Clinical Psychology and will remain under the custodianship of Fiona Eccles (research supervisor). After 10 years, the data custodian will arrange for the data to be deleted from the system.

A44. For how long will you store research data generated by the study?

Years: 10
Months: 0

A45. Please give details of the long term arrangements for storage of research data after the study has ended. *Say where data will be stored, who will have access and the arrangements to ensure security.*

As per the Lancaster University policy, following the completion of the study the data will be kept securely by the research coordinator of the Lancaster University Doctorate in Clinical Psychology and will remain under the custodianship of Fiona Eccles (research supervisor). After 10 years, the data custodian will arrange for the data to be deleted from the system.

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

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 database 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)

The results of this study will be written up as a Doctorate in Clinical Psychology thesis, assessed by Lancaster University. Following this, the lead researcher will seek to publish the results of this study in a relevant academic journal and may also present the results at relevant conferences.
The results of the thesis will be shared in the Lancaster Doctorate in Clinical Psychology programme's thesis presentation day and participants will also be asked if they would like to receive a copy of the results following the completion of the study.

A52. If you will be using identifiable personal data, how will you ensure that anonymity will be maintained when publishing the results?

No identifiable personal data will be included in the write up of the study. Only demographic and injury data will be used in order to describe the sample and this will be presented as group data (e.g. means, medians, percentages etc as appropriate)

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 informed that they can receive a copy of the results following the completion of the study by contacting the lead researcher on the contact details provided on the information sheet. Once the study results have been disseminated, all identifiable information (including names/emails/addresses etc) will be deleted.

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:
This study has been reviewed and approved by the Lancaster University Doctorate in Clinical Psychology research team. This process involved review by both clinical and research supervisors.

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	Fiona	Eccles
Department	Department of Health Research		
Institution	University of Lancaster		
Work Address	C34 Furness College Lancaster University Bailrigg		
Post Code	LA1 4YG		

Telephone	01524592807
Fax	0
Mobile	01524592807
E-mail	f.eccles@lancaster.ac.uk

Please enclose a copy of any available comments or reports from a statistician.

A57. What is the primary outcome measure for the study?

n/a (observational study).

The Rivermead Post-concussion Symptoms Questionnaire (RPQ; King, Crawford, Wenden, Moss & Wade, 1995) will be used to assess symptoms of PCS.

A58. What are the secondary outcome measures?*(if any)*

1) The Forms of Self-Criticising/attacking & Self-Reassuring Scale (FSCRS; Gilbert, Clark, Hempel, Miles & Irons, 2004)
2) The Attitude To Self Scale (ATS; Carver, 2013)
3) The Cognitive Functioning Questionnaire (CFQ; Gershon, Lai, Bode, Choi, Moy, Bleck et al., 2012)
4) The Brief Illness Perceptions Questionnaire (BIPQ; Broadbent, Petrie, Main & Weinman, 2006)
5) The Patient Health Questionnaire 9 (PHQ-9; Kroenke, Spitzer, Williams, 2001)

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:	100
Total international sample size (including UK):	100
Total in European Economic Area:	100

Further details:
Approximately 100 participants will be required in order to conduct the proposed analysis. As research question 1 requires participants to be split into two groups based on their RPQ scores, it is hoped that participants will be recruited relatively equally into the two groups. Previous research reported that 22% of a sample with mild traumatic brain injury met criteria for PCS. However, as a recruitment strategy of this study involving review of neuropsychology waiting lists and clinician caseloads too (as opposed to just hospital follow-up), it is anticipated that a higher proportion of individuals meeting criteria for PCS will be recruited to achieve a relatively equal split.

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.*

With regards to sample size, the exact number of negative (no PPCS) and positive cases (PPCS) in the population cannot be determined at this stage for logistic regression analyses. However, based on the rule of thumb suggested by Peduzzi et al, assuming 3 predictors, and PPCS being present in approximately 30% of the sample, approximately 100 participants will be required. A similar study (Hou, Moss-Morris, Peveler & Mogg; 2012) reporting on similar participants, had similar sample sizes.

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.

Quantitative analysis will be completed using multivariate logistic regression. Logistic regression was chosen as the most appropriate methodology due to the design of the study and recruitment of two distinct groups; those with PPCS

and those whose symptoms have resolved. Linear regression will also be used as an appropriate methodology to analyse research question 2.

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
	Dr	Lorraine	King
Post	Clinical Psychologist		
Qualifications	DClinPsy		
Employer	Salford Royal NHS Foundation Trust		
Work Address	Department of Clinical Neuropsychology, Salford Royal NHS Foundation Trust.		
	Stott Lane,		
	Salford		
Post Code	M6 8HD		
Telephone	01612064694		
Fax	0		
Mobile	01612064694		
Work Email	Lorraine.King@srft.nhs.uk		

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: Non-Commercial

If Other, please specify: n/a

Contact person

Name of organisation	Lancaster University
Given name	Becky
Family name	Gordon
Address	Lancaster University
Town/city	Bailrigg

Post code	LA1 4YT
Country	UNITED KINGDOM
Telephone	01524592981
Fax	0
E-mail	sponsorship@lancaster.ac.uk

A65. Has external funding for the research been secured?

Please tick at least one check box.

- [ ] Funding secured from one or more funders
- [ ] External funding application to one or more funders in progress
- [x] 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:
n/a

A66. Has responsibility for any specific research activities or procedures been delegated to a subcontractor (other than a co-sponsor listed in A64-1) ? *Please give details of subcontractors if applicable.*

( ) Yes (•) No

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
	Miss	Katie	Doyle
Organisation	Salford Royal NHS Foundation Trust		
Address	Summerfield House 1st Floor		
	544 Eccles New Road		
	Salford		
Post Code	M5 5AP		
Work Email	Katie.Doyle@srft.nhs.uk		

Telephone	01612064734
Fax	0
Mobile	01612064734

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: 01/10/2019
Planned end date: 30/06/2020
Total duration:
Years: 0 Months: 8 Days: 30

A71-1. Is this study?

( ) Single centre
(•) Multicentre

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 4

Does this trial involve countries outside the EU?
( ) Yes (•) No

A72. Which organisations in the UK will host the research? *Please indicate the type of organisation by ticking the box and give approximate numbers if known:*

- [x] NHS organisations in England 4
- [ ] 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
- [ ] Joint health and social care agencies (eg community mental health teams)
- [ ] Local authorities
- [ ] Phase 1 trial units
- [ ] Prison establishments
- [ ] Probation areas

☐ Independent (private or voluntary sector) organisations
☐ Educational establishments
☐ Independent research units
☐ Other (give details)

n/a

Total UK sites in study: 4

A73-1. Will potential participants be identified through any organisations other than the research sites listed above?

○ Yes ◉ No

A74. What arrangements are in place for monitoring and auditing the conduct of the research?

The lead researcher will have regular supervision with both clinical and research supervisors throughout the duration of the study.

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.

☐ 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)

n/a

Please enclose a copy of relevant documents.

A78. Could the research lead to the development of a new product/process or the generation of intellectual property?

○ Yes ◉ No ○ Not sure

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 further information please refer to guidance.*

Investigator identifier	Research site		Investigator Name	
IN1	◉ NHS/HSC Site ○ Non-NHS/HSC Site		Forename Middle name Family name Email	Lorraine n/a King lorraine.king@srft.nhs.uk
	Organisation name	SALFORD ROYAL NHS FOUNDATION TRUST	Qualification (MD...)	DClinPsy
	Address	SALFORD ROYAL STOTT LANE SALFORD GREATER MANCHESTER	Country	UNITED KINGDOM
	Post Code	M6 8HD		
	Country	ENGLAND		
IN2	◉ NHS/HSC Site ○ Non-NHS/HSC Site		Forename Middle name Family name Email	Roisin n/a Cunningham roisin.cunningham@aintree.nhs.uk
	Organisation name	AINTREE UNIVERSITY HOSPITAL NHS FOUNDATION TRUST	Qualification (MD...)	DClinPsy
	Address	UNIVERSITY HOSPITAL AINTREE FAZAKERLEY HOSPITAL LOWER LANE LIVERPOOL MERSEYSIDE	Country	UNITED KINGDOM
	Post Code	L9 7AL		
	Country	ENGLAND		
IN4	◉ NHS/HSC Site ○ Non-NHS/HSC Site		Forename Middle name Family name Email	Anna n/a Merrett Anna.merrett@nhs.net
	Organisation name	DORSET HEALTHCARE UNIVERSITY NHS FOUNDATION TRUST	Qualification (MD...)	DClinPsy
	Address	SENTINEL HOUSE 4-6 NUFFIELD ROAD NUFFIELD INDUSTRIAL ESTATE POOLE DORSET	Country	UNITED KINGDOM
	Post Code	BH17 0RB		
	Country	ENGLAND		
IN5	◉ NHS/HSC Site ○ Non-NHS/HSC Site		Forename Middle name Family name Email	Catherine n/a McMahon Catherine.mcmahon@thewaltoncentre.nhs.uk
	Organisation name	THE WALTON CENTRE NHS FOUNDATION TRUST	Qualification (MD...)	DClinPsy
	Address	LOWER LANE LIVERPOOL MERSEYSIDE	Country	UNITED KINGDOM
	Post Code	L9 7LJ		
	Country	ENGLAND		

IRAS Form Reference: 19/YH/0311 IRAS Version 5.13

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 fulfil the responsibilities of the chief investigator for this study as set out in the UK Policy Framework for Health and Social Care Research.
3. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.
4. 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.
5. 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.
6. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.
7. 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.
8. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.
9. 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 2018.
10. 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.
11. 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 2018.
12. 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 Health Research Authority (HRA) together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after the issue of the ethics committee's final opinion or the withdrawal of the application.

Contact point for publication *(Not applicable for R&D Forms)*

HRA 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
- ○ 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 MISS LINDSAY PRESCOTT on 04/09/2019 13:50.

Job Title/Post:	Trainee Clinical Psychologist
Organisation:	Lancashire Care NHS Foundation Trust
Email:	l.prescott@lancaster.ac.uk

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 responsibilities of sponsors set out in the UK Policy Framework for Health and Social Care Research will be fulfilled in relation to this research.

   Please note: *The declarations below do not form part of the application for approval above. They will not be considered by the Research Ethics Committee.*
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.
8. Specifically, for submissions to the Research Ethics Committees (RECs) I declare that any and all clinical trials approved by the HRA since 30th September 2013 (as defined on IRAS categories as clinical trials of medicines, devices, combination of medicines and devices or other clinical trials) have been registered on a publically accessible register in compliance with the HRA registration requirements for the UK, or that any deferral granted by the HRA still applies.

This section was signed electronically by An authorised approver at sponsorship@lancaster.ac.uk on 05/09/2019 08:41.

Job Title/Post:	Head of Research Quality and Policy
Organisation:	Lancaster University
Email:	b.gordon@lancaster.ac.uk

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 UK Policy Framework for Health and Social Care Research.

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 Mr Will Curvis on 04/09/2019 14:18.

Job Title/Post:	Clinical tutor
Organisation:	Lancaster University
Email:	w.curvis@lancaster.ac.uk

Academic supervisor 2

This section was signed electronically by Dr Fiona Eccles on 04/09/2019 14:04.

Job Title/Post:	Lecturer
Organisation:	Lancaster University
Email:	f.eccles@lancaster.ac.uk

2. Study Protocol

Research Protocol

The role of self-criticism in the experience of persistent post-concussion symptoms following traumatic brain injury

Research Team

Lead Researcher: Lindsay Prescott, Trainee Clinical Psychologist, Doctorate in Clinical Psychology, Lancaster University.

Field Supervisor: Dr Lorraine King**,** Clinical Psychologist, Department of Clinical Neuropsychology, Clinical Sciences Building, Salford Royal NHS Foundation Trust.

Research Supervisor: Dr Fiona Eccles, Lecturer in health research, Lancaster University.

Research Supervisor: Dr Will Curvis, Clinical Psychologist and tutor, Lancaster University.

Background & Rationale

Post-concussion symptoms (PCS), and more specifically, persistent PCS (PPCS) has been an issue of great controversy within the area of neuropsychology for several decades (Iverson, Zasler & Lange, 2007). PCS is a common experience following traumatic brain injury (TBI) and includes symptoms such as headaches, dizziness, sleep disturbance, irritability and memory and concentration difficulties. In most cases these symptoms are expected to resolve within three months although for some, symptoms remain and become persistent.

Long debates over the aetiology of PPCS continue with neurological, psychological and non-injury related factors demonstrating significant contributions in the research literature. Early theories posited that organic (neurobiological) factors were central to the experience of early PCS and psychological factors were only later influential in the persistence of symptoms

(Lishman, 1988). However, in their review article, Silverberg and Iverson (2011) proposed a new model of PCS development whereby an interaction between both neurobiological and psychological factors play a causal role from the outset.

Psychological theories for PPCS generally centre around individuals' attributions of their difficulties post TBI and expectations of recovery. Hou, Moss-Morris, Peveler and Mogg (2012) found that TBI illness perceptions were the biggest predictor of PCS at 6 months post-injury. Whittaker, Kemp and House (2007) also concluded from their longitudinal study of 73 patients that illness perceptions play a key part in the persistence of PCS. Broshek, De Marco and Freeman (2015) also reported on the contribution of cognitive bias and misattribution of symptoms from normal experiences to symptoms attributed to the TBI and PPCS. These findings correspond with other research positing that perceptions of stress and subsequent coping style significantly impact on symptom reporting and intensity of PCS symptoms (Machulda, Bergquist, Ito & Chew, 1998). Malec, Brown, Moessner, Stump and Monahan (2010) also reported that self-appraisal of post-TBI ability related to experiences of depression. These findings highlight the role of self-appraisal in distress relating to PPCS.

Some studies have reported on the effects of psychological intervention within the first few weeks of TBI, influencing individuals' expectations and perceptions of recovery as a preventative approach to the development of PPCS. Wade and colleagues (1998) for example, found a significant reduction in the emergence of PPCS following early psychological intervention focussed on information and advice giving (Wade, King, Wenden, Crawford & Caldwell, 1998). However, for those who do go on to develop PPCS, the research literature on effective psychological interventions remains in its infancy. A few studies demonstrate evidence of positive effects following cognitive behavioural therapy (CBT; Silverberg, Hallam & Rose, 2013; Mittenberg, Tremont, Zielinski, Fichera & Rayls, 1996; Scheenen, Visser-Keizer, & de Koning, 2017) and cognitive rehabilitation strategies (Tiersky, Anselmi, Johnston

& Kurtyka, 2005) although the standardisation of treatment approaches vary considerably within the studies, making conclusions difficult to draw. These findings from treatment studies supporting the use of education further indicate the importance of self-appraisal/attribution in the process of PPCS.

However, limitations of CBT have been noted across the research literature as challenging 'negative' thoughts are not always useful or appropriate for clinical change (Gilbert 2009a). This is particularly relevant within the TBI population whereby changes in self-concept and identity are so prominent. There is a growing body of research linking individuals' self-concept and their patterns of relating to themselves, to symptom reporting and quality of life after brain injury. Self-concept and self-esteem have been shown to impact on perceived quality of life after brain injury (Vickery, Gontkovsky & Caroselli, 2004), with these being rated as significantly lower in individuals following brain injury compared to age and gender matched controls (Ponsford, Cameron, Fitzgerald, Grant, Mikocka-Walus, & Schönberger, 2014). Reduced self-esteem has also been linked to psychological distress after TBI (Cooper-Evans, Alderman, Knight & Oddy, 2008) and therefore it is reasonable to hypothesise that intrapersonal variables may therefore also be involved in the maintenance of PPCS.

One specific intrapersonal variable that has received increasing attention across clinical populations in recent years is self-criticism. Self-criticism has been increasingly researched as a transdiagnostic process underlying many experiences of psychological distress (Gilbert, 2000) including depression (Gilbert, 2009b), chronic pain (Penlington, 2018) and has recently been applied to the wider brain injury population (Ashworth, 2014; Ashworth, Clarke, Jones, Jennings & Longworth, 2015). A self-critical intrapersonal style may well be an important factor in the maintenance of PPCS and uncovering this may provide a key focus of future treatment. The prevention studies above demonstrate the importance of patients receiving

positive messages and expectations regarding recovery following TBI. However, it makes sense that the small group of individuals who go on to develop PPCS are naturally more self-critical in their intrapersonal style, influencing more negative appraisals of their symptoms, increasing distress and thus exacerbating a self-critical style. This increasing psychological distress is hypothesised to influence the experience of PPCS.

Research Aims and Questions

The role of self-criticism and its impact on the development or maintenance of PPCS has not yet been investigated in the research literature and will therefore be the focus of this study. This will be investigated alongside measures of self-appraisal of cognitive functioning and illness perceptions. While psychological theories signify the role of cognitive appraisal and self-perceptions in persisting symptoms (McCrea, 2008), for example the "expectation as aetiology" hypothesis and the "nocebo effect", empirical studies remain scarce. As such, this study aims to confirm and build upon current theory and literature by investigating whether these three variables together, self-criticism, self-appraisal of cognitive functioning and illness perceptions, can predict PPCS.

In addition, given the increased rates of depression following traumatic brain injury (Singh, Mason, Lecky & Dawson, 2018;), the study also aims to investigate whether self-criticism, appraisal of cognitive functioning and illness perceptions can predict depression in individuals with PPCS.

The primary and secondary research questions are:

1. Does self-criticism, self-appraisals of cognitive functioning and illness perceptions predict PPCS?
2. Does self-criticism, self-appraisals of cognitive functioning and illness perceptions predict depression after TBI?

Method

Design

This study will take a quantitative methodological approach using an independent measures cross-sectional design. Participants will be categorised into two groups; PPCS and non-PPCS, depending on whether their scores on a measure of PCS meets the threshold for diagnosis or not. Research question 1 will use multi-variate logistic regression with all three predictor variables included in the model. If relevant, demographic and injury data will be controlled for.

In order to answer research question 2 linear multiple regression will be used in order to see if the three variables; self-criticism, appraisal of cognitive functioning and illness perceptions, are predictive of depression.

Participants

Participants eligible for inclusion in the study will i) be aged 18 years old and over, ii) be between 3- and 12-months post-injury, iii) have been admitted to an adult inpatient hospital ward due to traumatic head injury and subsequently discharged home (rather than to a specialist inpatient rehabilitation unit) and iv) be able to understand and complete questionnaires in the English language.

These inclusion criteria would ensure participants' injuries are of a milder severity (compared to those who require further specialist neuro-rehabilitation) and would be able to consent to taking part in the study. While injury demographic and injury data will not be used as an inclusion criterion, it will be used to described and situate the sample. The 3-month lower limit is clinically appropriate as this is the lower time limit for PCS to be categorised as 'persistent'.

Patients who have sustained a brain injury due to other non-traumatic causes (e.g. stroke, infection etc) will not be included in the study. Those who are unable to complete

questionnaires in the English language will also be excluded due to the resource limitations of the study and the measures used not being validated in other languages.

Materials

Demographic Information Sheet

Demographic data will be collected from the participants (with participants' consent) in order to situate the sample. Demographic data to be collected will include: age at time of injury, current age, gender, employment status, level of education, partnership status, ethnicity, previous use of mental health services, presence of ongoing litigation, any other ongoing medical conditions including the presence of orthopaedic injury and/or pain and a list of currently prescribed medications. The first seven items will be used to situate the sample whereas previous use of mental health services and the presence of ongoing litigation are important variables to consider in the analysis given previous research highlighting their potential role in the persistence of PCS (Lishman, 1988; Binder & Rohling, 1996). Gathering information about any ongoing pain, medical conditions and a list of current medications are also important variables to consider as they too can impact on the presence of PPCS. The side effects of certain medications can mirror some of the symptoms of PPCS and so it would be important to consider this during the analysis.

TBI Information Sheet

Injury data will be collected from the participants' clinical records with participants' consent in order to accurately describe the sample. Injury data to be collected from the service wherever possible will include: date of injury, earliest Glasgow Coma Scale (GCS) score, duration of unconsciousness, duration of post-traumatic amnesia (PTA), cause of injury and length of stay in hospital.

The Rivermead Post-concussion Symptoms Questionnaire (RPQ; King, Crawford, Wenden, Moss & Wade, 1995) will be used to assess symptoms of PCS in both groups. The

RPQ is a 16-item self-report questionnaire assessing the presence of symptoms on a 5-point Likert scale from "not experienced at all" to "a severe problem". Responses can be summed to give a total score. Thompson and colleagues (2016) found an optimal cut-off score of 16 on the RPQ which demonstrated 97% sensitivity and 87% specificity when comparing healthy controls with individuals experiencing PCS. The measure can also be split into the RPQ3 (first 3 items) and the RPQ13 (latter 13 items), both of which have demonstrated strong test-retest reliability (coefficients 0.89 and 0.72 respectively; Eyres, Carey, Gilworth, Neumann & Tennant, 2005).

The Forms of Self-Criticising/attacking & Self-Reassuring Scale (FSCRS; Gilbert, Clark, Hempel, Miles & Irons, 2004) will be used as a measure of self-criticism. The FSCRS is a 22 item self-report questionnaire measuring both self-criticism and self-reassurance/self-compassion. The FSCRS has demonstrated strong internal consistency (0.87 to 0.94; Baião, Gilbert, McEwan & Carvalho, 2015). The FSCRS has recently been used with individuals with a brain injury (Ashworth, Clarke, ones, Jennings & Longworth, 2015).

The Attitude To Self Scale (ATS; Carver, 2013) will be used as another measure of intrapersonal relating. The ATS consists of 10 questions measuring 3 constructs; high standards, self-criticism and generalisation. Each question is rated on a 5-point Likert scale from "I agree a lot" to "I disagree a lot". This measure assesses more a person's relationship with themselves overall as opposed to specific reactions to negative events as in the FSCRS. The ATS is reported to have strong internal consistency with average alpha reliabilities of 0.76 for the high standards scale, 0.78 for the self-criticism scale, and 0.78 for the generalisation scale (MIDSS, 2019).

The Cognitive Functioning Questionnaire (CFQ; Gershon, Lai, Bode, Choi, Moy, Bleck et al., 2012) will be used to assess participants appraisals of their current cognitive functioning. The CFQ is a 28-item self-report questionnaire assessing various aspects of

cognitive functioning on a 5-point Likert scale from "never" to "very often". It has been validated for use within the brain injury population (Tulsky, Kisala, Victorson, Carlozzi, Bushnik, Sherer et al, 2016) with a Cronbach's alpha value of 0.97.

The Brief Illness Perceptions Questionnaire (BIPQ; Broadbent, Petrie, Main & Weinman, 2006) will be used as a measure of participants' illness perceptions. The BIPQ consists of 9 questions covering both cognitive and emotional illness perceptions plus a question of perceived causality. Each question is rated on a 10-point Likert scale, with differing values dependent on the question. The BIPQ demonstrates good test-retest validity in a variety of health populations (for a full review see Broadbent, Wilkes, Koschwanez, Weinman, Norton & Petrie, 2015). The BIPQ has also been used widely in the brain injury population and demonstrated strong internal consistency with a Cronbach's alpha of 0.85 (Measurement Instrument Database for the Social Sciences, 2019).

The Patient Health Questionnaire 9 (PHQ-9; Kroenke, Spitzer, Williams, 2001) will be used to assess participant current levels of depression. The PHQ-9 consists of 9 questions identifying the frequency of cognitive, emotional and somatic symptoms of depression rated on a 4-point Likert scale from "not at all" to "nearly every day". The PHQ-9 has been evidenced as a valid and reliable tool for assessing depression after TBI with test-retest reliability r=0.76 (Fann, Bombardier, Dikmen, Esselman, Warms & Pelzer et al, 2005).

Gaining Informed Consent

An information sheet and consent form will be used alongside a cover letter for each host trust in order to ensure informed consent is gathered. A completed consent form for each participant will be required prior to their data being added to the dataset.

Procedure

Recruitment

Participants will be recruited from several major trauma sites and community/outpatient neuropsychology services locally and nationally. These will initially include: Salford Royal NHS Foundation Trust (SRFT; the lead trust), Aintree University Hospital NHS Foundation Trust, The Walton Centre NHS Foundation Trust and Dorset Healthcare University NHS Foundation Trust, but may be extended to include other trusts. In this case, additional NHS trusts will be required to adhere to the procedures outlined in this protocol.

Clinicians from each NHS trust will identify potential routes to recruit appropriate participants through a combination of reviews of clinician caseloads, reviews of waiting lists for treatment of follow-up and also a review of databases containing participants who have consented to be contacted about research. Clinicians will identify whether patients meet the inclusion criteria to partake in the study. The lead researcher can maintain regular contact with clinicians to offer guidance relating to inclusion criteria and study participation. Patients will have the opportunity to contact the lead researcher with any questions they have prior to taking part.

Data Collection

Patients identified as eligible to take part in the study will be sent a study pack containing the cover letter, information sheet, consent form and questionnaires (see "Materials" section). Dissemination of the study pack will depend on the recruitment route, for example in some cases the study pack may be sent to potential participants in the post prior to an upcoming appointment, allowing them to review the materials before deciding whether to take part. Alternatively, participants may be given the study pack in person by the clinician when they attend for an appointment. Or indeed participants may be sent the material in the post with no direct contact with clinicians (e.g. if on database where they have agreed to be sent information about research). As part of the consent process, participants will be asked to consent to their

injury data being collected from the service and shared with the research team. All participants will be allocated a unique ID by the clinician within each relevant NHS trust which will enable the clinical data (collected using the TBI Information sheet) to be added to the participant's data set while maintaining participant anonymity. While the consent form will contain the participants' names, no identifiable information will be logged on the study database. Each participant's unique ID will be used in place of the participant's name on all measures used in the study.

Following the completion of the measures by the participant the clinical data will be securely transferred from the relevant clinician to the lead researcher. This may take several forms depending on the processes of data security within each trust but may include: email encryption, upload of data to a secure cloud service, telephone call whereby data from the clinician can be entered directly into the database by the lead researcher or collection of data in person by the lead researcher. In the latter case, the lead researcher will transport the data securely, enter the data into the database at the earliest opportunity and then delete the hardcopies of the TBI information sheet. As an NHS employee (at Lancashire Care NHS Foundation Trust) and honorary researcher at SRFT (the lead trust and field supervisor's place of work), clinical data will be extracted from Trust databases/clinical records by the lead researcher at SRFT only. At all other sites, the data will be extracted by a clinician and passed to the lead researcher as outlined above. In all cases, data will be kept secure and unique IDs will be used in place of any identifiable data.

Data Storage

Completed hardcopies of the questionnaire packs will be kept securely either at the host trust until collected by or transferred to the lead researcher at the earliest opportunity or, if sent to the lead researcher directly, the hardcopies will be kept securely at Lancaster University. Completed questionnaire packs will be kept in a locked cabinet within a secure office space.

At the earliest opportunity, the lead researcher will scan the completed documents in electronically and save them to the university's secure server. The hardcopies will then be destroyed. Electronic copies of completed questionnaires will be destroyed following examination of the lead researcher's thesis.

As per University policy, the study data (including digital copies of the consent forms) will be stored on the University's secure server or a secure cloud service with the same security credentials and held for 10 years. Following the completion of the study, the data will be kept securely by the research coordinator of the Lancaster University Doctorate in Clinical Psychology and will remain under the custodianship of Fiona Eccles (research supervisor). After 10 years, the data custodian will arrange for the data to be deleted from the system.

Proposed Analysis

For research question 1, quantitative analysis will be completed using multivariate logistic regression. Logistic regression was chosen as the most appropriate methodology due to the design of the study and recruitment of two distinct groups; those with PPCS and those whose symptoms have resolved. Linear regression will also be used as an appropriate methodology to analyse research question 2 as the dependent variable (depression) is continuous.

Practical Issues

Due to the nature of the methodological design, recruitment of participants may present difficulties. Recruiting directly from services, whereby participant demographics and injury data can be accurately collected, was considered as the most preferred option as opposed to online recruitment. Recruitment from multiple host trusts was decided in order to mitigate against this risk. However, should direct recruitment from services become problematic, an online version of the materials (e.g. using the Qualtrics survey programme) will be used to disseminate the study wider to include third sector organisations such as Headway charity. In

such cases, participant injury data will rely on self-report rather than clinical data. In this case, an amendment will be sought to modify the recruitment materials appropriately.

Ethical concerns

There are no significant risks identified with participating in this study. However, it is possible that the sensitivity of the information being collated from participants may result in emotional distress. All participants will be provided with contact details for additional emotional support in the information sheet should they need it, including those reporting no ongoing symptoms. Participants are made aware that their participation is voluntary, and they can withdraw from the study at any time prior to the measures being returned to the research team. At this point the data will be anonymous and therefore difficult to separate from the data set. As participants will be recruited directly from services, they will be in contact with services during the recruitment phase. As such, it is likely that participants experiencing ongoing difficulties will remain open to the service and so any concerns raised regarding risk to participants' during the study can also be highlighted to the relevant clinical team. Should participants require additional support following the study if they are no longer open to the NHS service, as per clinical practice, participants are directed to their GP.

There are no identified risks to researchers and no lone -working is required as part of the study. Clinicians involved in the study will follow the relevant trusts' guidelines relating to seeing patients.

Service-User & Stakeholder Involvement

Service users from Salford Royal NHS Foundation Trust have been involved in the review of study materials, contributing to the design and usability for participants. Clinicians working in the area have been involved in the design and planning of the study to ensure its relevance and usefulness to clinical practice.

Dissemination

The results of this study will be written up as a Doctorate in Clinical Psychology thesis, assessed by Lancaster University. Following this, the lead researcher will seek to publish the results of this study in a relevant academic journal and may also present the results at relevant conferences and special interest groups.

The results of the thesis will be shared in the Lancaster Doctorate in Clinical Psychology programme's thesis presentation day and participants will also be asked if they would like to receive a copy of the results following the completion of the study.

Study Timeline

The timeline below is an estimate of the duration of time required for each aspect of the study and may be subject to change.

Time	**Stage of Study**
July/August 2019	Submit documentation for ethical approval NHS REC
September 2019	Receive ethical approval and HRA approval
October 2019 – January 2020	Data collection and data entry
January – February 2020	Data analysis
February -March 2020	Write up draft and submit to supervisor for review
April – May 2020	Amendments and write up of final draft
May 2020	Submit thesis to University

Protocol References

Ashworth, F., Clarke, A., Jones, L., Jennings, C. & Longworth, C. (2015). An exploration of compassion focused therapy following acquired brain injury. *Psychology and Psychotherapy: Theory, Research and Practice.* 88 (2), 143-162.

Ashworth, F., Gracey, F. & Gilbert, P. (2011). Compassion focused therapy after traumatic brain injury: Theoretical foundations and a case illustration. *Brain Impairment*. 12 (2), 128-139.

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3. HRA Approval Letter

Miss Lindsay Prescott
C34 Furness
Lancaster University
Lancaster
LA1 4YT

Email: hra.approval@nhs.net
HCRW.approvals@wales.nhs.uk

23 September 2019

Dear Miss Prescott

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

Study title:	**The role of self-criticism in the experience of persistent post-concussion symptoms following traumatic brain injury**
IRAS project ID:	**264755**
Protocol number:	**n/a**
REC reference:	**19/YH/0311**
Sponsor	**Lancaster University**

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

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

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

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

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

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

What are my notification responsibilities during the study?

The standard conditions document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

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

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

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

Your IRAS project ID is **264755**. Please quote this on all correspondence.

Yours sincerely,

Hayley Henderson
Approvals Manager

Email: hra.approval@nhs.net

Copy to: *Mrs Becky Gordon, Sponsor Contact*

4. Ethical Approval Letter

NHS
Health Research Authority

Yorkshire & The Humber - Bradford Leeds Research Ethics Committee
NHSBT Newcastle Blood Donor Centre
Holland Drive
Newcastle upon Tyne
NE2 4NQ

Telephone: 0207 104 8018

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

05 September 2019

Miss Lindsay Prescott
C34 Furness
Lancaster University
Lancaster
LA1 4YT

Dear Miss Prescott,

Study title:	**The role of self-criticism in the experience of persistent post-concussion symptoms following traumatic brain injury**
REC reference:	**19/YH/0311**
IRAS project ID:	**264755**

The Proportionate Review Sub-committee of the Yorkshire & The Humber - Bradford Leeds Research Ethics Committee reviewed the above application on 05 September 2019.

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.

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

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for

research is available in the Integrated Research Application System.

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

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

Registration of Clinical Trials

It is a condition of the REC favourable opinion that all clinical trials are registered on a publicly accessible database. For this purpose, clinical trials are defined as the first four project categories in IRAS project filter question 2. For clinical trials of investigational medicinal products (CTIMPs), other than adult phase I trials, registration is a legal requirement.

Registration should take place as early as possible and within six weeks of recruiting the first research participant at the latest. Failure to register is a breach of these approval conditions, unless a deferral has been agreed by or on behalf of the Research Ethics Committee (see here for more information on requesting a deferral: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/research-registration-research-project-identifiers/

As set out in the UK Policy Framework, research sponsors are responsible for making information about research publicly available before it starts e.g. by registering the research project on a publicly accessible register. Further guidance on registration is available at: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/transparency-responsibilities/

You should notify the REC of the registration details. We routinely audit applications for compliance with these conditions.

Publication of Your Research Summary

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit: https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/

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).

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, including early termination of the study

- Final report

The latest guidance on these topics can be found at https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

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").

Approved documents

The documents reviewed and approved were:

Document	*Version*	*Date*
Confirmation of any other Regulatory Approvals (e.g. CAG) and all correspondence [Lancaster University Approval]	0.1	04 July 2019
Covering letter on headed paper [Participant Cover Letter]	0.2	04 September 2019
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance Document]	0.1	18 July 2019
IRAS Application Form [IRAS_Form_07082019]		07 August 2019
IRAS Checklist XML [Checklist_05092019]		05 September 2019
Letter from sponsor [Sponsorship Letter]	0.1	06 August 2019
Non-validated questionnaire [Demographic Information Sheet]	0.1	01 August 2019
Non-validated questionnaire [TBI Information Sheet]	0.1	01 August 2019
Other [Response Document]	0.1	04 September 2019
Participant consent form [Participant Consent Form]	0.2	04 September 2019
Participant information sheet (PIS) [Participant Information Sheet]	0.2	04 September 2019
Research protocol or project proposal [Research Protocol]	0.1	01 August 2019
Schedule of Events or SoECAT [Schedule of Events]	0.2	19 August 2019
Summary CV for Chief Investigator (CI) [Lindsay Prescott CV]	0.1	23 July 2019
Summary CV for supervisor (student research) [Fiona Eccles CV]	0.1	23 July 2019
Summary CV for supervisor (student research) [Will Curvis CV]	0.1	23 July 2019
Validated questionnaire [PHQ-9]	0.1	02 August 2019
Validated questionnaire [BIPQ]	0.1	23 July 2019
Validated questionnaire [RPQ]	0.1	23 July 2019
Validated questionnaire [CFQ]	0.1	23 July 2019
Validated questionnaire [ATS]	0.1	02 August 2019
Validated questionnaire [FSCRS]	0.1	02 August 2019

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.

User Feedback

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

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: https://www.hra.nhs.uk/planning-and-improving-research/learning/

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

19/YH/0311	**Please quote this number on all correspondence**

Yours sincerely
pp

Dr Janet Holt
Chair

Email: nrescommittee.yorkandhumber-bradfordleeds@nhs.net

5. Participant Cover Letter

Doctorate in Clinical Psychology | Lancaster University

Insert relevant trust logo

Dear patient,

We are conducting a study to investigate the role of self-criticism in the experience of persistent post-concussion symptoms (PPCS) after traumatic brain injury. Post-concussion symptoms include symptoms such as headache, dizziness and forgetfulness and whilst they usually get better within weeks, for a small proportion of people, the symptoms can become persistent. We are investigating different factors that might influence the persistence of symptoms.

As such, we are looking for people who have experienced a traumatic brain injury within the last **two** years to take part in the study. Participants don't have to be experiencing ongoing symptoms in order to participate. A clinician from *[insert name of NHS service]* believes that you may be eligible to take part as you have experienced a traumatic brain injury within the last **two** year.

Further information about the study and what taking part will involve can be found in the information sheet attached. We would be grateful if you would read through this information and consider taking part in the study. If you are happy to take part, please complete the questionnaires enclosed and return them to *[insert name of clinician]* at *[insert name of NHS service]*. Alternatively, you can return completed questionnaires to the research team using the enclosed pre-paid envelope.

Research studies enable us to advance our knowledge and understanding of complex areas, such as traumatic brain injury, and your contribution would be greatly valued.

If you would like any further information or have any questions, please do contact us on the details provided on the information sheet.

With best wishes,

Lindsay Prescott
Trainee Clinical Psychologist

Under the supervision of:

Dr Lorraine King	**Dr Fiona Eccles**	**Dr Will Curvis**
Clinical Psychologist	**Research Supervisor**	**Research Supervisor**

6. **Participant Information Sheet**

Doctorate in Clinical Psychology | Lancaster University

Insert Relevant Trust Logo

Participant Information Sheet

The role of self-criticism in the experience of persistent post-concussion symptoms following Traumatic Brain Injury

My name is Lindsay Prescott and I am conducting this research as a student on the Doctorate of Clinical Psychology programme at Lancaster University.

What is the study about?

The purpose of this study is to investigate whether self-criticism plays a role in the experience of persistent post-concussion symptoms (PPCS) after traumatic brain injury. We are looking at the effect of self-criticism in relation to a person's view of their current thinking abilities and both their perceptions of and severity of post-concussion symptoms.

Why have I been approached?

You have been approached because the study requires information from people who have experienced a traumatic brain injury within the last year. We are looking for people who continue to have ongoing or persistent symptoms of post-concussion, and also those whose symptoms have resolved.

What will I be asked to do if I take part?

If you decide you would like to take part, you would be asked to complete a number of questionnaires asking you to rate your views of your current abilities, symptoms of post-concussion and levels of self-criticism. You will also be asked to provide some demographic information (such as your age, gender, partnership status etc) and complete a questionnaire relating to your mood.

If you agree to take part, you will also consent to the service providing the researcher with information relating to your brain injury including the date of injury, earliest Glasgow Coma Scale score (a measure used to assess level of alertness after head injury), duration of unconsciousness, duration of post-traumatic amnesia, cause of injury and length of stay in hospital.

Do I have to take part?

No. It's completely up to you to decide whether or not you take part. Taking part in the study will not have any impact on the care or treatment you receive. You can change your mind at any point during the completion of the questionnaires and withdraw from the study before returning them to the research team. However, once you have returned your questionnaires they will be anonymised and so it will not be possible to withdraw them at this stage.

Will my data be identifiable?

The information you provide will be kept confidential and anonymous as a unique ID will be allocated to your completed questionnaires in place of any identifiable information such as your name. The data collected for this study will be stored securely and only the researchers conducting this study will have access to this data. Hard copies of questionnaires will be kept in a locked cabinet. Any files on the computer will be encrypted (that is no-one other than the researcher will be able to access them) and the computer itself password protected.
During the study, completed questionnaires and consent forms will be scanned onto a secure computer and saved electronically. All hardcopies will then be destroyed. At the end of the study, the electronic data will be kept securely by the university for ten years. At the end of this period, they will be destroyed.

Lancaster University will be the data controller for any personal information collected as part of this study. Under the GDPR you have certain rights when personal data is collected about you. You have the right to access any personal data held about you, to object to the processing of your personal information, to rectify personal data if it is inaccurate, the right to have data about you erased and, depending on the circumstances, the right to data portability. Please be aware that many of these rights are not absolute and only apply in certain circumstances. If you would like to know more about your rights in relation to your personal data, please speak to the researcher on your particular study.

For further information about how Lancaster University processes personal data for research purposes and your data rights please visit our webpage: www.lancaster.ac.uk/research/data-protection

What will happen to the results?

The questionnaires from all participants will be analysed and reported in a thesis project to be assessed by Lancaster University. The study write up may also be submitted for publication in an academic or professional journal and presented at conferences. Participants can request a free copy of the final study by contacting the lead researcher on the details provided below.

Are there any risks?

There are no risks anticipated with participating in this study. However, if you experience any distress following participation you are encouraged to inform the researcher and contact the resources provided at the end of this sheet.

Are there any benefits to taking part?

There are no direct benefits to taking part in this study. Many people find pleasure in helping contribute to ongoing research and knowledge.

Who has reviewed the project?

This study has been reviewed and approved by an NHS Health Research Authority Research Ethics Committee. Your local NHS trust have also agreed to become a host site for the study and their involvement has been agreed by each trust's own research and development team.

How do I take part?

If you consent to take part in the study, please complete the attached consent form before completing the questionnaires in your pack. Once you have completed the questionnaires, you can return them to *[insert name of clinician]* at *[insert name of NHS service]*. Alternatively, you can return completed questionnaires to the research team using the enclosed pre-paid envelope.

Where can I obtain further information about the study if I need it?

If you have any questions about the study, please contact the main researcher:

Researcher &Trainee Clinical Psychologist
Name: Lindsay Prescott
Lancaster Doctorate in Clinical Psychology, Email: l.prescott@lancaster.ac.uk
Lancaster University, Lancaster, Contact Number: 07508 375 657

LA1 4YG

Alternatively, you can speak to the Research Supervisors from the Lancaster Clinical Psychology training programme on:

Name: Dr Fiona Eccles
Email: f.eccles@lancaster.ac.uk
Contact Number: 01524 592807

Name: Dr Will Curvis
Email: w.curvis@lancaster.ac.uk
Contact Number: 01524 593096

Postal Address: C34 Furness College, Lancaster University, Lancaster, LA1 4YG

Complaints

If you wish to make a complaint or raise concerns about any aspect of this study and do not want to speak to the researcher, you can contact:

Dr Ian Smith
Email: I.smith@lancaster.ac.uk
Research Director, Doctorate in Clinical Psychology,
Lancaster University, Lancaster
LA1 4YG

If you wish to speak to someone outside of the DClinPsy Doctorate Programme, you may also contact the Associate Dean for Research:

Professor Roger Pickup Tel: +44 (0)1524 593746
Email: r.pickup@lancaster.ac.uk
Faculty of Health and Medicine
Lancaster University, Lancaster
LA1 4YG

Resources in the event of distress

Should you feel distressed either as a result of taking part, or in the future, the following resources may be of assistance. If you feel that you require additional psychological support following the completion of the study, you can request this either from your GP, or alternatively, from the neuropsychology department if you are still attending appointments.

Headway Brain Injury Charity
Tel: 0808 800 2244 Email: helpline@headway.org.uk Web: www.headway.org.uk

7. Participant Consent Form

Doctorate in Clinical Psychology | Lancaster University

Insert relevant trust Logo

Consent Form

The role of self-criticism in the experience of persistent post-concussion symptoms following Traumatic Brain Injury

We are asking if you would like to take part in a research project investigating the role of self-criticism in the experience of persistent post-concussion symptoms in individuals who have sustained a traumatic brain injury. You are being asked to take part because you have previously sustained a traumatic brain injury.

Before you consent to participating in the study we ask that you read the participant information sheet and initial each box below if you agree. If you have any questions or queries before signing the consent form please speak to the principal investigator, Lindsay Prescott.

1. I confirm that I have read the information sheet and fully understand what is expected of me within this study ☐
2. I confirm that I have had the opportunity to ask any questions and to have them answered. ☐
3. I understand that my participation is voluntary and that I can choose not to take part, without my medical care or legal rights being affected. ☐
4. I consent to a clinician or researcher from the NHS trust accessing relevant information about my TBI and passing these to the principal investigator. ☐
5. I understand that the principal investigator will discuss the data I provide with their supervisors as needed. ☐
6. I consent to Lancaster University keeping the anonymised data and my consent form for a minimum of 10 years after the study has finished. ☐
7. I consent to take part in the above study. ☐

Name of Participant_____ **Signature**_____ **Date** _____

(2 copies to be signed; one for the participant and one for the researcher)

8. Participant Study Questionnaires

Doctorate in Clinical Psychology | Lancaster University

Insert Relevant Trust Logo

Demographic Information Sheet

Participant ID: **(staff to complete)**	

Current age: ☐☐ years ☐☐ months

Age at time of injury: ☐☐ years ☐☐ months

Gender: ☐ Male ☐ Female ☐ Non-binary ☐ Prefer not to say

How would you best describe your current employment status:

☐ Full-time employed ☐ Part-time employed ☐ Self-employed

☐ Unemployed - looking for employment ☐ Unemployed – not looking for employment

☐ Other (please state):_____

How would you best describe your level of education:

☐ Some secondary school ☐ Completed secondary school ☐ GCSE qualifications

☐ A-level qualifications ☐ Undergraduate degree ☐ Post-graduate degree

☐ Other (please state):_____

How would you best describe your current partnership status:

☐ Married / Civil Partnership / Co-habiting ☐ Divorced / Separated

☐ Single ☐ Widow(er)

How would you best describe your ethnicity:

☐ White ☐ Mixed / Multiple ethnic groups ☐ Asian / Asian British

☐ Black / African / Caribbean / Black British ☐ Other ethnic group

Have you ever accessed mental health services prior to your head injury?

□ Yes □ No □ Prefer not to say

Have you ever lost consciousness prior to your recent head injury?

□ No □ Yes *(If 'Yes' how many times?)*

If 'yes', please provide brief details below (e.g. cause, how long you were unconscious for and medical care received)

_____

_____

Are you currently involved in a legal process in relation to your recent head injury?

□ Yes □ No □ Planning to seek legal support □ Prefer not to say

Do you have any other ongoing medical or mental health conditions (e.g. epilepsy, chronic health condition, pain, post-traumatic stress, depression etc)?

□ Yes □ No

If 'yes' please state (if able):

_____

_____

Please provide a list of your currently prescribed medications

Thank you for your time

The Rivermead Post-Concussion Symptoms Questionnaire*

After a head injury or accident some people experience symptoms which can cause worry or nuisance. We would like to know if you now suffer from any of the symptoms given below. As many of these symptoms occur normally, we would like you to compare yourself now with before the accident. For each one, please circle the number closest to your answer.

0 = Not experienced at all
1 = No more of a problem
2 = A mild problem
3 = A moderate problem
4 = A severe problem

Compared with before the accident, do you now (i.e., over the last 24 hours) suffer from:

Headaches	0	1	2	3	4
Feelings of Dizziness	0	1	2	3	4
Nausea and/or Vomiting	0	1	2	3	4
Noise Sensitivity, easily upset by loud noise	0	1	2	3	4
Sleep Disturbance	0	1	2	3	4
Fatigue, tiring more easily	0	1	2	3	4
Being Irritable, easily angered	0	1	2	3	4
Feeling Depressed or Tearful	0	1	2	3	4
Feeling Frustrated or Impatient	0	1	2	3	4
Forgetfulness, poor memory	0	1	2	3	4
Poor Concentration	0	1	2	3	4
Taking Longer to Think	0	1	2	3	4
Blurred Vision	0	1	2	3	4
Light Sensitivity, Easily upset by bright light	0	1	2	3	4
Double Vision	0	1	2	3	4
Restlessness	0	1	2	3	4

Are you experiencing any other difficulties?

1. _____	0	1	2	3	4
2. _____	0	1	2	3	4

*King, N., Crawford, S., Wenden, F., Moss, N., and Wade, D. (1995) J. Neurology 242: 587-592

06/23/08

Cognitive Function

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

	How much DIFFICULTY do you currently have…	**None**	**A little**	**Somewhat**	**A lot**	**Cannot do**
NQCOG15r1	keeping track of time (eg., using a clock)?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQCOG16r1	checking the accuracy of financial documents, (e,g., bills, checkbook, or bank statements)?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQCOG22r1	reading and following complex instructions (e.g., directions for a new medication)?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQCOG24r1	planning for and keeping appointments that are not part of your weekly routine, (e.g., a therapy or doctor appointment, or a social gathering with friends and family)?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQCOG25r1	managing your time to do most of your daily activities?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQCOG26r1	planning an activity several days in advance (e.g., a meal, trip, or visit to friends)?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQCOG31r1	getting things organized?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQCOG38r1	remembering where things were placed or put away (e.g., keys)?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQCOG39r1	remembering a list of 4 or 5 errands without writing it down?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQCOG40r1	learning new tasks or instructions?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

	In the past 7 days…	Never	Rarely (once)	Sometimes (2-3 times)	Often (once a day)	Very often (several times a day)
NQCOG46r1	I made simple mistakes more easily……....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQCOG53r1	Words I wanted to use seemed to be on the "tip of my tongue"……	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQCOG64r1	I had to read something several times to understand it……...	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQCOG65r1	I had trouble keeping track of what I was doing if I was interrupted……...	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQCOG66r1	I had difficulty doing more than one thing at a time……...	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQCOG67r1	I had trouble remembering whether I did things I was supposed to do, like taking a medicine or buying something I needed…	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQCOG68r1	I had trouble remembering new information, like phone numbers or simple instructions…….……..	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQCOG69r1	I walked into a room and forgot what I meant to get or do there……..	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQCOG70r1	I had trouble remembering the name of a familiar person…….……	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQCOG72r1	I had trouble thinking clearly……..	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQCOG73r1	I reacted slowly to things that were said or done…….……	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQCOG74r1	I had trouble forming thoughts…….	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQCOG75r1	My thinking was slow…….……	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQCOG77r1	I had to work really hard to pay attention or I would make a mistake…….	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

	In the past 7 days…	Never	Rarely (once)	Sometimes (2-3 times)	Often (once a day)	Very often (several times a day)
NQCOG80r1	I had trouble concentrating…….	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQCOG83r1	I had trouble getting started on very simple tasks……	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQCOG84r1	I had trouble making decisions……...	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
NQCOG89r1	I had trouble planning out steps of a task...	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

The Brief Illness Perceptions Questionnaire

For the following questions below, please refer to your recent head injury and its impact on you as the 'illness'.

For the following questions, please circle the number that best corresponds to your views:

How much does your illness affect your life?

0	1	2	3	4	5	6	7	8	9	10
no affect at all										severely affects my life

How long do you think your illness will continue?

0	1	2	3	4	5	6	7	8	9	10
a very short time										forever

How much control do you feel you have over your illness?

0	1	2	3	4	5	6	7	8	9	10
absolutely no control										extreme amount of control

How much do you think your treatment can help your illness?

0	1	2	3	4	5	6	7	8	9	10
not at all										extremely helpful

How much do you experience symptoms from your illness?

0	1	2	3	4	5	6	7	8	9	10
no symptoms at all										many severe symptoms

How concerned are you about your illness?

0	1	2	3	4	5	6	7	8	9	10
not at all concerned										extremely concerned

How well do you feel you understand your illness?

0	1	2	3	4	5	6	7	8	9	10
don't understand at all										understand very clearly

How much does your illness affect you emotionally? (e.g. does it make you angry, scared, upset or depressed?)

0	1	2	3	4	5	6	7	8	9	10
not at all affected emotionally										extremely affected emotionally

Please list in rank-order the three most important factors that you believe caused your illness.

The most important causes for me:-

1. _____
2. _____
3. _____

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THE FORMS OF SELF-CRITICISING/ATTACKING &

SELF-REASSURING SCALE (FSCRS)

When things go wrong in our lives or don't work out as we hoped, and we feel we could have done better, we sometimes have *negative and self-critical thoughts and feelings*. These may take the form of feeling worthless, useless or inferior etc. However, people can also try to be supportive of them selves. Below are a series of thoughts and feelings that people sometimes have. Read each statement carefully and circle the number that best describes how much each statement is true for you.

Please use the scale below.

Not at all like me 0	A little bit like me 1	Moderately like me 2	Quite a bit like me 3	Extremely like me 4

When things go wrong for me:

1.	I am easily disappointed with myself.	0	1	2	3	4
2.	There is a part of me that puts me down.	0	1	2	3	4
3.	I am able to remind myself of positive things about myself.	0	1	2	3	4
4.	I find it difficult to control my anger and frustration at myself.	0	1	2	3	4
5.	I find it easy to forgive myself.	0	1	2	3	4
6.	There is a part of me that feels I am not good enough.	0	1	2	3	4
7.	I feel beaten down by my own self-critical thoughts.	0	1	2	3	4
8.	I still like being me.	0	1	2	3	4
9.	I have become so angry with myself that I want to hurt or injure myself.	0	1	2	3	4
10.	I have a sense of disgust with myself.	0	1	2	3	4
11.	I can still feel lovable and acceptable.	0	1	2	3	4
12.	I stop caring about myself.	0	1	2	3	4
13.	I find it easy to like myself.	0	1	2	3	4
14.	I remember and dwell on my failings.	0	1	2	3	4
15.	I call myself names.	0	1	2	3	4

THE Compassionate Mind FOUNDATION

16.	I am gentle and supportive with myself.	0	1	2	3	4
17.	I can't accept failures and setbacks without feeling inadequate.	0	1	2	3	4
18.	I think I deserve my self-criticism.	0	1	2	3	4
19.	I am able to care and look after myself.	0	1	2	3	4
20.	There is a part of me that wants to get rid of the bits I don't like.	0	1	2	3	4
21.	I encourage myself for the future.	0	1	2	3	4
22.	I do not like being me.	0	1	2	3	4

ATS

Respond to each of the following statements by marking a number on your answer sheet. Do not leave any items blank. Please be as honest as you can throughout, and try not to let your answer to one item influence your answers to other items. There are no correct or incorrect answers. You are simply to express your own personal feelings. For each statement, indicate how much you agree or disagree with it, by choosing one of the following responses:

1 = I agree a lot
2 = I agree a little
3 = I'm in the middle--I neither agree nor disagree
4 = I DISagree a little
5 = I DISagree a lot

1. Compared to other people, I expect a lot from myself.
2. When even one thing goes wrong I begin to wonder if I can do well at anything at all.
3. I get angry with myself if my efforts don't lead to the results I wanted.
4. When it comes to setting standards for my behavior, I aim higher than most people.
5. I hardly ever let unhappiness over one bad time influence my feelings abut other parts of my life.
6. When I don't do as well as I hoped to, I often get upset with myself.
7. I set higher goals for myself than other people seem to.
8. If I notice one fault of mine, it makes me think about my other faults.
9. I get unhappy with anything less than what I expected of myself.
10. A single failure can change me from feeling OK to seeing only the bad in myself.

Reverse-code all items except 5

High Standards = Items 1, 4, 7
Self-Criticism = Items 3, 6, 9
Generalization = Items 2, 5, 8, 10

Patient Health Questionnaire (PHQ-9)

Patient Name: _____ **Date:** _____

	Not at all	Several days	More than half the days	Nearly every day
1. Over the *last 2 weeks,* how often have you been bothered by any of the following problems?				
a. Little interest or pleasure in doing things	☐	☐	☐	☐
b. Feeling down, depressed, or hopeless	☐	☐	☐	☐
c. Trouble falling/staying asleep, sleeping too much	☐	☐	☐	☐
d. Feeling tired or having little energy	☐	☐	☐	☐
e. Poor appetite or overeating	☐	☐	☐	☐
f. Feeling bad about yourself or that you are a failure or have let yourself or your family down	☐	☐	☐	☐
g. Trouble concentrating on things, such as reading the newspaper or watching television.	☐	☐	☐	☐
h. Moving or speaking so slowly that other people could have noticed. Or the opposite; being so fidgety or restless that you have been moving around a lot more than usual.	☐	☐	☐	☐
i. Thoughts that you would be better off dead or of hurting yourself in some way.	☐	☐	☐	☐
2. If you checked off any problem on this questionnaire so far, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?	Not difficult at all	Somewhat difficult	Very difficult	Extremely difficult
	☐	☐	☐	☐

Section Five - Additional Appendices

Appendix A - Author submission guidance for target journal "Neuropsychological Rehabilitation"

Instructions for authors

COVID-19 impact on peer review

As a result of the significant disruption that is being caused by the COVID-19 pandemic we understand that many authors and peer reviewers will be making adjustments to their professional and personal lives. As a result they may have difficulty in meeting the timelines associated with our peer review process. Please let the journal editorial office know if you need additional time. Our systems will continue to remind you of the original timelines but we intend to be flexible.

Thank you for choosing to submit your paper to us. These instructions will ensure we have everything required so your paper can move through peer review, production and publication smoothly. Please take the time to read and follow them as closely as possible, as doing so will ensure your paper matches the journal's requirements.

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For editing support, including translation and language polishing, explore our Editing Services website

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About the Journal

Neuropsychological Rehabilitation is an international, peer-reviewed journal publishing high-quality, original research. Please see the journal's Aims & Scope for information about its focus and peer-review policy.

Please note that this journal only publishes manuscripts in English.

Neuropsychological Rehabilitation accepts the following types of article: original articles, scholarly reviews, book reviews.

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Preparing Your Paper

All authors submitting to medicine, biomedicine, health sciences, allied and public health journals should conform to the Uniform Requirements for Manuscripts Submitted to Biomedical Journals, prepared by the International Committee of Medical Journal Editors (ICMJE).

Clinical trials: must conform to the Consort guidelines http://www.consort-statement.org. Submitted papers should include a checklist confirming that all of the Consort requirements have been met, together with the corresponding page number

of the manuscript where the information is located. In addition, trials must be pre-registered on a site such as clinicaltrials.gov or equivalent, and the manuscript should include the reference number to the relevant pre-registration.

Systematic reviews: submitted papers should follow PRISMA http://www.prisma-statement.org/ guidelines and submission should also be accompanied by a completed PRISMA checklist, together with the corresponding page number of the manuscript where the information is located.

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The EQUATOR Network (Enhancing the Quality and Transparency of Health Research) website provides further information on available guidelines.

Structure

Your paper should be compiled in the following order: title page; abstract; keywords; main text introduction, materials and methods, results, discussion; acknowledgments; declaration of interest statement; references; appendices (as

appropriate); table(s) with caption(s) (on individual pages); figures; figure captions (as a list).

Word Limits

Please include a word count for your paper. There are no word limits for papers in this journal.

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Authors may submit their paper in any scholarly format or layout. Manuscripts may be supplied as single or multiple files. These can be Word, rich text format (rtf), open document format (odt), or PDF files. Figures and tables can be placed within the text or submitted as separate documents. Figures should be of sufficient resolution to enable refereeing.

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Between 5 and 5 **keywords**. Read making your article more discoverable, including information on choosing a title and search engine optimization.

Funding details. Please supply all details required by your funding and grant-awarding bodies as follows:

For single agency grants

This work was supported by the [Funding Agency] under Grant [number xxxx].

For multiple agency grants

This work was supported by the [Funding Agency #1] under Grant [number xxxx]; [Funding Agency #2] under Grant [number xxxx]; and [Funding Agency #3] under Grant [number xxxx].

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Data availability statement. If there is a data set associated with the paper, please provide information about where the data supporting the results or analyses presented in the paper can be found. Where applicable, this should include the hyperlink, DOI or other persistent identifier associated with the data set(s). Templates are also available to support authors.

Data deposition. If you choose to share or make the data underlying the study open, please deposit your data in a recognized data repository prior to or at the time of submission. You will be asked to provide the DOI, pre-reserved DOI, or other persistent identifier for the data set.

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