PROFESSIONAL DOCTORATES

Personal Resources in Recovery: A Quantitative Study of Resiliency, Grit, and Coping in Rehabilitation Following Acquired Brain Injury

Todd Jones, Jenna

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Personal Resources in Recovery: A Quantitative Study of Resiliency, Grit, and Coping in Rehabilitation Following Acquired Brain Injury

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North Wales Clinical Psychology Programme, Bangor University

Submitted in partial fulfilment of the requirements for the degree of Doctor of Clinical Psychology

June 2018
“Failure to study the intimate interaction of cognition and personality leads to an inadequate understanding of many issues in cognitive (neuro)sciences and neuropsychological rehabilitation.”

Principles of Neuropsychology Rehabilitation, Prigatano, 1999
Acknowledgements

I would like to thank the North Wales Brain Injury Service for making the final year of my clinical training an experience I will never forget. I am incredibly grateful for the opportunity to have worked with such dedicated, skilled, and kind colleagues. Neither this thesis nor my clinical practice would have been possible without your support. In particular, I would like to thank Rudi Coetzer as my research supervisor. You have allowed me to be myself in this research process, an experience I am unfamiliar with but which I hugely appreciate. Thank you for your care and dedication in guiding this project from start to finish.

A huge thank you to each participant who volunteered their time to share their extraordinary stories with me. I feel privileged to have met every one of you. Your experiences of struggles and success have provided me with a special insight into the day-to-day challenges of those living with brain injuries. I look forward to conducting more research with others like you.

I recognise the huge amount of support provided by the Research Team to all of us as trainees, and I thank you personally for all the timely, insightful, and life-saving help you have provided me. I am grateful to my placement supervisors along the way who have helped to shape me as a clinician, and my training coordinators Helen Healy and Robert Jones for fighting my corner and always being available to listen.

I would also like to thank the trainees of the 2015 cohort for making this experience 100% worthwhile. Alongside the heartache and frustration of deadlines and targets #teaminterdependent found a place where we could support each other and laugh together. I look forward to graduating with you all and moving forward together in our qualified work!

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Thesis Abstract

This thesis explores the role of personal resources, including personality and coping style, in rehabilitation following acquired brain injury (ABI).

The first chapter consists of a systematic literature review and meta-analysis addressing the effectiveness of coping skills groups in improving coping in those with an ABI. Five articles were eligible for inclusion and comprised single group design and blind randomised controlled trials. A small, statistically non-significant effect size was found for improving coping following coping skills group interventions. This was the first meta-analytic review of its kind, finding no evidence to support the implementation of coping skills groups for improving coping in ABI. Some articles reported improvements across other physical, psychological, and social outcomes.

The second chapter reports empirical research investigating the influence of personality traits on successful return to meaningful activity (RTMA) and return to work (RTW) following ABI. Twenty-six participants were prospectively recruited from a rural community brain injury rehabilitation service more than a year following ABI. Participants completed several questionnaires capturing resilience, grit, awareness, cognitive function, demographic, and vocational information. Only higher cognitive function scores predicted RTMA, but not RTW. This suggests that of the antecedent, mediating, and post-injury factors examined measures of grit and resiliency did not predict outcome following ABI after accounting for cognitive function. The implications and limitations of this finding are discussed.

The third chapter explores the outcome of the meta-analytic review and empirical papers, discussing implications for theory, further research, and clinical practice. An explanatory model of recovery in ABI is used to contextualise the thesis, followed by a discussion of potential research regarding personality and attachment in recovery. Clinical implications of personality style and coping in individualised and systemic interventions are discussed.

The thesis concludes with a reflective piece exploring the personal and professional thoughts of the trainee.
# Abbreviations used in this thesis

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>ABI</td>
<td>Acquired Brain Injury</td>
</tr>
<tr>
<td>BICS</td>
<td>Brain Injury Coping Scale</td>
</tr>
<tr>
<td>CBT</td>
<td>Cognitive Behavioural Therapy</td>
</tr>
<tr>
<td>CISS</td>
<td>Coping Inventory for Stressful Situations</td>
</tr>
<tr>
<td>CSA</td>
<td>Coping Scale for Adults</td>
</tr>
<tr>
<td>CSE</td>
<td>Coping Self-Efficacy scale</td>
</tr>
<tr>
<td>MDT</td>
<td>Multi Disciplinary Team</td>
</tr>
<tr>
<td>MoCA</td>
<td>Montreal Cognitive Assessment</td>
</tr>
<tr>
<td>NEO FFI</td>
<td>Neuroticism, Extraversion, Openness Five Factor Inventory</td>
</tr>
<tr>
<td>NEO PI-R</td>
<td>Neuroticism, Extraversion, Openness Personality Inventory – Revised</td>
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<tr>
<td>RCT</td>
<td>Randomised Controlled Trial</td>
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<tr>
<td>RTMA</td>
<td>Return To Meaningful Activity</td>
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<td>RTW</td>
<td>Return To Work</td>
</tr>
<tr>
<td>SGD</td>
<td>Single Group Design</td>
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<tr>
<td>SRSI</td>
<td>Self Regulation Skills Interview</td>
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<tr>
<td>TBI</td>
<td>Traumatic Brain Injury</td>
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</table>
Chapter 1

Meta-Analysis and Systematic Literature Review
Instructions for contributors – Archives of Physical Medicine and Rehabilitation

The Effectiveness of Coping Skills Groups in Improving Coping Following Acquired Brain Injury: A Systematic Review and Meta-Analysis

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Abstract

Objective: To synthesise the current literature examining the effectiveness of coping skills groups in improving coping following acquired brain injury (ABI) in adults.

Data Sources: A search of Web of Science, PsychInfo, and PubMed (1990 – 2017) was conducted, including both concepts of ABI and coping skills groups. References were also identified by extending the previous search to include names of frequently used measures of coping, and review of references of eligible articles.

Article Selection: The review included articles written in English with a quantitative, experimental design where participants with a mild, moderate, or severe ABI completed a group-based intervention to develop coping skills, and that included at least one outcome measure of coping.

Data Extraction: Following PRISMA guidelines 65 full-length articles were reviewed; 5 articles, with a total of 238 participants, met the inclusion criteria. Baseline and post-intervention data for coping measures were extracted for single group design articles, and for both the intervention and control arms of randomised controlled trial design articles from each eligible article by the principal author.

Data Synthesis: Articles were assessed for quality based on Reichow (2011) indicators of quality; all articles were found to have weak methodological rigor. A random effects meta-analysis revealed an overall effect size of 0.21 (95% CI = -0.12 to 0.53).

Conclusions: The present meta-analysis found that coping skills groups do not improve coping following ABI, although they do show improvement in measures of psychological wellbeing, cognitive functioning, and quality of life. Issues around the heterogeneity of measures of coping are discussed. Since only a small number of RCTs exist in the literature the authors recommend that further research with coping skills groups use this experimental design.

Key words: Brain injuries; Group Psychotherapy; Rehabilitation; Psychological Adaptation; Meta-Analysis

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Conflict of interest
All authors declare that they have no financial or personal relationships with other people or organisations that could inappropriately influence their work.
List of abbreviations:

ABI Acquired Brain Injury
CBT Cognitive Behavioural Therapy
SGD Single Group Design
RCT Randomised Controlled Trial
TBI Traumatic Brain Injury

Introduction

Acquired brain injury (ABI) is any form of brain injury sustained after birth and is one of the leading causes of death and disability worldwide (Colantonio et al., 2004; Feigin, Barker-Collo, Krishnamurthi, Theadom, & Starkey, 2010; Fleminger & Ponsford, 2005; Millis et al., 2001). In the UK, someone is admitted to hospital with an ABI every 90 seconds (Headway, 2015). ABI may be sustained as a result of traumatic brain injury (TBI; e.g., closed or penetrative injury to the head), cerebrovascular incident (e.g. stroke), oxygen deprivation, exposure to toxins or infection, or cancers. Mild, moderate, and severe ABI is associated with chronic disability (Tagliaferri, Compagnone, Korsic, Servadei, & Kraus, 2006; Thornhill et al., 2000), increased incidence of psychiatric illness (Deb, Lyons, Koutzoukis, Ali, & McCarthy, 1999; Scholten et al., 2016), and significant economic cost (Olesen, Gustavsson, Svensson, Wittchen, & Jönsson, 2012).

Re-entering society following ABI requires both short- and long-term, individualised intervention that addresses the medical, psychological, and social needs of each unique form of brain injury (Cullen, Chundamala, Bayley, & Group, 2007; Truelle, Fayol, Montreuil, & Chevignard, 2010). Rehabilitation goals often centre on participation in activities of daily living (Häggström & Lund, 2008), and a myriad of external and internal factors mediate a person’s successful reintegration into their community. This includes beliefs around self-efficacy and the ability to cope with new challenges that recovery from an ABI presents (Velzen, Bennekom, Edelaar, Sluiter, & Frings-Dresen, 2009).

The diverse range of definitions of coping encompasses variations in the theoretical underpinnings, research concept, and applied skills of coping. Generally the term coping reflects how people respond to stress such that they experience short-term
effects of resolution of a stressor, and long-term effects of improved wellbeing and health as a result of coping. Coping occurs when a personally relevant situational demand is appraised as exceeding one’s capacity and requires engagement in strategies to re-establish a balance between function and demands. This process is a form of cognitive and physiological homeostasis, an attempt to achieve on-going equilibrium through adaptation to novel challenges in our environment.

Attempts to operationalise coping as an organisational construct have produced a variety of theoretical models since the 1970s based on descriptions of stress, self-efficacy, and personality (Bandura, 1977; Frydenberg & Lewis, 1997; Haan, Joffe, Morrissey, & Naditch, 1977; Lazarus, 1996; Ptacek & Pierce, 2003; Skinner, Edge, Altman, & Sherwood, 2003; Vaillant, 1992). An exhaustive survey within the literature of categories of coping found 400 different labels of coping, with the most dominant categories linked to their appearance in the most frequently used psychometric measures of coping. A synthesis and analysis of this review identified five core families of coping: problem solving, supporting seeking, avoidance, distraction, and positive cognitive restructuring (Skinner et al., 2003). Broadly, engagement in coping strategies that are a good ‘fit’ for a particular demand leads to improved psychological wellbeing and long-term wellness, while maladaptive coping strategies lead to increased distress (Kato, 2015; Park, Folkman, & Bostrom, 2001). While coping strategies can be conceptualised as passive or active, this does not necessarily translate to ‘positive’ or ‘negative’ coping. Coping is not defined by a successful attempt to meet a demand or alleviate a stressor, but by the act of an effortful attempt to cope itself – even if this means ‘giving up’ to conserve resources.

A sudden shift in the frequency of novel stressors and potentially poor subjective appraisal of self-efficacy following ABI makes coping a natural choice for intervention (Krpan, Stuss, & Anderson, 2011). While individualised therapy can include the development of coping skills, the use of group therapy has natural appeal in order to economise the delivery of interventions. Group rehabilitation following ABI has demonstrated effectiveness for those struggling with adjustment to a new life (Lexell, Alkhed, & Olsson, 2013), cognitive impairments (Nair, Martin, & Sinclair, 2015), and acceptance (Mensenkampff et al., 2015). Group-based intervention is considered to be particularly valuable for those with ABI as it provides an opportunity to socialise with
others who experience the same difficulties, which often leads to shared validation and normalisation of their experiences (Appleton et al., 2011; Bédard et al., 2003). The number of group interventions targeting coping following ABI appears to be growing, with mixed findings. While some have found no apparent influence of group-based coping interventions on measures of coping, others have suggested that “observing others...who find solutions to their problems could be another way to improve self-efficacy beliefs” (Dumont, Gervais, Fouseyrollas, & Bertrand, 2004, p. 440). This systematic review and meta-analysis aims to determine the effectiveness of group-based interventions in improving coping following ABI.

**Method**

**Identification of articles**

Three electronic databases (Web of Science, PsychInfo, and PubMed) were searched in November 2017 using the following search terms: (“brain damage” OR “brain injury” OR “head trauma” OR “ABI”) AND (“coping” OR “coping skills” OR “skills group”). Further articles were found by using the same search terms combined with the name of frequently used coping measures found in Table 1 and by review of the reference section of found articles. Articles with titles indicating they may include an eligible intervention and outcome measures were read. The entire article was read if the abstract indicated that the article potentially met the inclusion criteria.

**Article inclusion criteria**

Articles were included in this review based on the following criteria: having been written in English; published between January 1990 and November 2017; include participants who have sustained a mild, moderate, or severe ABI (not including spinal injury); include only adult participants; include participants completing a group-based intervention to develop coping skills; include at least one outcome measure of coping; study data is quantitative; and, study design is experimental. Where data were missing in the identified articles, authors were contacted by email (three reminders were sent to non-responders at fortnightly intervals).
Assessment of article quality

The quality rating of methodological rigour of each article included in the analysis was assessed using criteria of primary (e.g. participant characteristics and statistical analysis) and secondary (e.g. randomised methods and social validity) indicators of quality from Reichow (2011). Each primary indicator was rated as being of high, acceptable, or unacceptable quality, and each secondary indicator was rated dichotomously (being either present, or not). Subsequently a level of rigour (strong, adequate, or weak) was determined from the number of ratings for each article, based on Reichow, Volkmar, & Cicchetti’s original classification (2008; see Table 2).

Data extraction and analysis

Full data for all measures of coping skills were extracted from the articles by the principal author. These data were statistically analysed using the Metafor package (Viechtbauer, 2010) for the statistical software environment, R (The R Foundation, 2018). The effect sizes for each study were calculated using the mean change in scores divided by the baseline standard deviation. For uncontrolled trials, the effect size from baseline to post-intervention was calculated relative to zero. For randomised controlled trials (RCTs), the difference between effect sizes for the two arms of the trial were used (Viechtbauer, 2010). Standard error of the calculated effect sizes for single group design (SGD) articles were estimated from pre- and post-test correlations (Schmidt & Hunter, 2004).

Due to the heterogeneity of the interventions and measures used within the articles a random effects model was used. This assumes that the effect sizes would differ between studies and allows estimation of this variance (Borenstein, Hedges, & Rothstein, 2007). The effect sizes of each article were weighted by sample size and pooled to provide an overall effect size of the effect of coping skills groups. Positive values represent an improvement in average scores from baseline to post-intervention measures. An effect size of 0.2 is typically considered to be a small effect, 0.5 a medium effect, and 0.8 a large effect (Cohen, 1988).
<table>
<thead>
<tr>
<th>Name</th>
<th>Author(s), Year</th>
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<tr>
<td>AACS</td>
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<td>Backhaus, Ibarra, Klyce, Trexler, &amp; Malec, 2010</td>
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<tr>
<td>BPST</td>
<td>Baycrest Psychosocial Stress Test</td>
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<td>CASQ</td>
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<td></td>
<td>Seiffge-Krenke, 1989</td>
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<td>CHIP</td>
<td>Coping With Health Injuries and Problems</td>
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<td>Coping Strategies Questionnaire</td>
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<tr>
<td>CSI</td>
<td>Coping Strategy Indicator</td>
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<td>Discourse Coping Scale</td>
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<td>FQCI</td>
<td>Freiburg Questionnaire on Coping with Illness</td>
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<td>Jalowiec Coping Scale</td>
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<td>Mental Adjustment to Cancer Scale</td>
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<td>MASS</td>
<td>Mental Adjustment to Stroke Scale</td>
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<td>PCI</td>
<td>Pain Coping Inventory</td>
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<tr>
<td>PCQ</td>
<td>Pain Coping Questionnaire</td>
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<td>R-COPE</td>
<td>Religious Coping Orientation for Problem Experiences</td>
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<td>RSQ</td>
<td>Responses to Stress Questionnaire</td>
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<tr>
<td>SEC</td>
<td>Symptom Expectancy Checklist</td>
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<tr>
<td>SRSI</td>
<td>Self-Regulation Skills Interview</td>
</tr>
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<td>TCS</td>
<td>Trier Coping Scales</td>
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<td>UCL</td>
<td>Utrecht Coping List</td>
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<td>VPMI</td>
<td>Vanderbilt Pain Management Inventory</td>
</tr>
<tr>
<td>WCCL-R</td>
<td>Ways of Coping Checklist Revised</td>
</tr>
<tr>
<td>WCQ</td>
<td>Ways of Coping Questionnaire</td>
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Results

Of the 746 articles that met inclusion criteria for this review, 681 were excluded based on review of the article abstracts, and a further 57 were excluded based on review of the full article; eight met the review inclusion criteria (Figure 1). Two of these articles included data from the same intervention, and two authors did not respond to requests for data. Therefore five articles were included for analysis (Anson & Ponsford, 2006; Appleton et al., 2011; Backhaus, Ibarra, Parrott, & Malec, 2016; Lundqvist, Linnros, Orlenius, & Samuelsson, 2010; Visser et al., 2016). Two of the studies used a blind RCT design, and three used a SGD with pre-test, post-test comparisons of outcome measures.

Characteristics of the articles

The main characteristics of the five articles are shown in Table 2 and Table 3. The median year of publication was 2011. Three SGD articles and two RCT articles were included in the analysis.

Participants

Three SGD articles were included in the analysis, with an overall mean age of participants of 39 (SD = 4.9). All articles varied considerably in the sample size included although most had roughly similar retention rates at follow-up. For the SGD articles the largest study included 33 participants with TBI only tested at pre- and post-intervention, and at 5-week follow-up (Anson & Ponsford, 2006). Lundqvist et al. (2010) similarly maintained 21 participants with TBI, stroke, infection, or heart irregularity at pre- and post-intervention, but included no follow-up. Appleton at al. (2011) lost 1 participant to attrition at post-intervention with 8 assessed, and a further 1 lost at 3-month follow-up. All participants were recruited from the community as outpatients with the exception of one study (Appleton et al., 2011) where participants were recruited as they engaged in inpatient rehabilitation. All participants had sustained moderate to severe brain injuries (although injury severity was not reported for Lundqvist et al., 2010).
For the RCT articles, with an overall mean age of 53 ($SD = 0.7$), Backhaus et al. (2016) maintained 10 participants at follow-up for both the intervention and control arms who had sustained TBI or other (undefined) ABIs. Visser et al.’s (2016) more robust study lost four participants in the intervention arm to follow-up (with 84 in the final analysis) and maintained 78 participants at follow-up in the control arm, all of whom had sustained a stroke only. In both cases participants were recruited directly at the point of inpatient or outpatient admission, however, the severity of ABI was unreported in both articles.

**Intervention**

The interventions varied in terms of length, frequency of session, format of delivery, and content. Of the SGD articles Anson and Ponsford (2006) and Appleton et al. (2011) both implemented a cognitive behavioural therapy (CBT) based intervention across 10- and 12-sessions respectively, Lundqvist et al. (2010) implemented an 11-session psychoeducation group. Anson and Ponsford (2006) taught participants a structured problem-solving technique alongside a ‘thoughts, feelings, behaviour’ model to address maladaptive thinking twice weekly. Participants were also encouraged to engage with problems rather than using avoidant coping, and were taught relaxation techniques. Written handouts and homework were provided each session to encourage practice. Appleton et al.’s (2011) intervention, termed the ‘social club’, was based upon a previously developed social skills program mixed with additional content from an individual CBT program for managing social anxiety following ABI over three sessions weekly. The sessions included strategies for developing social, coping, and assertiveness skills, relaxation techniques, cognitive strategies, and graded exposure. Lundqvist et al.’s (2010) psychoeducation-style group involved learning about brain organisation, cognitive, behavioural, and emotional changes after ABI, self-awareness, and stress management in 11 sessions across 6 months. Shared problem-solving and self-reflection, and practice of coping strategies outside the group, were encouraged. There was a particular focus on anticipatory self-awareness that involved discussion around planning for challenging situations ahead of time.
Figure 1. PRISMA diagram showing the process of study selection (Moher, Liberati, Tetzlaff, Altman, & Group, 2009).
Of the RCT articles Backhaus et al. (2016) used a combination of psychoeducation, CBT, stress management, and problem-solving skills delivered once weekly. Unlike the programs delivered by the SGD articles they engaged in role-play, although they similarly included homework and engaged in practice in-group. Visser et al. (2016) conducted an ‘add-on’ module weekly over the last 8 weeks of inpatient treatment as usual. In contrast to all other articles this group was dynamic, where participants entered and left the groups at individually designated time-points. The group focussed on problem-orientation and -solving based on a general model of coping with stress.

**Outcome measures**

Psychometric measures across all articles were of self-report design and evaluated dispositional or situation specific coping. Of the SGD articles, one used the Coping Scale for Adults (CSA), one the Self Regulation Skills Interview (SRSI), and one the Coping Self-Efficacy scale (CSE; see Table 2). The CSA short-form (Frydenberg & Lewis, 1997) is a 20-item scale developed in an Australian population (where participant recruitment was conducted). The measure uses ratings of the frequency of coping behaviours that are then divided into sub-scales of productive coping and non-productive coping. The productive and non-productive sub-scales have been linked with positive and negative outcomes respectively, indicating good construct validity, and they have adequate reliability ($\alpha = 0.65$ and 0.73 respectively; Frydenberg & Lewis, 2000). The scale was not developed for the ABI population but has a history of use in ABI populations (Anson & Ponsford, 2006; Curran, Ponsford, & Crowe, 2000; Hsieh et al., 2012; Aminah, Normah, & Ponnusamy, 2008).

The SRSI (Ownsworth, McFarland, & Young, 2000) is a six-item semi-structured interview developed in Australia used to assess a range of skills employed in rehabilitation following an ABI and their change over time. The scale was developed based on theoretical research of self-awareness and self-regulation. The measure has good construct validity with a three-factor solution: Strategy Behaviour (strategy generation, strategy use, and effects of strategies); Awareness (emergent awareness and anticipatory awareness); and, Readiness to Change (readiness to change). The SRSI has good test-retest reliability ($\alpha = 0.69$ to 0.91) and good inter-rater reliability ($\alpha = 0.81$ to
0.92) across its sub-scales, good concurrent validity with other measures of neuropsychological functioning, and demonstrates good discriminant validity between ABI and non-ABI groups (Ownsworth, McFarland, & Young, 2000). The scale was developed with an ABI population and has a history of use in ABI populations, although mainly within the same research group (Fleming, Shum, Strong, & Lightbody, 2005; Goverover, Johnston, Toglia, & DeLuca, 2007; Ownsworth, Desbois, Grant, Fleming, & Strong, 2006; Ownsworth, McFarland, & Mc Young, 2000; Toglia, Johnston, Goverover, & Dain, 2010).

The CSE (Chesney et al., 2006) is a 26-item questionnaire used to determine an individuals’ confidence in their ability to cope effectively with challenges or threats. The measure has good construct validity with a three-factor solution: use problem-focused coping; stop unpleasant emotions and thoughts; and, get support from friends and family. The CSE has adequate test-retest reliability (α = 0.40 to 0.68) and good internal consistency (α = 0.80 to 0.91) across its sub-scales (Chesney et al., 2006). The scale was not developed in an ABI population (although the study employed a chronic health group, men with HIV), and only two known studies have used this scale with an ABI population – including the article used in this meta-analysis (Appleton et al., 2011; Johnson et al., 2018).

Of the RCT design articles, one used the Brain Injury Coping Scale (BICS) and the other, the Coping Inventory for Stressful Situations (CISS; see Table 2). The BICS is a 35-item scale designed by the authors of the article used in this meta-analysis to measure an individual’s self-efficacy regarding their injury within six domains: effects of brain injury; caregiver role; factors affecting recovery; managing difficult situations; effective communication; and, practicing realistic self-appraisal. The scale has been used in only two papers from the same research group, and has not yet been validated in ABI (Backhaus et al., 2010, 2016).

The CISS (Endler & Parker, 1990) is a 48-item scale used to measure the typical ways in which individuals react to stressful situations, which can be expressed in 3 sub-scales: task-oriented coping; emotion-oriented coping; and, avoidance-oriented coping (although there is evidence to support a four-factor model where avoidance-oriented coping is further divided into the ‘distraction’ and ‘social diversion’ sub-scales). The measure has been validated within an ABI population using the Dutch version of the
CISS (De Ridder & Van Heck, 2004), which demonstrated support for a four-factor model, with good internal reliability (\(\alpha = 0.88\) to 0.92), and moderate discriminant validity between task-oriented and avoidance sub-scales (Brands, Köhler, Stapert, Wade, & van Heugten, 2014). The study used a situation specific version (CISS Situation Specific coping; CISS-SSC) contrary to the typical method of applying the CISS to any non-specified stressful situation. Accordingly, the authors did not assess test-retest reliability, citing the dynamic change in problem situations over time for their participants. Nonetheless, the initial validation of the Dutch CISS has previously shown good test-retest reliability (\(\alpha = 0.78\) to 0.90). The CISS is well used in research of ABI populations (Brands, Bol, Stapert, Kohler, & van Heugten, 2018; Brands et al., 2014; Haller, 2017).

Across all articles participants reported basic demographic information. In addition, psychometric self-report measures (aside from coping) were used to assess psychological distress (3 out of 5 articles), quality of life (2), anger (2), cognitive function (2), communication (2), neurobehavioural dysfunction (2), psychiatric diagnoses (2), psychosocial dysfunction (2), self-awareness (2), and self-esteem (2).

**Article quality**

The methodological rigour of all SGD articles included in the analysis was weak, where the main difficulties with primary quality indicators lay in participant characteristics and the detail included for dependent variables. The methodological rigour of all RCT design articles included in the analysis was weak, where the main difficulties with primary quality indicators lay in participant characteristics, the detail included for dependent variables, and the level of detail provided for replicability of the independent variable and the comparison (control) condition. Secondary quality indicators of methodological rigour for both study designs demonstrated weak evidence of inter-observer agreement of dependent variables, measures of fidelity of the intervention, and insufficient reporting of effect sizes.
Table 2. Main characteristics of articles included in this meta-analysis.

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Design (recruitment)</th>
<th>Type(s) of ABI</th>
<th>Severity of ABI*</th>
<th>Coping Outcome Measure(s)</th>
<th>Other Outcome Measure(s)</th>
<th>Intervention (led by)</th>
<th>Setting (location)</th>
<th>Quality rating†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anson &amp; Ponsford, 2006</td>
<td>Single Group Design (referred by treating neuro-psychologist)</td>
<td>TBI</td>
<td>GCS: 9 (4), PTA: 32 days (31), LOA: 9.7 (8.1) weeks</td>
<td>CSA</td>
<td>BADS, HADS, NART, PCRS, RAVLT, SADI, SIP, STAXI-2</td>
<td>10-session CBT-based coping skills group (two psychologists)</td>
<td>Inpatient (Australia)</td>
<td>Weak</td>
</tr>
<tr>
<td>Lundqvist, Linnros, Orlenius, &amp; Samuelsson, 2010</td>
<td>Single Group Design (from community)</td>
<td>TBI, stroke, infection, heart irregularity</td>
<td>Unreported, most in part-time work or preparatory work</td>
<td>SRSI</td>
<td>Focus group interview, self-report questionnaire</td>
<td>11-session psychoeducation group (neuropsychologist certified in psychotherapy)</td>
<td>Outpatient (Sweden)</td>
<td>Weak</td>
</tr>
<tr>
<td>Appleton et al., 2011</td>
<td>Single Group Design (via treating consultant)</td>
<td>Stroke, TBI, Tumour</td>
<td>GCS: 9 (5.5), LOA: 36.6 (13.5) weeks</td>
<td>CSE</td>
<td>BEST-2, CIU, HADS, LCQ, MINI, WHOQOL BREF</td>
<td>12-session social skills and CBT group (speech pathologist and clinical psychologist)</td>
<td>Inpatient (Australia)</td>
<td>Weak</td>
</tr>
<tr>
<td>Backhaus, Ibarra, Parrott, &amp; Malec, 2016</td>
<td>Randomised Controlled Trial, Blind (referred by treating clinician)</td>
<td>TBI, Other (undefined)</td>
<td>Unreported</td>
<td>BICS</td>
<td>BSI-18, GCQ, FrSBe</td>
<td>16-session coping skills group (neuropsychologist and graduate student)</td>
<td>Inpatient (USA)</td>
<td>Weak</td>
</tr>
<tr>
<td>Visser et al., 2016</td>
<td>Randomised Controlled Trial, Blind (via treating physiatrist)</td>
<td>Stroke</td>
<td>Unreported</td>
<td>CISS</td>
<td>CES-D, EQ-5D-5L, SPSI-R, SSQOLS-12</td>
<td>8-session problem-solving therapy add-on to typical rehabilitation (neuropsychologist)</td>
<td>Inpatient (Netherlands)</td>
<td>Weak</td>
</tr>
</tbody>
</table>

* At baseline, brackets shows standard deviation; † Reichow, 2011; ABI = Acquired Brain Injury; BADS = Behavioural Assessment of the Dysexecutive Syndrome; BEST-2 = Bedside Evaluation Screening Test; BICS = Brain Injury Coping Skills questionnaire; BSI-18 = Brief Symptom Inventory; CES-D = Center for Epidemiological Studies Depression scale; CISS = Coping Inventory for Stressful Situations; CIU = Correct Information Unit; CSA = Coping Scale for Adults; CSE = Cope Self-Efficacy scale; EQ-5D = EuroQol scale; FrSBe = Frontal Systems Behavioral Scale; GCQ = Group Climate Questionnaire; GCS = Glasgow Coma Scale; HADS = Hospital Anxiety and Depression Scale; LCQ = La Trobe Communication Questionnaire; LOA = Length Of Admission in inpatient rehabilitation; MINI = Mini International Neuropsychiatric Interview; NART = National Adult Reading Test; PCRS = Patient Competency Rating Scale; PTA = post-traumatic amnesia; RAVLT = Rey Auditory Verbal Learning Test; SADI = Self-Awareness of Deficits Interview; SIP = Sickness Impact Profile; SPSI-R = Social Problem Solving Inventory - Revised; SRSI = Self Regulation Skills Interview; SSQOLS = Stroke Specific Quality of Life Scale; STAXI-2 = State-Trait Anger Expression Inventory, second edition; TBI = Traumatic Brain Injury; WHOQOL BREF = World Health Organisation Quality of Life assessment - brief.
Table 3. Methodological characteristics and findings of articles included in the meta-analysis.

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Intervention Group (or Single Group)</th>
<th>Control Group</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N (pre)</td>
<td>N (post)</td>
<td>Age (SD)</td>
</tr>
<tr>
<td>Anson &amp; Ponsford, 2006</td>
<td>33</td>
<td>33</td>
<td>37 (12)</td>
</tr>
<tr>
<td>Lundqvist, Linnros, Orlenius, &amp; Samuelsson, 2010</td>
<td>21</td>
<td>21</td>
<td>45 (10)</td>
</tr>
<tr>
<td>Appleton et al., 2011</td>
<td>9</td>
<td>8</td>
<td>36 (18)</td>
</tr>
<tr>
<td>Backhaus, Ibarra, Parrott, &amp; Malec, 2016</td>
<td>9</td>
<td>9</td>
<td>52 (10)</td>
</tr>
<tr>
<td>Visser et al., 2016</td>
<td>88</td>
<td>84</td>
<td>53 (10)</td>
</tr>
</tbody>
</table>

* Shows mean and (standard deviation); † Statistically significant improvement in coping found within article.
Effect of coping skills group interventions

Two of the articles found statistically significant effects of coping following intervention with a coping skills group. Lundqvist et al. (2010) found an improvement in pre-test, post-test changes in anticipating difficult situations and generating and applying coping strategies effectively \((p = 0.01, d \text{ not reported})\). Lundqvist and colleagues did not conduct a follow-up assessment. Visser et al. (2016) found an improvement in task-oriented coping \((p = 0.008, d = 0.43)\) and a reduction in avoidant coping \((p \text{ not reported}, d = 0.33)\) in the intervention arm relative to the control arm. Further, they found an equivalent reduction in emotion-oriented coping in both arms across time \((p = 0.004, d \text{ not reported})\). The control arm had developed an equivalent level of task-oriented coping at 12-month follow-up. Only Visser et al. included a power analysis that indicated a requirement of 132 participants, eventually including 166 participants in their analysis. Given the absence of a control group for Lundqvist et al. it is difficult to ascertain whether such improvements occurred as a result of the intervention or not, particularly when considered alongside an equivalent improvement for both the intervention and control arms of Visser et al. at 12 months.

Three articles reported no statistically significant improvement in coping either following intervention (Anson & Ponsford, 2006; Appleton et al., 2011) or in contrast to a control group (Backhaus et al., 2016). Nonetheless, Anson and Ponsford (2016) found a small increase in adaptive coping post-intervention (13% improvement in their measure), Appleton et al. (2011) found an increase in coping self-efficacy (29% improvement in their measure) for only two participants post-intervention, and Backhaus et al. (2016) found an equivalent increase in perceived self-efficacy in both treatment and control arms. This analysis indicates that some who engage in coping skills group interventions may experience a small increase in coping, though this is not supported by statistically significant findings.

The 5 studies used 19 other self-report outcome measures assessing cognitive, emotional, and functional outcomes. Of the SGD articles Anson and Ponsford (2006) reported an improvement in depression scores following intervention that was linked to higher premorbid levels of IQ, self-awareness, and anxiety, while longer post-traumatic amnesia duration was associated with poorer outcome on the measure of depression. While Lundqvist et al. (2010) did not administer any outcomes measures
further to the SRSI, a self-report questionnaire developed for the study indicated that the majority of participants felt they had increased knowledge of their difficulties and this had had an effect on their life and functioning. Appleton et al. (2011) reported greater quality of life and increased communicative ability at 3-month follow-up, while qualitative feedback demonstrated that participants found the group intervention a positive experience and half preferred it to individual therapeutic work. Of the RCT articles Backhaus et al. (2016) found no improvement for either their treatment or control arms on measures of emotional functioning (though no participants were within the clinical range at pre-intervention). A significant improvement across time was found for neurobehavioural functioning in both groups, specifically in disinhibition and executive functioning. Visser et al. (2016) found an improvement for both the control and intervention arms in general quality of life and depression at intervention and at 12-month follow-up.

A Forest plot illustrating the results of the meta-analysis of five studies examining coping skills group interventions for improving coping, with a total of 238 participants, is shown in Figure 2. This yielded a small, non-significant pooled standardised mean change of 0.21 for an increase in coping skills overall (95% CI = -0.12 to 0.53). Analysis of heterogeneity was not statistically significant (p = .11); however, given the small number of studies in the meta-analysis this may be a meaningful amount of heterogeneity among the articles. This analysis shows changes from baseline where statistically significant effects were found in the articles (that is, the change from baseline to six-month follow-up in task-oriented coping is shown for Visser et al. rather than baseline to post-intervention). A further analysis examining only changes from baseline to post-intervention for all articles revealed a similar small, non-significant pooled standardised mean change of 0.17 for an increase in coping skills overall (95% CI = -0.09 to 0.44). A final analysis examining all scales of the CISS used in Visser et al. (following reverse coding of the emotion-oriented and avoidant scales where a negative change indicates an improvement) for change from baseline to post-intervention revealed a similar small, non-significant pooled standardised mean change of 0.16 for an increase in coping skills overall (95% CI = -0.07 to 0.39).
Figure 2. Meta-analysis of coping skills group interventions in improving coping following acquired brain injury.

Discussion

The current study synthesised and expanded the available literature on the effectiveness of coping skills groups in improving coping following ABI through systematic review and meta-analysis. The small non-significant effect size found does not provide evidence that coping skills groups are an effective intervention for improving coping following acquired brain injury (ABI). Nonetheless, the articles reported improvements across other physical, psychological, and social outcomes, which corroborates similar findings of improvement in depression and anxiety following group interventions for coping, social skills, and anger management in non-ABI populations (Fonagy & Roth, 2005).

The current meta-analysis does not support the implementation of group-based interventions in coping skills in order to improve coping. This is comparable to a finding from Mueller et al. (2018) that group interventions did not enhance coping following
TBI, however individualised interventions appeared to be effective. It is possible that attending a group is not as effective in improving coping as individualised therapy, which is supported by the finding that individualised motivational interviewing plus CBT led to a decrease in maladaptive coping following TBI (Hsieh, Schubert, Hoon, Mioshi, & Hodges, 2013). This has important implications for clinical practice such that group interventions, while appealing for services from an economic standpoint, may not be the most effective clinical treatment for improving coping. There may in fact be a middle-ground for services wishing to improve coping, based on the finding that a peer-mentoring intervention following TBI also appears to reduce maladaptive coping (Hibbard et al., 2002). This form of intervention is likely to provide the aspects of validation and normalisation ordinarily found in a group-based intervention (Bédard et al., 2003), while also reducing the involvement of costly staffing resources required for individual intervention.

There are several potential confounding factors that may explain the null finding in the present review, and these may have contributed to the variability of findings across the articles. The two articles finding statistically significant improvements in coping (Lundqvist et al., 2010; Visser et al., 2016) included stroke populations. A core element of coping relates to the perceived level of control one has over a situation, and perceived control appears to affect the likelihood of recovery following stroke (Frank, Johnston, Morrison, Pollard, & MacWalter, 2000; Johnston, Morrison, Macwalter, & Partridge, 1999). It is possible that these interventions may produce an increase in perceived sense of control (and therefore coping) following a sudden, unexpected physical health problem such as a stroke relative to other forms of ABI. Additionally, four of the five studies included participants with moderate to severe TBI (as indicated by reported GCS and LOA data). Poor executive control is a common impairment following ABI, especially in TBI, and is linked to passive coping (Rakers et al., 2018). This form of coping was possibly targeted by the interventions used, but it is not clear that adaptation of material and approaches were made for those with TBI, which may be necessary in order to improve long-term coping in this group (Mueller et al., 2018).

Careful consideration must be given to comparison across these articles since the measures used in each article capture discreet constructs of coping. Table 4 shows the constructs of coping captured by the measures of coping used in each article side-by-
side with the main elements of intervention for developing coping strategies in each article. It is clear that both the constructs of coping and the focus of interventions vary considerably across the articles, which mirrors the field of research in coping generally (Skinner et al., 2003). This variance may complicate the findings of the present review and meta-analysis, and the results should be interpreted with caution. It is possible that statistically non-significant findings in three of the five articles relates to a mismatch between the focus of the coping intervention and the measured construct of coping. In this sense, the interventions may have in fact increased coping, but the measures used failed to capture this change.

Consideration should also be given to the suitability of the chosen measures for an ABI population. Only one measure (the SRSI) was initially developed and validated in an ABI population, one measure was developed for ABI use but has not been validated and has shown limited use (the BICS), and one other had been adapted and validated for ABI use (the CISS). A recent review from Gregório et al. (2014) assessed the conceptualisation, feasibility, and psychometric properties of measure of coping in ABI, and made cautious recommendations for use of the brief COPE (Coping Orientation for Problem Experiences), Coping Scale for Adult - short form, and Utrecht Coping List. None of the articles in the present meta-analysis used these measures. This is an important consideration for clinical practice, which would require thorough examination of the specific needs of coping in patients, and selection of a pre- and post-test measure that is both suitable for an ABI population and captures change in the construct most closely linked to the intervention focus.

The most robust study in the present review (Visser et al., 2016) demonstrated improvement in task-oriented coping for the intervention arm relative to control. Further, this was maintained at 12-month follow-up for the intervention arm and the control arm developed equivalent levels of task-oriented coping without intervention. This suggests that coping may spontaneously develop across time regardless of intervention, or be attributable to factors related to group participation only (Appleton et al., 2011; Bédard et al., 2003). Time since injury is an important factor in recovery, where varying progress tends to be made in the first six to twelve months. The three studies finding no evidence of improved coping were conducted in an inpatient setting within the first year following injury. Appleton et al. (2011) noted that this was a
Table 4. Comparison of constructs measured by coping outcome measures used in each article and the coping focus of each article intervention.

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Coping outcome measure</th>
<th>Construct(s) of coping captured by measure</th>
<th>Coping focus of intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anson &amp; Ponsford, 2006</td>
<td>Coping Scale for Adults</td>
<td>Adaptive coping, non-productive coping</td>
<td>Coping techniques (problem-solving technique(^1), and social support seeking)</td>
</tr>
<tr>
<td>Lundqvist, Linnros, Orlenius, &amp; Samuelsson, 2010 *</td>
<td>Self Regulation Skills Interview</td>
<td>Awareness, strategy behaviour, and readiness to change</td>
<td>Anticipatory coping (social and emotional problem-solving, and self-reflection)</td>
</tr>
<tr>
<td>Appleton et al., 2011</td>
<td>Coping Self-Efficacy scale</td>
<td>Problem-focused coping, stopping unpleasant thoughts and emotions, and social support</td>
<td>Adapted social skills groups (coping with disagreements(^2))</td>
</tr>
<tr>
<td>Backhaus, Ibarra, Parrott, &amp; Malec, 2016</td>
<td>Brain Injury Scoping Skills Group Questionnaire</td>
<td>Self-efficacy (skills for managing difficult situations)</td>
<td>Problem-solving strategies (tips on managing various challenging problems)</td>
</tr>
<tr>
<td>Visser et al., 2016 *</td>
<td>Coping Inventory for Stressful Situations – Situation Specific</td>
<td>Task-oriented coping sub-scale used in analysis (measure also captures emotion-oriented and avoidant coping)</td>
<td>Problem-solving therapy (define problem, investigate solutions, implement, and evaluate)</td>
</tr>
</tbody>
</table>

* Statistically significant improvement in coping found; \(^1\) Further detail of technique not included in article; \(^2\) Further detail not included in article, summary derived from McDonald et al. (2008) upon which the adapted social skills group intervention was based. Please refer to Table 1 for measure authors.
deliberate choice in order to provide a safe environment for early intervention. Nonetheless, it has been suggested that the greatest advantage may be found in improving adaptive coping in the chronic, rather than acute, stage of ABI (Wolters, Stapert, Brands, & van Heugten, 2011).

Strengths and limitations

To the authors’ knowledge this is the first meta-analytic review of coping skills groups within the field of clinical neuropsychology. Thorough and extensive search strategies were used for article selection; nonetheless the file-drawer problem of publication bias for positive findings may have influenced the findings. All articles used in this review were assessed for quality and were all found to be weak, indicating that there is some risk of bias. Moreover, this does not meet criteria for recommending evidence based practice requiring two group design of adequate rigour to be promising, and two of strong rigour (Reichow et al., 2008).

The theoretical motivations of both the interventions and psychometric measures used varied considerably across the articles. Further four out of the five studies were significantly under-powered, and only two used a gold-standard blind RCT design. A meta-analysis was attempted despite this disparity among the articles in an attempt to elucidate the effects of group interventions in improving coping, since their popularity appears to be increasing despite no statistical assessment of the evidence base.

Further, care must be taken in interpreting individual effect-sizes in this meta-analysis, as many factors in an individual study can give rise to a particular effect-size. In particular a pre-post intervention may by more likely to reveal a statistically significant effect size due to a comparison to no intervention, in contrast to a comparable intervention in a RCT design.

Conclusion

This review does not support the implementation of coping-skills group interventions for improving coping following ABI. Results from individual articles suggests that there is some limited evidence of improved coping following participation in a coping skills group intervention, as well as improvement in emotional and neurobehavioural functioning. Nonetheless, participation in a group-based intervention does not appear to
provide any advantage in improving coping, and it is possible that individualised interventions are more effective in improving coping.

An agreed operational definition, and appropriate pairing of intervention and assessment of coping, are still in development. Future research in this area would benefit from selection of measures based on recommendations in published work that match the intended goals of intervention for patients. This research would benefit from being conducted with a blind RCT design to provide high-quality evidence to contribute to further review. It is suggested that RCTs examining group-based interventions for coping are contrasted with individualised coping skills interventions to establish the specific contribution of group attendance in improving coping following ABI.
References


5


Chapter 2

Empirical Paper
Instructions for contributors – Neurorehabilitation

https://www.iospress.nl/journal/neurorehabilitation/
The Influence of Grit and Resilience in Returning to Meaningful Activity Following Acquired Brain Injury in Adults: A Pilot Feasibility Study in a Community Setting

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OBJECTIVE: To determine the influence of present cognitive impairment, premorbid IQ, age, grit, and resilience on the likelihood that participants returned to meaningful activity (RTMA) or returned to work (RTW) following an acquired brain injury (ABI).

METHODS: A total of 25 participants were prospectively recruited from a rural community brain injury service more than a year following ABI and completed the Test of Premorbid Functioning (TopF), Montreal Cognitive Assessment (MoCA), Connor-Davidson Resilience Scale (CD-RISC), Grit Scale, and Awareness Scale (which was also completed by their treating clinician). Participants also provided demographic and vocational information.

RESULTS: A binomial logistic regression revealed that only higher cognitive function scores (MoCA) predicted RTMA, but not RTW. Levels of grit and resilience were moderately correlated, and did not contribute to a model explaining either RTMA or RTW.

CONCLUSIONS: A number of antecedent, mediating, and post-injury factors were assessed to determine that measures of grit and resiliency did not predict outcome following ABI after accounting for known factors (cognitive function).

Key words: Acquired brain injury, rehabilitation, return to work, participation, resilience, grit, cognitive function

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Conflict of interest
All authors declare that they have no financial or personal relationships with other people or organisations that could inappropriately influence their work.
1. Introduction

Acquired brain injury (ABI) is any form of brain damage sustained after birth and is one of the leading causes of death and disability worldwide (Colantonio et al., 2004; Feigin et al., 2010; Fleminger & Ponsford, 2005; Millis et al., 2001). In the UK someone is admitted to hospital with an ABI every 90 seconds (Headway, 2015). ABI may be sustained as a result of traumatic brain injury (TBI; e.g., closed or penetrative injury to the head), cerebrovascular incident (e.g. stroke, haemorrhage), oxygen deprivation, exposure to toxins or infection, or cancers. The heterogeneity of the physical and cognitive effects of ABI is matched only by the diversity in how each individual adjusts to their injury. Accordingly, each case of ABI requires unique, tailor-made rehabilitation in order to improve functional outcomes and well-being. Rehabilitation success is influenced by risk factors that increase vulnerability for poor outcomes, and by protective factors that buffer or ameliorate poor outcomes.

Rehabilitation goals following ABI broadly relate to supporting people to not only survive, but thrive following their injury through engaging in meaningful activities in their everyday life. Rehabilitation success has historically been linked to an individual’s participation in meaningful activities including return to work (RTW), which is considered an important contributor to psychological, social, and economic well-being (Groswasser, Melamed, Agranov, & Keren, 1999; Shames, Treger, Ring, & Giaquinto, 2007). Research attempting to predict the likelihood of return to meaningful activity (RTMA) and RTW has demonstrated the influence of antecedent factors such as gender (Walker, Marwitz, Kreutzer, Hart, & Novack, 2006), premorbid intelligence (O’connell, 2000), pre-injury education (Franulic, Carbonell, Pinto, & Sepulveda, 2004; Schretlen, 2000), and category of employment prior to injury (Andelic, Stevens, Sigurdardottir, Arango-Lasprilla, & Roe, 2012). Mediating factors also contribute to RTMA including age (Sigurdardottir et al., 2018; Willemse-van Son, Ribbers, Verhagen, & Stam, 2007), injury severity (Radford et al., 2013; Shames et al., 2007a; Wäljas et al., 2014), and cause of injury (Ketchum et al., 2012). In addition, outcome factors, such as psychological distress (Felmingham, Baguley, & Crooks, 2001; Tennant, Macdermott, & Neary, 1995; Vikane et al., 2016), cognitive and behavioural function (Andelic et al., 2012; Cifu et al., 1997; Colantonio et al., 2004), and fatigue (Colantonio et al., 2004; McRimmon & Oddy, 2006) are found to influence RTMA and RTW, among others.

Studies of ABI rehabilitation have also assessed personality characteristics as a risk factor for poor outcomes, and less commonly as a protective factor for improved outcomes.
(Campbell-Sills, Cohan, & Stein, 2006a; Connor & Davidson, 2003). It has been suggested that personality is linked to outcomes related to engagement in important activities following ABI (Peoples & Fortune, 2011; Shames et al., 2007), and is a fruitful area for further research (Quale & Schanke, 2010).

A study using the NEO (neuroticism, extraversion, and openness) personality inventory in relation to rehabilitation found no link between pre-injury informant estimates of personality and vocational reintegration following moderate-to-severe TBI (Malec, Brown, & Moessner, 2004). However, a more detailed analysis revealed a weak but significant association between pre-injury self-report levels of neuroticism and poorer early and long-term social role engagement. ‘Social role engagement’ in this case included vocational independence, measures of disability, and independent living; it is therefore unclear whether self-reported personality in these cases predicted meaningful activity or work specifically. Conversely, a later study from Sela-Kaufman, Rassovsky, Agranov, Levi and Vakil (2013) using the same inventory found pre-injury personality characteristics (specifically low neuroticism) to be a robust predictor of RTW in a TBI population.

Studies using post-injury ratings of personality found that post-injury informant ratings of personality accounted for a significant proportion of the variance in successful outcomes in participation and social adaptation a year after severe ABI (Cattran, Oddy, Wood, & Moir, 2011). Schretlen (2000) found that informant ratings of the NEO personality inventory showing increased neuroticism were predictive of poorer self-report (but not informant-report) social role engagement eight years after TBI. However, personality accounted for relatively little variability in the model, and this became non-significant with the addition of cognitive test performance. In addition, similarly to the study from Malec and colleagues the measures of social participation and engagement in these studies included employment status and several other outcomes unrelated to vocation. In this case it is difficult to distinguish between participation in a personally meaningful sense and an economic sense.

The majority of research addressing outcomes following ABI is deficit-focused, and this appears no different in regard to the influence of personality factors. Nonetheless, interest in the positive psychology movement is growing, and research focussing on protective factors likely to aid and improve wellbeing is increasing (Bertisch, Rath, Long, Ashman, & Rashid, 2014; Masten, 2001; Seligman & Csikszentmihalyi, 2000). In particular, the construct of resilience and associated factors is evidenced to contribute to improved physical
and psychosocial health, and greater life expectancy (Anderson & Anderson, 2003; Berkman & Syme, 1979; Cal, Sá, Glustak, & Santiago, 2015). Resilience can be summarised as a set of personal skills and qualities that enhance the likelihood of a positive outcome subsequent to an adverse event, and that can lead to adaptation and a ‘steeling’ effect against future stressors (Rutter, 2012; White, Driver, & Warren, 2010).

Quale and Schanke (2010) found that the most common trajectory of recovery following a serious physical injury involves resilience, lending support to the notion of resiliency as an ‘ordinary magic’ that is part of the native adaptation process of all humans in response to stress (Masten, 2001). Nonetheless, levels of resiliency among those with ABI tend to be lower than non-clinical population norms (Dumont, Gervais, Fougéryrollas, & Bertrand, 2004; Lukow et al., 2015; but see McCauley et al. 2012 finding similar levels in mild-TBI). It has been proposed that high levels of resilience can lead to improved rehabilitation outcomes following ABI, although empirical evidence to support this is mixed (Neils-Strunjas et al., 2017).

McCauley et al. (2012) demonstrated the influence of pre-injury resiliency and depressed mood in post-injury anxiety, PTSD, and post-concussion symptoms. Similarly, Lukow et al. (2015) found a correlation between low post-injury resiliency and increased psychological distress and maladjustment. Dumont, Gervais, Fougéryrollas, and Bertrand (2004) suggested that half of a measure of social participation in a TBI population was explained by resiliency factors including dynamism, self-efficacy, and will. While Losoi et al. (2015) found that resilience measured at one month following mild-TBI was associated with less fatigue, low mood, and fewer post-concussion symptoms, although it did not correlate with RTW. A further study from Losoi et al. (2016) demonstrated that 96% of people with a mild-TBI had returned to work within one year, including a small sup-group experiencing low resiliency and persistent cognitive and physical symptoms.

Grit is a similar but discreet construct to resilience, and has recently gained momentum in the positive psychology movement. Grit is composed of two facets: first, perseverance in the face of adversity; and second, a consistent commitment to long-term goals (Duckworth & Gross, 2014; Duckworth & Quinn, 2009). Although the construct of grit first developed in the areas of education, workplace attainment, and staff retention (Arouty, 2015; Duckworth & Quinn, 2009) it has begun to be applied within clinical health settings. High levels of grit have been linked to decreased suicide risk (Anestis & Selby, 2015; Blalock,
Grit and resilience scales have enormous potential for informing the treatment of ABI. Their simplicity and short completion time lends well to populations who may struggle with fatigue and acquired cognitive deficits. Further, grit and resilience scales may be useful tools for assessing the likely trajectory of patient recovery. That is, there is potential value in understanding that low levels of grit or resilience may lead to longer rehabilitation time and facilitate greater or different intervention(s) from the treating clinician (Cattran et al., 2011; Dumont et al., 2004; Lukow et al., 2015; White et al., 2010).

The current study explores the potential influence of post-injury resilience, grit, and other common factors in RTMA following ABI, in order to contribute to on-going efforts to determine protective factors of individuals’ rehabilitation success following ABI.

2. Method

2.1 Participants and study design

Participants were selected for inclusion in the study based upon the following criteria: aged between 18 and 65 years; if they had sustained any form of ABI more than 12 months prior to participation in the study; the ability to provide full, informed consent; the strong likelihood that they were able to fully complete the study despite difficulties resulting from ABI; no risk of violent behaviour; not participating in active substance misuse; no comorbid mental health diagnoses; and, no hereditary neurological illness, as determined by their treating clinician. Twenty-six participants were recruited with a range of ABIs of varying severity.
2.2 Procedure

Full ethical approval was granted by the National Health Service Research Ethics Committee and the School of Psychology at Bangor University, UK. Following approval, participants were approached in the first instance by their treating clinician at the North Wales Brain Injury Service to declare their interest in the study, and gain verbal consent for the principal author to contact them via telephone. Each participant was contacted and provided with written information regarding the study. The principal author answered any questions and arranged a time for testing if they wished to participate. Testing was completed in an NHS clinic room local to the participant or in their own home at their convenience or preference. Fully informed verbal and written consent was gained from each participant who agreed to take part. Testing was completed in a quiet environment free from distractions and took around one hour on average with as many breaks as required. All participants were debriefed following assessment.

2.2 Design

Binomial logistic linear regressions were conducted using SPSS (Version 24, IBM Corp.) to determine the effects of present cognitive function, premorbid IQ, age, grit, and resilience on the likelihood that participants return to meaningful activity (RTMA) or return to work (RTW) following an acquired brain injury. The dependent variable was classified as: RTMA, including return to fulltime education, paid or voluntary work, or skills/education classes, or not; and, RTW, including return to education or paid work, or not. Those who did RTW were also included in the RTMA group.

2.3 Measures

2.3.1 Montreal Cognitive Assessment (MoCA)

The Montreal Cognitive Assessment (MoCA) is a brief screening tool for cognitive impairment, with high sensitivity and specificity (Nasreddine et al., 2005). The MoCA establishes the quality of functioning in: visuospatial/executive, naming, attention, language, abstraction, immediate and delayed memory, and orientation domains. Out of a total possible
score of 30 on the MoCA the higher the score the greater the individuals level of function; a score above 26 is considered normal.

### 2.3.2 Test of Premorbid Function (ToPF)

The Test of Premorbid Functioning (ToPF; Wechsler, 2011) is a 70-item measure used to determine premorbid IQ, and has been validated and normed against the Wechsler Adult Intelligence Scale - Revised (Wechsler, 2011). This is a more recent and well-trusted test for IQ relative to the historically used National Adult Reading Test (NART). The higher the score out of 70 on the ToPF the higher the level of estimated premorbid IQ.

### 2.3.3 Connor-Davidson Resilience Scale (CD-RISC)

The Connor-Davidson Resilience Scale (CD-RISC; Connor & Davidson, 2003) is a self-report 25-item measure that will be used to establish each individual's level of resilience. The CD-RISC has been validated as a tool for measuring degree of resilience and can be used as a predictor of outcome of psychological treatment. A recent review of resilience scales found the CD-RISC to be one of the three best tools available for assessing resilience, with good internal consistency, test-retest reliability, construct validity, and predictive validity (Connor & Davidson, 2003; Windle, Bennett, & Noyes, 2011). The higher the score (up to 100) on the CD-RISC the higher the level of resilience.

### 2.3.4 Grit Scale

The Grit Scale is a 12-item self-report measure used to establish a person's level of grit, indicated by consistency of interests and perseverance of effort (Duckworth & Quinn, 2009). The higher the score on the Grit Scale (on a scale of 1 to 5) the greater the level of grit. The Grit Scale has demonstrated good internal consistency, test-retest reliability, and predictive validity (Duckworth, Peterson, Matthews, & Kelly, 2007).

### 2.3.5 Awareness Questionnaire

The Awareness Questionnaire was used to determine the amount of insight of each participant in terms of their functioning by contrasting their ratings on the patient version of the questionnaire with the clinician version of the scale (Sherer, Bergloff, Boake, High Jr, & Levin, 1998). A discrepancy score greater than 20 (ranging between -68 to 68) represents a clinical impairment in insight (Evans, Sherer, Nick, Nakase-Richardson, & Yablon, 2005). The
scale has good internal consistency (Carroll & Coetzer, 2011). This measure was used to screen clinical-level poor insight participants who may be excluded from statistical analysis.

2.4 Demographic data

The principal author collected demographic information from each participant, including: age, sex, highest education level, length of time in full-time employment prior to their ABI, occupation at pre- and post-injury (if applicable), time since injury, nature and severity of injury, and participation in meaningful activities (return to: paid work, voluntary work, fulltime education, or skills/education classes). This information is shown in Table 5. The average age of all participants was 50.8 (12), average age at injury was 42.5 (12.6), and average time since injury was 8.4 (8.9) years.
Table 5. Demographic information for all participants organised by return to meaningful activity (RTMA) or not, and return to work (RTW) or not.

<table>
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<th>Injury type</th>
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<th>Did not RTMA</th>
<th>Did RTW</th>
<th>Did not RTW</th>
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<td>6</td>
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<td>7</td>
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<td>4</td>
<td>3</td>
<td>5</td>
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<td>3</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
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<td>2</td>
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</tr>
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</tr>
<tr>
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<td>0</td>
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<td></td>
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<td>4</td>
<td>1</td>
<td>4</td>
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<td>5</td>
<td>4</td>
<td>1</td>
<td>8</td>
</tr>
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<td>4</td>
<td>4</td>
<td>3</td>
<td>5</td>
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<td>2</td>
<td>1</td>
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<td>7</td>
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<td></td>
<td></td>
</tr>
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<td>3</td>
<td>5</td>
<td>2</td>
<td>6</td>
</tr>
<tr>
<td>Construction/Mechanical</td>
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<td>4</td>
<td>1</td>
<td>1</td>
<td>4</td>
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<tr>
<td>Technical/Engineering</td>
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<td>1</td>
<td>1</td>
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</tr>
<tr>
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<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td><strong>Vocation post-injury</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Construction/Mechanical</td>
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<td></td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Technical/Engineering</td>
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<tr>
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<tr>
<td><strong>Total</strong></td>
<td>11</td>
<td>14</td>
<td>6</td>
<td>19</td>
<td></td>
</tr>
</tbody>
</table>

* Injury severity was determined from reports of loss of consciousness, Glasgow Coma Scale score, post-traumatic amnesia, and size and location of lesion determined from neuroimaging. \(^1\) Indicates school-leavers at the age of approximately 15 years with no qualifications.
3. Results

3.1 Recovery success

Several linear regression models were produced including: an initial model using known factors to influence RTMA and RTW (cognitive function, premorbid IQ, and age); a further model adding grit and resilience to establish their contribution beyond these known factors; and, a final model examining the contribution of grit and resilience alone. Table 6 shows the averaged psychometric data for all participants.

Initial exploratory analysis revealed a single outlier related to the measure of grit and this participant was removed leaving an n of 25. No outliers were found for the Awareness Scale, and no participant met the clinical cut-off representing poor insight (therefore no further participants were excluded). A Pearson product-moment correlation coefficient was computed for all predictor variables and revealed that grit and resilience were significantly moderately positively correlated ($r = .447, n = 25, p = .03$). Accordingly, these measures were converted to Z scores and combined additively for further analysis to prevent multicollinearity of data in the regression calculation. A significant strong correlation was found between age and length of time in full-time occupation ($r = .827, n = 25, p < .001$), therefore only age was included in the regression model. A further significant moderate correlation was found between time since injury and cognitive function ($r = .415, n = 25, p = .04$). The level of resiliency across all participants was substantially more than one standard deviation below population norms (Connor & Davidson, 2003).

| Table 6. Average data from psychometric measures of awareness, resilience (CD-RISC), grit, cognitive function (MoCA), and premorbid intelligence (ToPF) for 25 participants, organised by return to meaningful activity (RTMA) or not, and return to work (RTW) or not. |
|-------------------------------------------------|----------------|----------------|----------------|----------------|
| Did RTMA                                        | Did not RTMA   | Did RTW        | Did not RTW    |                |
| Awareness Questionnaire$^1$                     | 2 (6)          | -3 (9)         | 4 (6)          | -2 (8)         |
| Resilience (CD-RISC)$^2$                        | 61 (18.5)      | 59 (11.8)      | 56 (22)        | 59 (22)        |
| Grit Scale$^2$                                  | 3.5 (0.6)      | 3.2 (0.6)      | 3.7 (0.6)      | 3.2 (0.5)      |
| Cognitive function (MoCA)$^2$                   | 24 (3)         | 20 (2)         | 24 (4)         | 21 (3)         |
| Premorbid IQ (ToPF)$^2$                         | 100 (6)        | 96 (7)         | 100 (6)        | 97 (6)         |

$^1$The discrepancy between participant- and clinician-rated awareness, a positive score indicates good insight. $^2$A higher score indicates a higher level of the measured construct.
3.1.1 Return to meaningful activity

The first logistic regression model including cognitive function, premorbid IQ, and age was statistically significant \( (p = .02) \), explained 45\% \( (\text{Nagelkerke } R^2) \) of the variance in RTMA, and correctly classified 80\% of cases. Only a higher score on the MoCA indicating less cognitive impairment predicted a RTMA. A further regression added resilience and grit to determine the contribution of the remaining predictor variables, this was significant \( (p = .04) \), explained 45\% \( (\text{Nagelkerke } R^2) \) of the variance in RTMA, and correctly classified 76\% of cases (the MoCA continued to be the only significant predictor, \( p = .03 \)). A final regression was conducted using grit and resilience as predictor variables alone, this was non-significant \( (p = .85) \). All assumptions were met; see Table 7 and Table 8 for all model findings.

3.1.2 Return to work

The first logistic regression model including cognitive function, premorbid IQ, and age was statistically significant \( (p = .04) \), explained 43\% \( (\text{Nagelkerke } R^2) \) of the variance in RTW, and correctly classified 84\% of cases. Only a higher score on the MoCA indicating less cognitive impairment approached significant for predicting a RTW \( (p = .056) \). A further regression added resilience and grit to determine the contribution of the remaining predictor variables, this approached significance \( (p = .05) \). A final regression was conducted using grit and resilience as predictor variables alone, this was non-significant \( (p = .66) \). All assumptions were met; see Table 7 and Table 8 for all model findings.
Table 7. Full regression model findings.

<table>
<thead>
<tr>
<th></th>
<th>P</th>
<th>Nagelkerke r²</th>
<th>Group Status</th>
<th>Predicted Group Status</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>RTMA</td>
<td>N-RTMA</td>
</tr>
<tr>
<td>Model 1</td>
<td></td>
<td></td>
<td>RTMA</td>
<td>N-RTMA</td>
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<td>N-RTMA</td>
</tr>
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<td></td>
<td>.02*</td>
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<td>RTMA</td>
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<td></td>
<td></td>
<td>N-RTMA</td>
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<td>Overall</td>
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<td>N-RTW</td>
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<td></td>
<td></td>
<td>RTW</td>
<td>3 3 50</td>
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<td>.04*</td>
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<td>N-RTMA</td>
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<td>Overall</td>
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<td></td>
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<td></td>
<td>RTW</td>
<td>N-RTW</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>RTW</td>
<td>3 3 50</td>
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<tr>
<td></td>
<td>.05</td>
<td>.465</td>
<td>N-RTW</td>
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<td>Model 3</td>
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<td>N-RTMA</td>
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<td>.66</td>
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<td>N-RTMA</td>
<td>0 14 100</td>
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<td>Overall</td>
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<td>RTW</td>
<td>N-RTW</td>
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<td>Overall</td>
<td>76</td>
</tr>
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</table>

RTMA = Return To Meaningful Activity, RTW = Return To Work, N- = No, * indicates statistically significant finding.
Table 8. Full regression predictor variable findings.

<table>
<thead>
<tr>
<th>Model 1</th>
<th>Variable</th>
<th>B</th>
<th>Std. Error</th>
<th>Wald</th>
<th>Sig.</th>
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RTMA = Return To Meaningful Activity, RTW = Return To Work, MoCA = Montreal Cognitive Assessment, ToPF = Test of Premorbid Function, * indicates statistically significant finding.
4. Discussion

The present study evaluated the influence of antecedent, mitigating, and post-injury factors in outcome following acquired brain injury (ABI). Measures of cognitive function, premorbid IQ, age, grit, and resilience were used to predict a return to meaningful activity (RTMA) or return to work (RTW).

With respect to the outcome of this investigation it was established that only a higher score on a measure of cognitive function (the Montreal Cognitive Assessment, or MoCA), indicating fewer cognitive impairments, predicted RTMA but not RTW. This is in agreement with findings of previous studies (Edwards, Kapoor, Linkewich, & Swartz, 2018; Lilja et al., 2018; Mani, Cater, & Hudlikar, 2017; Schretlen, 2000; Sigurdardottir et al., 2018; Wallmark, Ronne-Engstrom, & Lundstrom, 2016). For clinicians working with ABI the impact of cognitive impairment upon the likelihood of RTMA is clear, and there are often secondary effects on patient’s perceptions of self-confidence and ability to cope (e.g., due to processing speed, Sigurdardottir et al., 2018; executive function, Fride et al., 2015; and, memory, Esbjornsson et al., 2013). Indeed, a qualitative study from Velzen et al. (2011) found that a significant number of the personally meaningful factors reported to influence non-RTMA were related to cognitive impairment.

The addition of grit and resilience to the basic model comprised of known factors to influence outcome (cognitive function, IQ, and age) did not increase explanatory power, and the percentage of participants correctly classified as RTMA decreased. This adds to an already mixed literature on the influence of resilience in outcomes following ABI, and does not provide support for research suggesting grit’s importance in other at-risk and chronic health groups. Grit and resilience were found to be moderately correlated, in keeping with previous studies (Maddi, Matthews, Kelly, Villarreal, & White, 2012; Martin, Byrd, Watts, & Dent, 2015), suggesting that they are overlapping but distinct constructs of personality. Levels of resiliency reported in the present study were substantially more than one standard deviation below population norms, and were in fact closer to norms of those with significant mental health difficulties (Connor & Davidson, 2003). Levels of grit in the present study were comparable to population norms (Duckworth et al., 2007), and although it is clear that those who did RTMA or RTW appear to have higher levels of grit, this difference was not statistically significant within the regression models.
In the present study participants were asked to complete the Grit Scale according to how much they believed the statements to truly reflect them generally, and not specifically following their ABI. It is possible that participants provided their answers based on their perception of themselves existing at pre- and post-injury, while being unaware of how their cognitive impairments may affect their grittiness per se. Recent research has determined that grit is associated with neural mechanisms in the dorsomedial prefrontal cortex, an area responsible for executive actions related to goal planning and execution, and counterfactual thinking for reflecting on past failure (Wang et al., 2017). In addition, a study found that encouraging people to reflect on previous failures resulted in a significant reduction in error rates on a cognitive task requiring perseverance (DiMenichi & Richmond, 2015). Cognitive difficulties, including executive function, are common following ABI, which may hinder a person's capacity to appropriately reflect and plan for long-term goals (Duckworth & Steinberg, 2015). Levels of grit and cognitive function (MoCA) were not statistically significantly correlated in the present study, which might be expected if grit has a cognitive basis that would impact a person’s ‘grittiness’ following ABI. Nonetheless, it should be noted that the MoCA does not measure only executive function as in the studies noted above, therefore effects of poor executive function would likely not be revealed by the MoCA in this case. Research has also demonstrated that coping styles following ABI often reflect non-productive coping characterised by worry, self-blame, and avoidance (Anson & Ponsford, 2006; Kortte, Wegener, & Chwalisz, 2003). It is possible that those experiencing ABI are less likely to engage in problem-focused thinking, thus lacking the opportunity to reflect on mistakes in their rehabilitative journey and ultimately learn from them. This in turn may result in a lower frequency of gritty behaviour and therefore a subjective mis-estimation of their grittiness.

It is possible that a null finding in the present study related to RTW (but not RTMA) was a result of a small sample size for those returning to paid work or full-time education ($n = 6, 24\%$). This seemingly low percentage of RTW is somewhat in keeping with published work, where rates of RTW following ABI generally range between 30 and 40\% (Carlsson, Möller, & Blomstrand, 2003; Edwards, Hahn, Baum, & Dromerick, 2006; Harradine et al., 2004; Radman et al., 2012; Velzen, Bennekom, Edelaar, Sluiter, & Frings-Dresen, 2009). However, some studies have found RTW rates as low as 16\% in those with severe TBI (Andelic et al., 2012; Lippert-Grüner, Maegele, Haverkamp, Klug, & Wedekind, 2007; Odgaard, Johnsen, Pedersen, &
Nielsen, 2017), and 4% in a mixed group of TBI and stroke (Blicher, Jensen, Westh, & Hellemann, 2007).

The authors had anticipated that a low rate of RTW may be found given the rurality and limited employment opportunities of the area from which the participants were sampled (Coetzer, Hayes, & Du Toit, 2002). However, interestingly research from Harradine et al. (2004) and Young, Wasiak, Webster, and Shayne (2008) found that RTW rates for those with ABI or physical injuries in rural areas was in fact similar or better than those living in urban areas in Australia and the US respectively. Nonetheless, it is likely that the complex geography of North Wales and its inevitable impact on ease of travel is likely to have had an effect on RTW rates in the present study. A further consideration relates to improvement in functioning over time following ABI, where the greatest improvement often occurs within the first several years and then continues at a slower pace (Velzen et al., 2011; Willemse-van Son et al., 2007). In the present study the amount of time that had elapsed since injury and cognitive function were moderately, positively correlated, indicating that cognitive function had improved with time. This suggests that over time more participants may RTW, and further RTMA (see Edwards, Kapoor, Linkewich, & Swartz, 2018), meaning that long-term rehabilitative goals would benefit from a focus on cognitive rehabilitation in order to reduce cognitive impairment that appears to predict RTMA. Finally, the median age of participants in the present study was 52 years. This may have accounted for a reduced likelihood of RTW, since older age and proximity to traditional retirement age has been linked to non-RTW (Willemse-van Son et al., 2007).

Although this is an exploratory feasibility study the small sample size may have limited the findings in this study. In addition, for the sake of brevity a limited number of measures were used in the present study to account for the increased likelihood of cognitive impairments and cognitive fatigue of participants. A more robust replication and extension of this study with more participants would allow for further analysis including stratifying participants by type of injury, level of awareness, and occupation, among other possibilities. It would also be advantageous to administer more measures over several sessions. For example, to establish premorbid ratings of personality constructs by the individual and an informant. Presently no informant-rating version of the Connor-Davidson Resilience (CD-RISC) or Grit Scale exists, although some research has used the CD-RISC as a self-report of past personality in the presence of a corroborating informant (Law, Richmond, & Kay-Lambkin, 2014).
Nonetheless, it was felt to be of greatest clinical relevance to understand how participants appraised their levels of resilience and grit in the present, rather than prior to their injury in the present study (see Tate, 2003). In addition, repetition of these scales across time would allow a better understanding of the dynamic nature of these phenomena, and potentially allow for measuring the trajectory of recovery longitudinally within the context of a chronic health condition (Quale & Schanke, 2010).

A further important consideration regards poor mental health, a common outcome of ABI (Waldron, Casserly, & O’Sullivan, 2013). Increased anxiety and depression have been linked to poorer outcomes following ABI (Malec, Brown, & Moessner, 2004; Quale & Schanke, 2010), and early experience of depression in particular can contribute to persistent symptoms while others without depression recover more rapidly (Losoi et al., 2016). While levels of depression and anxiety were not measured in the present study it is likely that a number of participants did experience these difficulties, possibly impacting upon their subjective appraisal of their own resiliency and grit. The question then stands, is it that the presence of grit and resilience are unimportant factors in the rehabilitative process following ABI? Or, are those experiencing significant cognitive, physical, and emotional challenges understandably less likely to report feeling particularly resilient and gritty?

5. Conclusion

The present results indicate that measures of grit and resilience do not provide additional predictive power in people returning to meaningful activity following an acquired brain injury, over and above traditional predictors (in this case, cognitive function). While this presents a null finding for these measures of personality it is important to understand the relative influence of different factors in recovery following ABI.

In the present study 88% of participants intended to return to work following their injury, substantiating research demonstrating the presence of significant will and determination to engage and participate in meaningful life activities subsequent to an ABI (Dumont et al., 2004; Velzen et al., 2011). While it appears that the most likely trajectory of recovery following a serious physical injury involves resilience (Quale & Schanke, 2010), it is critical that the compounded factors of physical, cognitive, and psychological impairments in ABI are taken into account. As Dumont et al. note, “will, even when very strong, cannot
compensate for severe impairments” (2004, p. 439). While the results of the present study do
not wholly endorse previously found effects of personality on outcomes following ABI this
remains a fruitful area for further research.
References


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between the trait grit and academic performance. Social Cognitive and Affective Neuroscience, 12(3), 452–460.


Chapter 3

Contributions to Theory and Clinical Practice
Implications for Future Research and Theory Development

The two initial papers of this thesis aimed to assess the overall influence of personal resources in rehabilitation following acquired brain injury (ABI). The meta-analysis addressed whether coping skills groups are an effective intervention in improving coping following ABI. This was the first meta-analysis and systematic review of its kind and as such there was no previous literature with which to compare it. Finding a small, statistically non-significant effect this paper indicates that coping-skills groups are not an effective means of improving coping following acquired brain injury. The latter empirical paper examined the potential predictive value of personality characteristics, namely resilience and grit, alongside demographic and neuropsychological factors in predicting a return to meaningful activity (RTMA) following ABI. The results indicated that only a higher cognitive function score predicted a RTMA, while resilience and grit contributed no added explanatory power. The present paper intends to review the outcomes of these two papers and demonstrate how both contribute to an improved understanding of personal resources in recovery following ABI.

An organisational model of disability and functioning from the World Health Organisation is shown in Figure 3 that emphasises the complex, dynamic interplay between a health condition and contextual factors. This model is intended to provide a primary language upon which more elaborate models of health can be based. Figure 4 shows a condition-specific version of this model based around brain injury developed by Gracey and Ownsworth (2012). This model demonstrates the contribution of personal resources, self-efficacy, and coping in living with an ABI, including the role of pre-injury style of adjustment to adversity, responses post-injury, and long-term outcomes. This model contextualises the research discussed in the empirical paper and meta-analytic review and the studies included in this thesis.

In the present empirical study post-injury personality factors did not appear to explain long-term recovery in employment and productivity. Instead, neuro-cognitive factors (shown in Figure 4) better explained the likelihood of RTMA, with similar findings in both quantitative (Edwards et al., 2018; Lilja et al., 2018; Mani et al., 2017; Sigurdardottir et al., 2018; Wallmark et al., 2016) and qualitative research (Velzen et al., 2011). Despite the null finding in this case, previous research confirms that personality factors contribute to positive changes in quality
Figure 3. Interaction between components of functioning and disability, adapted from WHO International Classification of Functioning (2001).

Figure 4. Model of interactions between personal, social, and environmental aspects of recovery in acute and chronic stages of an acquired brain injury, adapted from Gracey and Ownsworth (2012).
of life, emotional functioning, and RTMA (Hanks, Rapport, Perrine, & Millis, 2016; Malec, Brown, & Moessner, 2004; Rutterford & Wood, 2006; Schretlen, 2000; Sela-Kaufman et al., 2013). For example, Rutterford and Wood found that personality factors significantly influenced all outcomes in those with acquired brain injury more than ten years after injury (including community integration, life satisfaction, anxiety, and depression; 2006). It is worth nothing that the measure used by Wood and Rutterford in this case, the Eysenck Personality Questionnaire – Revised (Eysenck, Barrett, & Eysenck, 1984), captured only psychoticism, neuroticism, and extraversion. As discussed in the empirical paper of the present thesis neuroticism appears to be one of the most significant personality factors relating to RTMA and RTW. However, resiliency and grit have been found to map to the conscientiousness construct of the ‘Big Five’ five-factor model of personality (John & Srivastava, 1999), which can be captured using the Neuroticism Extraversion Openness Personality Inventory – Revised (NEO PI-R; Costa & McCrae, 1992). Only one study using the NEO FFI (Five Factor Inventory), a shortened version of the NEO PI-R, assessed conscientiousness in relation to RTW finding a positive correlation (Sela-Kaufman et al., 2013). Further research must more adequately capture the construct of conscientiousness in order to fully explore the contribution of resilience and associated factors in RTMA and RTW.

Levels of conscientiousness (and accordingly resilience and grit) tend to be lower in ABI populations (Malec et al., 2004). This must also be addressed in future research since a high level of conscientiousness is associated with mental resilience, while a high level of neuroticism is linked to low tolerance for stress (Campbell-Sills, Cohan, & Stein, 2006). This relates directly to the findings of the meta-analytic review in the present thesis. Appraisal of a stressor ultimately determines the coping response, and one might expect that those with high levels of neuroticism (and thus a low tolerance for stress) may not cope as well as others. This is borne out in research demonstrating that those with high levels of neuroticism make more negative appraisals of stressors than those with low levels, and engage more often in non-productive coping strategies such as avoidance (Gunthert, Cohen, & Armeli, 1999). Conversely, those with high levels of conscientiousness are more likely to engage in productive problem-solving coping (Connor-Smith & Flachsbart, 2007). From a theoretical

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2 Neuroticism can be described as a tendency to experience negative emotions, instability of mood, and is linked to low tolerance for stress.
standpoint coping style and personality traits are intrinsically linked, reflected in the relationship between premorbid personal resources and coping resources shown in Figure 4. Personality factors were not captured in the articles used in the meta-analytic review of the present thesis, and this may be a fruitful area for further research in determining factors in improving coping following ABI via group interventions.

An as yet under-studied area of coping in ABI relates to the development of personality from attachment styles. Patterns of attachment develop in early childhood based upon the nature of the relationship between the child and their primary caregiver (Bowlby, 1969). A strong emotional and physical bond in early life is a biological imperative. This bond is required in order for an infant to feel safe to explore the world and to confidently develop an understanding of themselves and others. The quality of this child-caregiver relationship determines lifelong intra- and inter-personal behaviour. Ainsworth, Blehar, Waters and Wall (1978) developed a theory of 'styles' of attachment based on the presence or absence of sensitive and responsive care. The three major attachment styles encompass secure attachment (appropriate care, child feels safe to explore, upset by caregiver absence), anxious/ambivalent (unpredictable care, child feels unsafe in exploring, highly distressed by caregiver absence), and avoidant (unresponsive care, child feels unsafe in exploring, not distressed by caregiver absence – a ‘mask’ of peace). The form of this attachment ultimately shapes our personality, and can explain individual differences in ability to cope with stressful situations (Ainsworth & Bowlby, 1991). Securely attached individuals appraise stressful situations as surmountable given their experience of safely overcoming challenges in early life, and will engage in adaptive coping that may mitigate some of the detrimental effects of an ABI. Conversely anxiously- or avoidantly-attached people appraise stressors as exceeding their capacity, and consequently engage in less productive coping strategies and experience on-going distress and ill health (Meredith, Strong, & Feeney, 2005; Mikulincer & Florian, 1995; Wei, Heppner, & Mallinckrodt, 2003).

Using this classification scheme studies have established the correlation of attachment style and coping in childhood (McElwain, Holland, Engle, Wong, & Emery, 2015; Zimmer-Gembeck et al., 2017), and in numerous health conditions (Aarts, Hinnen, Gerdes, Acherman, & Brandjes, 2014; Mikulincer & Florian, 2000; Monin, Zhou, & Kershaw, 2014; Pietromonaco & Powers, 2015; Sirois & Gick, 2016). Only two recent studies have established the influence of attachment style in RTW in spinal cord injury (Blake, Brooks, Greenbaum, & Chan, 2017;
Umucu et al., 2016). Just one study has established the influence of attachment style on any outcome following ABI (Sela-Kaufman et al., 2013), finding that attachment mediated RTW and psychological wellbeing. This is supported by research from Karreman and Vingerhoets (2012) finding a relationship between secure attachment style, resilience, and greater psychological wellbeing in a non-health population. This has important implications for recovery related to premorbid personality development, and appraisal of demands relative to coping resources and relationships in the acute and chronic stages of an ABI.
Implications for Clinical Practice

The findings of the meta-analysis suggest that group-based interventions in coping skills do not adequately improve coping following acquired brain injury (ABI). This has important implications for clinical practice where group interventions may be considered a preferable choice to individualised interventions for economic reasons. Research directly assessing the effectiveness of individualised interventions in coping skills following ABI are rare, presumably because approaches thought to improve coping (such as problem-solving) are an integral part of many cognitive therapies. One study from Wolters, Stapert, Brands, and Van Heugten (2010) assessed a cognitive rehabilitation intervention including problem-solving skills based upon Prigatano (1999) and outcomes related to coping. The authors found that positive, problem-focused coping decreased during treatment while passive emotion-focused coping style increased, both of which correlated with poor quality of life. An important additional finding was that an increased time between intervention and measurement at follow-up was linked to increased quality of life, indicating an improved adjustment over time irrespective of the coping strategies used.

While this appears to suggest that intervention may produce maladaptive coping strategies, several other studies have also found an increase in passive coping styles in the chronic stages of an ABI (Dawson, Cantanzaro, Firestone, Schwartz, & Stuss, 2006; Hepp, Moergeli, Büchi, Wittmann, & Schnyder, 2005; Krpan, Levine, Stuss, & Dawson, 2007). This counter-intuitive direction of change in coping styles could be explained in several ways. One possibility from Kendall and Terry (1996) is that patients have increased awareness in their rehabilitative journey over time, coming to face the prospect of permanently living with any acquired difficulties (see also Fleminger, Oliver, Williams, & Evans, 2003). Alternatively, it is possible that support and structure in a patient’s environment provided by professionals and caregivers reduces the discrepancy between perceived demand and ability, allowing the patient to feel able to respond to stressors and to engage in problem-focused coping (Ben-Yishay & Diller, 2008; Goldstein, 1952). This may lead to a high sense of self-efficacy during rehabilitation, which then reduces when intensive professional support ends and thus adaptive coping may also reduce.

3 It is worth noting that while group interventions have several positive effects in allowing normalisation and validation, it is also possible that peer feedback during group participation may increase self-awareness of acquired difficulties, and therefore subsequent maladaptive coping and low mood.
An understanding of this natural course of development in coping following ABI is critical to professional intervention. In the case of the former theory clinical rehabilitation goals may be best oriented towards living a valued life notwithstanding the reality of their decreased capabilities (Riley, Brennan, & Powell, 2004). An appropriate intervention might include a model such as Acceptance and Commitment Therapy, using a mixture of cognitive, behavioural, and mindfulness exercises to increase psychological flexibility in the face of new challenges (Hayes, Strosahl, & Wilson, 1999). In this way patients gradually move away from avoidance of unpleasant feelings, thoughts, and activities to a life where they can more comfortably pursue meaningful activities within the remit of their capacity and interests. This is supported by research from Ditchman, Sung, Easton, Johnson, and Batchos who found that disability acceptance is directly linked to life satisfaction, with the authors calling for more strengths-based interventions in ABI as a result (2017).

In the case of the latter theory intervention might best be targeted at the system around the patient with an ABI, to help provide an environment conducive to productive coping strategy use. Ben-Yishay and Diller note that “a state of ‘health’ can be established if the patient’s environment is so organized and structured by others that the patient can cope with the...demands that confront him or her” (2008, p. 80). This requires further consideration of coping within the system around a person with an ABI. Changes within the patient often impacts upon their family system, and consequent caregiver burden has been extensively researched in relation to ABI. Up to one third of caregivers report clinical levels of psychological distress and difficulties coping, and this understandably impacts upon the potential for rehabilitation success for the person with an ABI (Anderson, Parmenter, & Mok, 2002; Carnes & Quinn, 2005; Kreutzer et al., 2009; Rivera, Elliott, Berry, Grant, & Oswald, 2007). Functional and non-functional coping in caregivers is directly influenced by professional support, and evidence suggests that intervention with caregivers is critical for increasing coping even many years after a patient sustained an ABI (Verhaeghe, Defloor, & Grypdonck, 2005). The responsibility of the clinician therefore lies in providing appropriate support to both the individual and their caregiver system on an on-going basis. Yeates (2007) describes this as “avoiding the skull seduction” where clinicians tend to focus solely on the ‘problems’ found within the patient as a result of insult to the brain, where it is in fact preferable to take a more systemic view of intervention and recovery.
The findings of the empirical paper suggest that personality traits do not influence the likelihood of return to meaningful activity (RTMA) or return to work (RTW) following an ABI, while cognitive function does. In a systematic review from Mani, Cater, and Hudlikar (2017) ten studies were identified where cognitive variables predicted RTW following traumatic brain injury (TBI). These cognitive variables included information processing, attention, executive function, verbal skills, and memory - in keeping with the diverse range of difficulties occurring following TBI. Further, the presence of attentional neglect and difficulties in perceiving and expressing affective responses were found to influence RTW following stroke, reflecting the need for appropriate social skills in the workplace in addition to cognitive function (Hofgren, Esbjörnsson, & Sunnerhagen, 2010).

As noted in Chapter 2, 88% of the empirical research participants wished to RTW following their ABI, but just 24% achieved this. From a clinical standpoint it is important to consider how this number might be increased, given the cognitive difficulties present within the participant sample. This is particularly important given that those with even severe ABI are able to RTW with appropriate levels of support and effort invested (Shames, Treger, Ring, & Giaquinto, 2007). Indeed, the findings of the present empirical paper show that the majority of those who did RTW had sustained severe ABIs.

Vocational rehabilitation interventions involving cognitive rehabilitation have found some success in improving RTMA and RTW rates (Ownsworth & McKenna, 2004). An intervention with intensive cognitive rehabilitation, and educational and experiential learning opportunities from Murphy et al. (2006) led to RTW in 41% of participants with ABI at discharge from services. While a program of neuropsychological rehabilitation, education, and psychotherapy following TBI found a RTMA in 89% of the intervention arm of their non-randomised controlled trial (RCT), compared with 55% of the control arm (Sarajuuri et al., 2005). However, two further RCTs found no difference between their groups with respect to RTW following cognitive rehabilitation in a TBI population (Salazar et al., 2000; Vanderploeg et al., 2008).

While cognitive difficulties are an important factor in RTW and RTMA following ABI, they are not the full story. A review from Donker-Cools, Daams, Wind, and Frings-Dresen (2016) confirms this, finding that the strongest evidence for improving RTW lies in interventions related to adaptation of work tasks, education, and coaching, and some evidence indicating that skills training (e.g. social skills) also improves RTW. Importantly, a further
crucial element in successful RTW related to cooperation of the employer, and their willingness to adapt the workplace and work tasks. It is also worth noting that holistic multidisciplinary team (MDT) intervention yields the best outcome, including occupational therapists, physiotherapists, psychologists, and social workers. These findings are relevant for planning care in clinical practice related to RTW goals, particularly since recovery to pre-injury levels of cognitive competency are observed in as little as 40% of cases following ABI (Dikmen et al., 2009). If cognitive function cannot be restored, then compensation in the form of personal and workplace intervention and adaptation by a MDT would be required (Coetzer et al., 2002). The true feasibility of this in standard brain injury rehabilitation services remains to be assessed.

Broadly the evidence in the present thesis combined with previous research suggests that interventions for improving coping may best be applied within the system around those with an ABI. Alternatively, interventions that foster a more flexible approach to living that embraces coping with decreased capability can be applied as an individualised intervention. While the contribution of personality in recovery is still unclear, cognitive rehabilitation can contribute to increased likelihood of RTW. Improvement in cognitive function, as well as quality of life and life satisfaction, appears to develop across time for many years after an ABI (Rutterford & Wood, 2006; Wolters et al., 2010). It may be that RTMA and RTW following ABI is more likely as more time passes. Nonetheless, adaptation and support within the workplace system around the individual with an ABI is likely to be necessary in the acute stages of recovery.
Reflective Commentary

There were a number of factors in the empirical paper process that I reflected upon while conducting this research. Chief among which was the vulnerability of the participants who volunteered their time to answer sometimes challenging questions about their life and personality. Being fortunate enough to practice clinically in brain injury at the North Wales Brain Injury Service (NWBIS) alongside completing this research I constantly reflected on the impact my line of questioning may have on their wellbeing. This began in the initial stages of planning the research with careful consideration of the measures used and how any resulting distress may be managed. It was certainly possible that discussing a participants’ perception of their resilience and grit, or a lack thereof, may cause distress. Similarly, a discussion around a return to meaningful activity may lead to the realisation that this has not happened for them as they would wish. Often, participants reported being at the mercy of a ‘hidden disability’ or ‘invisible illness’, feeling misunderstood by themselves and others. This was often a significant barrier to engaging in activities in their community or workplace. As is typical for me I felt the desire to try and make things feel more positive during my participant testing sessions, not wanting to welcome distress where it had perhaps not been present before. However, upon reflecting upon this I felt it was equally important in this empirical work as in my clinical work to allow people to express the difficult reality of their lives. Accordingly, I spent time supporting participants through any upsetting conversations as they arose, allowing time for them to reach an emotionally stable space before leaving the research session.

An important reflective process for me personally related to the contrast in my experience with my clinical clients in the acute stages of an ABI, relative to the research participants in the later, chronic phase of living with their injury. Finding that the personal narrative around their ABI changed from the acute to chronic stages I became interested in how an understanding of this journey might be applied in my clinical work. I found that the topics of identity, loss, and grief often dominated conversation for those immediately following their ABI. Understandably this is a time of acute stress and uncertainty, and often confusion given the unforeseen nature of most brain injuries. By contrast those who have adjusted to their injury after several years tend to discuss growth, new opportunities, and finding a life they can live. Having spent several months working clinically with ABI patients before beginning my research, my perception of them had in part come to match their feelings of hopelessness in those early stages. However, spending time with so many people in the
later stages of their injury allowed me to take a more positive perspective on recovery. I began to express hopefulness in my clinical work in a new way, encouraging cautious optimism in light of seeing so many people cope and adjust following their injury. It also further cemented my passion for positive psychology in both the clinical and research aspects of my professional role.

Acting as a scientist-practitioner is a fundamental part of the work of any clinical psychologist. Having come from a research background I felt ready to embrace this idea, and to put theory into practice and vice versa – to hopefully contribute meaningful findings to the evidence base. Spending a great deal of time reading through the long history of theoretical motivations and applied constructs of resiliency, grit, and coping contributed to on-going development in my therapeutic work. Encouraged by a growing empirical interest in strengths-based rehabilitation I was motivated to organise a group-therapy program within my clinical placement. Using an Acceptance and Commitment Therapy framework I hoped to provide an opportunity for the most ‘stuck’ patients known to NWBIS. In particular, I recruited those with severe or extremely severe ABIs who experienced significant disability, such as complete loss of limb function or difficulties with communication. I deliberately chose to include these patients who might otherwise find it challenging to join third sector events through a combination of lack of confidence and the obvious challenge for those charitable organisations to support someone with significant barriers to participation. The scientist-practitioner role played a part here also, as I registered the group as a service evaluation with an intention to publish the findings. The outcome of the meta-analysis in the present thesis, finding that coping-skills groups don’t improve coping, had not convinced me that groups generally are unimportant. Having participated in a psychoeducation group at NWBIS I had watched those patients develop their understanding of themselves, and begin relationships they had previously not thought possible. I have reflected on my personal high standards for achievement across my training and am always aware of my tendency to focus on measured outcomes. However, in the moment of watching this process of growth in our patients I understood that ‘success’ isn’t just what numbers can tell us.
References


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Appendices

Appendix A - Bangor University, School of Psychology Ethics Committee Application
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Appendix H - Participant Consent Form – English
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Appendix A - Bangor University, School of Psychology Ethics Committee Application

Application for Ethical Approval

Project Title: An Investigation Of Grit And Resilience In Rehabilitation Success Following Acquired Brain Injury

Principal Investigator: Todd Jones, Jenna

Other researchers: Coetzer, Rudi
Pre-screen Questions

Type of Project
D.Clin.Psy

What is the broad area of research
Clinical/Health

Funding body
Internally Funded

Type of application (check all that apply)
Project requiring scrutiny from an outside body which has its own ethical forms and review procedures

Proposed methodology (check all that apply)
Questionnaires and Interviews

Do you plan to include any of the following groups in your study?

Does your project require use of any of the following facilities and, if so, has the protocol been reviewed by the appropriate expert/safety panel? If yes please complete Part 2:B

If your research requires any of the following facilities MRI, TMS/ tCS, Neurology Panel, has the protocol been reviewed by the appropriate expert/safety panel?
Not applicable (the research does not require special safety panel approval)

Connection to Psychology, (i.e. why Psychology should sponsor the question)
Investigator is a student in Psychology (including the North Wales Clinical Psychology Programme) Further details: Second investigator is a staff member of the School of Psychology, Bangor University, and also the North Wales Brain Injury Service.

Does the research involve NHS patients? (NB: If you are conducting research that requires NHS ethics approval make sure to consult the Psychology Guidelines as you may not need to complete all sections of the Psychology online application)
Yes, NHS IRAS application attached.. Yes. R form attached

Has this proposal been reviewed by another Bangor University Ethics committee?
No

NHS checklist. Does your study involve any of the following?
Involve research participants identified from or because of their past or present use of NHS services. Including participants recruited through these services as healthy controls?. Use of NHS Staff or resources e.g. recruitment through the NHS, access to Medical records, use of premises etc.
Further details: Research participants to be recruited through the North Wales Brain Injury Service (NWBIS); suitability for potential recruitment to be decided by their treating clinician at NWBIS.
**Part 1: Ethical Considerations**

**Will you describe the main experimental procedures to participants in advance, so that they are informed about what to expect?**
Yes
Further details: The CI will explain each test and questionnaire in detail, participants will have an opportunity to ask any questions they may have.

**Will you tell participants that their participation is voluntary?**
Yes
Further details: Participants will be made aware that their participation is entirely voluntary and that they are free to withdraw at any time without giving a reason.

**Will you obtain written consent for participation?**
Yes
Further details: Prior to inclusion in the study, the CI will gain full informed written consent to participate from each participant. Participants will be provided with a written consent document in Welsh and English.

**If the research is observational, will you ask participants for their consent to being observed?**
N/A

**Will you tell participants that they may withdraw from the research at any time and for any reason?**
Yes
Further details: Participants will be made aware that they are free to withdraw at any time without giving a reason.

**With questionnaires, will you give participants the option of omitting questions they do not want to answer?**
Yes
Further details: Participants will be allowed to omit any questions that they do not wish to answer.

**Will you tell participants that their data will be treated with full confidentiality and that, if published, it will not be identifiable as theirs?**
Yes
Further details: All paper data will be stored at the NWBIS in each participant's file which will be stored in a locked filing cabinet. Raw data will be entered into a computerised statistical package in anonymised form (i.e. using unique identification numbers) on a password protected laptop only available to the CI and the academic supervisor. The CI will comply with Data Protection Legislation. At the end of the project (July 2018), all data (raw and statistical) will remain at the NWBIS. All data will be destroyed after a specified time period in line with BCUHB policies. Each participant will be given a unique identification number which will be used for all paper and electronic data collected. Paper copies of questionnaires and test sheets will use the unique identification number only and will be stored in a locked filing cabinet in the NWBIS. A record of identification numbers will be kept in a separate locked location at the NWBIS and will only be accessible to the CI and the academic supervisor. Any data that is analysed electronically will be anonymous, using the unique identification number and will contain no personal identification information. Paper data will be retained at the NWBIS and will be destroyed in line with BCUHB policy on data management. The research team (i.e. Jenna Todd Jones and Dr Rudi Coetzee) will have access to participants' personal data during the study along with each patient's treating clinician.
With questionnaires, will you give participants the option of omitting questions they do not want to answer?
Yes
Further details: Participants will be allowed to omit any questions that they do not wish to answer.

Will you tell participants that their data will be treated with full confidentiality and that, if published, it will not be identifiable as theirs?
Yes
Further details: All paper data will be stored at the NWBIS in each participant's file which will be stored in a locked filing cabinet. Raw data will be entered into a computerised statistical package in anonymised form (i.e. using unique identification numbers) on a password protected laptop only available to the CI and the academic supervisor. The CI will comply with Data Protection Legislation. At the end of the project (July 2018), all data (raw and statistical) will remain at the NWBIS. All data will be destroyed after a specified time period in line with BCUHB policies. Each participant will be given a unique identification number which will be used for all paper and electronic data collected. Paper copies of questionnaires and test sheets will use the unique identification number only and will be stored in a locked filing cabinet in the NWBIS. A record of identification numbers will be kept in a separate locked location at the NWBIS and will only be accessible to the CI and the academic supervisor. Any data that is analysed electronically will be anonymous, using the unique identification number and will contain no personal identification information. Paper data will be retained at the NWBIS and will be destroyed in line with BCUHB policy on data management. The research team (i.e. Jenna Todd Jones and Dr Rudi Coetzer) will have access to participants' personal data during the study along with each patient's treating clinician.

Is there any realistic risk of any participants experiencing discomfort or risk to health, subsequent illness or injury that might require medical or psychological treatment as a result of the procedures?
No

Does your project involve work with animals? If "Yes" please complete Part 2: B
No

Does your project involve payment to participants that differs from the normal rates? Is there significant concern that the level of payment you offer for this study will unduly influence participants to agree to procedures they may otherwise find unacceptable? If "Yes" please complete Part 2: B and explain in point 5 of the full protocol
No
Further details: Participants will have their travel expenses to and from the NWBIS reimbursed. If participants wish to claim for travel expenses, they will be required to give the CI a receipt to allow the CI to reimburse the value of the journey.

If your study involves children under 18 years of age have you made adequate provision for child protection issues in your protocol?
N/A

If your study involves people with learning difficulties have you made adequate provision to manage distress?
N/A

If your study involves participants covered by the Mental Capacity Act (i.e. adults over 16 years of age who lack the mental capacity to make specific decisions for themselves) do you have appropriate consent procedures in place? NB Some research involving participants who lack capacity will require review by an NHS REC. If you are unsure about
whether this applies to your study, please contact the Ethics Administrator in the first instance

N/A
Further details: Clinicians at NWBIS will not approach clients on their case load whom do not have capacity to provide informed consent.

If your study involves patients have you made adequate provision to manage distress?

Yes
Further details: The study has been deemed not to present any direct risks but participants will be asked questions about their return to work following their brain injury. Additionally participants may find the cognitive tests challenging and frustrating. If any participant experiences any distress they will be encouraged to speak to their treating clinician at the NWBIS or their GP. In circumstances where it is clear that the participant is experiencing significant distress, with the participant's consent, the CI will write to their GP via letter. As participants will be completing a number of questionnaires and tests, any participant may request feedback on their results which will be given by the CI or the supervisor. If there are any concerns, these will be discussed with the participant's treating clinician at the NWBIS with the participant's consent to do so. If a participant experiences any distress as a consequence of taking part in the study, the participant will be advised to speak to their treating clinician at the NWBIS or their GP.

Does your study involve people in custody?

No

If your study involves participants recruited from one of the Neurology Patient Panels or the Psychiatry Patient Panel then has the protocol been reviewed by the appropriate expert/safety panel?

N/A
Further details: The Chief Investigator (CI) Jenna Todd Jones) will approach clinicians at NWBIS and present the research proposal. Clinicians will be asked to identify clients on their case load that meet inclusion and exclusion criteria. Neither the Neurology Patient Panel nor the Psychiatry Patient Panel will be used.

If your study includes physically vulnerable adults have you ensured that there will be a person trained in CPR and seizure management at hand at all times during testing?

N/A

Is there significant potential risk to investigator(s) of allegations being made against the investigator(s). (e.g., through work with vulnerable populations or context of research)?

No
Further details: Clinicians at NWBIS will be asked to identify clients on their case load that meet inclusion and exclusion criteria. Treating clinicians at the NWBIS will be aware of any risks from the client to the CI and as such clients who represent a risk to the CI will not be approached. Potential risks include those related to lone working for the CI who may be required to undertake testing at the participant's home address. Where possible, lone working will be avoided and it is anticipated that the majority of testing will take place at the NWBIS or GP Surgery. When lone working is necessary, the Betsi Cadwaladr University Health Board Lone Worker Policy will be adhered to.

Is there significant potential risk to the institution in any way? (e.g., controversiality or potential for misuse of research findings.)

No
Part 3: Risk Assessment

Is there significant potential risk to participants of adverse effects?
No

Is there significant potential risk to participants of distress?
No

Is there significant potential risk to participants for persisting or subsequent illness or injury that might require medical or psychological treatment?
No

Is there significant potential risk to investigator(s) of violence or other harm to the investigator(s) (e.g., through work with particular populations or through context of research)?
No

Is there significant potential risk to other members of staff or students at the institution? (e.g., reception or other staff required to deal with violent or vulnerable populations.)
No

Does the research involve the investigator(s) working under any of the following conditions: alone; away from the School; after-hours; or on weekends?
Yes
Further details: Potential risks include those related to lone working for the CI who may be required to undertake testing at the participant's home address. Where possible, lone working will be avoided and it is anticipated that the majority of testing will take place at the NWBIS or GP Surgery. When lone working is necessary, the Betsi Cadwaladr University Health Board Lone Worker Policy will be adhered to.

Does the experimental procedure involve touching participants?
No

Does the research involve disabled participants or children visiting the School?
No
Declaration

Declaration of ethical compliance: This research project will be carried out in accordance with the guidelines laid down by the British Psychological Society and the procedures determined by the School of Psychology at Bangor. I understand that I am responsible for the ethical conduct of the research. I confirm that I am aware of the requirements of the Data Protection Act and the University’s Data Protection Policy, and that this research will comply with them.

Yes

Declaration of risk assessment: The potential risks to the investigator(s) for this research project have been fully reviewed and discussed. As an investigator, I understand that I am responsible for managing my safety and that of participants throughout this research. I will immediately report any adverse events that occur as a consequence of this research.

Yes

Declaration of conflict of interest: To my knowledge, there is no conflict of interest on my part in carrying out this research.

Yes
Part 2: A

The potential value of addressing this issue

Hypotheses

Participants recruitment. Please attach consent and debrief forms with supporting documents

Research methodology

Estimated start date and duration of the study.

For studies recruiting via SONA or advertising for participants in any way please provide a summary of how participants will be informed about the study in the advertisement. N.B. This should be a brief factual description of the study and what participants will be required to do.
Part 2: B

Brief background to the study
Further details: It has been proposed that high levels of trait resilience (Rutter, 2012) can lead to improved rehabilitation (indicated by community integration outcomes) following ABI, although evidence of this in published research is mixed (Dumont, Gervais, Fougeryrollas, Bertrand, 2004; Losoi et al., 2015; Lukow et al., 2015; McCauley et al., 2012). Presently no research exists addressing trait grit and outcomes of any kind following ABI (Duckworth Quinn, 2009). The current study aims to explore further the potential influence of trait resilience and grit on outcomes following ABI, and contribute to on-going efforts to determine protective and mitigating factors of individuals’ functioning following ABI. Grit and resilience scales have enormous potential for informing the treatment of ABI. Their simplicity and short completion time lends well to populations who may struggle with concentration or acquired cognitive deficits. Further, grit and resilience scales may be useful tools for assessing the likely trajectory of patient recovery. That is, there is potential value in understanding that low levels of grit or resilience may lead to longer rehabilitation time, or require greater or different input from the treating clinician (Dumont et al., 2004; Lukow et al., 2015; White, Driver, Warren, 2010). Patients attending the North Wales Brain Injury Service (NWBIS) with an ABI that occurred at least one year previously would be eligible to participate. Participants will likely be enrolled in the study for up to 12 months and participation would include completing cognitive tests (paper and pencil type tests designed to measure intelligence quotient) and questionnaires that should take no more than two hours.

The hypotheses
Further details: Hypothesis 1: high levels of grit are associated with increased rehabilitative success following ABI (as measured by community integration). Hypothesis 2: high levels of resilience are associated with increased rehabilitative success following ABI (as measured by community integration).

Participants: recruitment methods, age, gender, exclusion/inclusion criteria
Further details: Participants will be recruited from service users attending the NWBIS for routine outpatient appointments, identified by their clinician as having sustained a traumatic brain injury and who do not meet any of the exclusion criteria. In the first instance the CI will approach clinicians at NWBIS and present the project and answer any questions they may have. Clinicians will be asked to identify participants who meet the inclusion criteria from their current case load. Only members of the participant’s clinical care team will have direct access to identifiable personal information in the individual’s clinical file. The relevant NWBIS clinician will screen the individual’s clinical file to check for eligibility for the study. The treating clinician will then make the first contact with the potential participant to query whether they would be interested in taking part in the research and if so do they consent for the clinician to pass on their contact details to the CI who will contact them to discuss it further. The CI will ONLY contact the potential participants once she has been informed by the treating clinician that the individual is interested to hear more about the research study. Accordingly, potential participants will be approached by their treating clinicians and asked if they would like a study information sheet and if they consent to the CI (Jenna Todd Jones) contacting them approximately one week following via the telephone to discuss the study further and at this point potential participants will be asked if they wish to participate in the study. Prior to inclusion in the study, the CI will gain full informed written consent to participate from each participant. Participants will be given the opportunity to discuss the research with the CI and ask any questions they may have. The CI will take responsibility for asking clinicians to identify potential participants and for testing once participants have agreed to take part. After the initial phone conversation, participants will be asked to let the researcher know within one week whether they would like to participate. If they would like to continue with the research a time will be made for the participant to attend the NWBIS to complete the testing. If the participant is unable to travel to the NWBIS then the researcher will arrange to meet the participant at their GP surgery or at their home. Travel expenses will be reimbursed when the participant is travelling to complete the testing. Participants should expect to be in the testing session for no more than 2 hours. The session will involve completing short questionnaires and answering demographic questions including whether
they have returned to work. If the participant would rather complete the testing over two sessions, that can be arranged. Patients will be excluded from participating in this study if they meet the following criteria: Severe cognitive impairment that would impair their ability to participate (determined by treating clinician at NWBIS) Unable to provide informed consent (clinician determined as above) Existing comorbid psychiatric condition (determined by the treating clinician and/or patient file) Current substance misuse/dependence Brain injury having occurred within the last year At risk of violent behaviour (i.e. those with frontal lobe trauma or history of violent behaviour, determined by treating clinician) Brain injury acquired within the last 12 months (determined by the treating clinician and/or patient file) Participant sample will be drawn from the following populations: Stroke, neurological, injuries and accidents Age: 18-65 Gender: Male and female

Research design
Further details: Participants will be recruited from service users attending the NWBIS for routine outpatient appointments, identified by their clinician as having sustained a traumatic brain injury and who do not meet any of the exclusion criteria. Clinicians will approach the individuals in the first instance and provide them with some verbal and written information. If the individual is interested, a time will be arranged for the researcher to phone them and to discuss the study further at a time of their convenience. Presently it is estimated that a sample of n=30 is a realistic achievement given the time constraints of the project. This project is considered a pilot experiment intended to begin exploration of the influence of grit and resilience in rehabilitation. After the initial phone conversation, participants will be asked to let the researcher know within one week whether they would like to participate. If they would like to continue with the research a time will be made for the participant to attend the NWBIS to complete the testing. If the participant is unable to travel to the NWBIS then the researcher will arrange to meet the participant at their GP surgery or at their home. Travel expenses will be reimbursed when the participant is travelling to complete the testing. Participants should expect to be in the testing session for no more than 2 hours. The session will involve completing short questionnaires and answering demographic questions (including whether they have returned to work). If the participant would rather complete the testing over two sessions, that can be arranged. Once the tests are completed the participant will receive verbal feedback from the researcher on the testing and be offered more comprehensive feedback on the results of the tests at a later date if the participant would like. This can be given over the phone or the researcher can arrange to meet with the participant if they would rather. Once the research has been written up, the researcher will create a newsletter to circulate to all participants outlining the general findings of the study. It is anticipated that this will be in June 2018.

Procedures employed
Further details: The study will employ a cross-sectional design. Multiple correlation coefficients, coefficient of determination, and F-ratios will be calculated from anonymised data using SPSS to explore associations between measures of personality and rehabilitation (as measured by community integration) following acquired brain injury. Participants will be asked to complete self-report questionnaires pertaining to levels of grit and resilience and insight, as well as reporting basic demographic information including whether they are employed. Participants will also be asked to complete a standardised cognitive assessment to establish their present and premorbid cognitive functioning. Measures will be administered in one session (or two at the participant's request) and will take between 1-2 hours. Participants will be recruited from the North Wales Brain Injury Service (NWBIS) which is a multi disciplinary community based outpatient brain injury rehabilitation service. 1) Initial telephone consultation 2) Seeking consent 3) Grit scale 4) Resilience scale 5) Insight measure 6) Test of premorbid functioning 7) Montreal cognitive assessment 8) Debrief To be completed by Jenna Todd Jones, CI at the NWBIS or clients home/GP at their request.

Measures employed
Further details: Participants will complete several questionnaires and basic demographic data will be collected, including: age, gender, greatest educational attainment, occupation prior to TBI, and whether they have returned to work (including previous occupation and current or most recent
occupation, including length of time in occupation). Return to work will be measured on three levels: (1) whether they had returned to work (and remained in employment) and/or were in a school/training programme; (2) whether they had previously returned to work but were no longer employed; or (3) had not attempted return to work. The Test of Premorbid Functioning (ToPF) is a 70-item measure that will be used to determine premorbid IQ (Wechsler, 2011). This is a more recent and well-trusted test for IQ relative to the historically used National Adult Reading Test (NART). The ToPF has been validated and normed against the Weschler Adult Intelligence Scale Revised. The Montreal Cognitive Assessment (MoCA) is a brief screening tool for cognitive impairment, with high sensitivity and specificity (Nasreddine et al., 2005). The MoCA establishes the quality of functioning in visuospatial/executive, naming, memory, attention, language, abstraction, delayed recall, and orientation domains. Out of a total possible score of 30 on the MoCA the higher the score the greater the individuals level of function; a score above 26 is considered normal. The MoCA has demonstrated excellent internal consistency, test-retest reliability, and criterion validity. The Grit Scale is a 12-item self-report measure that will be used to establish each individual’s level of grit, on a scale of 1 to 6. The Grit Scale has demonstrated good internal consistency, test-retest reliability, and predictive validity (Duckworth Quinn, 2009). The higher the score on the Grit Scale the greater the level of grit. The Connor-Davidson Resilience Scale (CD-RISC; Connor Davidson, 2003) is a self-report 25-item measure that will be used to establish each individual’s level of resilience, on a scale of 1 to 100. The CD-RISC has been validated as a tool for measuring degree of resilience and can be used as a predictor of outcome of psychological treatment. A recent review of resilience scales found the CD-RISC to be one of the three best tools available for assessing resilience, with good internal consistency, test-retest reliability, and predictive validity (Windle, Bennett, Noyes, 2011). The higher the score on the CD-RISC the higher the level of resilience. The Awareness Questionnaire (Sherer, Berglöff, Boake, Jr Levin, 1998) is formed of two separate 17-item self-report and clinician-report ratings of insight. On each form the abilities of the person with TBI to perform various tasks after the injury as compared to before the injury are rated on a five point scale ranging from "much worse" to "much better." A score is established from the difference between the self-report and clinician-rated scores. The greater the discrepancy between the two forms the greater the likelihood of poor insight. The Awareness Questionnaire has been shown to have good internal consistency and criterion validity. The Community Integration Questionnaire (CIQ) is a self-report 15-item measure used to establish rehabilitative success in the form of reintegration into the community. The CIQ measures levels of social integration, integration at home, and integration in productive activities (e.g. work or schooling). These three scales sum to provide a total possible score of 29. The higher the score the greater the level of community integration. The CIQ has shown good internal consistency, excellent test-retest reliability, and acceptable construct validity.

Qualifications of the investigators to use the measures (Where working with children or vulnerable adults, please include information on investigators’ CRB disclosures here.)

Further details: Dr Jenna Todd Jones BSc Psychology - First, Bangor University 2009 MSc Clinical Neuropsychology - Distinction, Bangor University 2010 PhD Experimental Psychology - Pass, University of Bristol 2016 Trainee Clinical Psychologist with experience of neuropsychological assessment and working with those who have an Acquired Brain Injury. Criminal Records check completed. Dr Rudi Coetzee BA (cum laude) BA Hons Clin Psych (cum laude) MA Clin Psych (cum laude) D Clin Psy Qualified Clinical Neuropsychologist, head of the North Wales Brain Injury Service. Criminal Records check completed. The recruitment procedure whereby the treating clinicians at the NWBIS identify suitable potential participants from their caseload will prevent unsolicited communication regarding the study and will prevent individuals who are vulnerable or unsuitable being put forward.

Venue for investigation

Further details: Where possible, testing will take place at the North Wales Brain Injury Service but if participants are unable to attend, home visits or using a convenient GP surgery will be offered.

Estimated start date and duration of the study (N.B. if you know that the research is likely to continue for more than three years, please indicate this here).
Data analysis
Further details: The dependent variable (Community Integration Scale score) is continuous, interval level data. Each independent variable (gender, age, level of educational attainment, level of occupation prior to TBI, return to work, gait score, resilience score, and insight score, premorbid IQ, present cognitive function) is either nominal or continuous, interval level data. Independence of observations will be assessed using the Durbin-Watson statistic. Scatter plots will be used to determine a linear relationship between the dependent variable and each independent variable (as well as all independent variables combined), and also the residuals (errors). If non-linearity is found a transformation will be performed on the data. Outliers will be determined casewise, and histograms and PP/QQ plots will be used to establish an estimate of the normality of data distribution. Homoscedasticity and multicollinearity will be assessed using SPSS and Tolerance VIF values. Multiple correlation coefficients, coefficient of determination, and F-ratios will then be calculated from anonymised data using SPSS to explore associations between measures of personality and rehabilitation (as measured by community integration) following acquired brain injury.

Potential offence/distress to participants
Further details: While no direct risks are anticipated, the study will take up to about two hours of each participant's time. There is a small possibility that participants might find some of the tasks more difficult than expected which can sometimes be frustrating or upsetting. In addition there is a small possibility that when participants are asked questions about their return to work following their brain injury they may find this upsetting. If any participant experiences any distress they will be encouraged to speak to their treating clinician at the NWBIS or their GP. In circumstances where it is clear that the participant is experiencing significant distress, with the participant's consent, the CI will write to the GP via letter. Clients will be selected by their treating clinicians. The CI will explain each test and questionnaire in detail and clients will be aware that they are free to withdraw at any time without giving a reason. If any distress is caused as a direct result of the study, participants will be encouraged to speak to their treating clinician at the NWBIS or their GP. In extreme cases, the CI would seek the participant's consent to write directly to their GP. The recruitment procedure whereby the treating clinicians at the NWBIS identify suitable potential participants from their caseload will prevent unsolicited communication regarding the study and will prevent individuals who are vulnerable or unsuitable being put forward. As participants will be completing a number of questionnaires and tests, any participant may request feedback on their results which will be given by the CI or the supervisor. If there are any concerns, these will be discussed with the participant's treating clinician at the NWBIS with the participant's consent to do so. If a participant experiences any distress as a consequence of taking part in the study, the participant will be advised to speak to their treating clinician at the NWBIS or their GP. Once the testing session has finished with each participant, they will receive a full debrief from the CI and additionally the option for a more extensive feedback about test results and/or a newsletter outlining the main results of the study.

Procedures to ensure confidentiality and data protection
Further details: All paper and electronic data will be stored at the NWBIS. Paper data will be stored securely in the client's file at NWBIS. Electronic data will be stored on a secure NHS networked computer at the NWBIS. Anonymised electronic data will be analysed on a password protected laptop and only made available to the CI and the Academic Supervisor. The CI will comply with BCUHB data protection policy and legislation. At the end of the project (July 2018) all data will remain securely at the NWBIS. All data will be destroyed after a specified time period in line with BCUHB policy. The data will be used for academic research publications in the form of journal articles and conference presentations (all data will be anonymous and presented as a group average). Participants will receive a brief news letter following completion of the research, alternatively they can request individual explanation of the results from the CI. Participant names will only be recorded once for consent purposes, following which, a unique identification number will be assigned and used thereafter and will be used exclusively if referring to specific data in
research publications. Additional safeguards include keeping all consent forms and any paper copies of tasks or questionnaires in a locked filing cabinet at the NWBIS. Computer data will be stored anonymously on a password protected computer. All data and consent forms will be retained by the academic supervisor based at NWBIS following completion of the study for a minimum of 5 years, after which they will be safely disposed in line with BCUHB confidential waste policy. The study will involve access to medical records by those outside of the direct healthcare team (CI Dr J Todd Jones), use of personal addresses, postcodes, dates, e-mails, or telephone numbers, and the storage of personal data on manual files and NHS computers. The CI Jenna Todd Jones will access the clients medical notes to record details of the brain injury and brain scan findings. Storage of personal data will confined to NHS computers and any paper containing personal information will be stored securely in the participant's clinical file at the NWBIS. The telephone number of potential participants will be made available to the CI (Jenna Todd Jones) only with the participant's consent. Home addresses will only be made available to the CI if the participant is unable to travel to the NWBIS or the GP and as such the CI would visit them at home, addresses will only be made available to the CI with the resident's consent.

*How consent is to be obtained (see BPS Guidelines and ensure consent forms are expressed bilingually where appropriate. The University has its own Welsh translations facilities on extension 2036)*

Further details: The Chief Investigator (CI; Jenna Todd Jones) will approach clinicians at NWBIS and present the research proposal. Clinicians will be asked to identify clients on their case load that meet inclusion criteria. Clinicians will not approach clients on their case load whom do not have capacity to provide informed consent. These potential participants will be approached in the first instance by their treating clinician and asked if they would like a participant information sheet and if they consent to the CI contacting them by telephone approximately 1 week later to discuss the research. Participants who agree to be contacted will be given the opportunity to ask any questions about the research and to discuss the study. They will be asked if they would like to participate in the study. Prior to inclusion in the study, each participant will give their fully informed, written consent to participate. The consent form will be available bilingually. The battery of measures is only available and validated in English so participants will be made aware that tests and questionnaires will have to be carried out in English in order to maintain validated results. The CI Jenna Todd Jones is not a Welsh speaker so participants will be informed of this.

*Information for participants (provide actual consent forms and information sheets)*

including if appropriate, the summary of the study that will appear on SONA to inform participants about the study. N.B. This should be a brief factual description of the study and what participants will be required to do.

Further details: Information sheet attached. The information sheet will be available bilingually. The battery of measures is only available and validated in English so participants will be made aware that tests and questionnaires will have to be carried out in English in order to maintain validated results. The CI Jenna Todd Jones is not a Welsh speaker so participants will be informed of this. The study will not appear on SONA.

*Approval of relevant professionals (e.g., GPs, Consultants, Teachers, parents etc.)*

Further details: Participants suitable for the study will be identified and approved for inclusion by their treating clinician at NWBIS.

*Payment to: participants, investigators, departments/institutions*

Further details: Participants will not be paid for their participation. Participants have their travel expenses to and from the NWBIS reimbursed. If participants wish to claim for travel expenses, they will be required to give the CI a receipt to allow the CI to reimburse the value of the journey. Neither individual researchers nor the institution will receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research.

*Equipment required and its availability*
Further details: No equipment is required for this study. Adequate copies of all measures used (including license payment in the case of the Connors-Davidson Risk Scale) will be provided by the CI, Dr J Todd Jones.

*If students will be engaged a project involving children, vulnerable adults, one of the neurology patient panels or the psychiatric patient panel, specify on a separate sheet the arrangements for training and supervision of students. (See guidance notes)*

*If students will be engaged in a project involving use of MRI or TMS, specify on a separate sheet the arrangements for training and supervision of students. (See guidance notes)*

Further details: N/A

*What arrangements are you making to give feedback to participants? The responsibility is yours to provide it, not participants' to request it.*

Further details: For those who take part in the study, a full debrief at the end of the testing session will be offered and further feedback session outlining the results of the tests if the participant is interested. This will be provided by the CI Dr J Todd Jones. All participants will receive a newsletter at the end of the study outlining the general findings.

*Finally, check your proposal conforms to BPS Guidelines on Ethical Standards in research and sign the declaration. If you have any doubts about this, please outline them.*

Further details: N/A

**Part 4: Research Insurance**

*Is the research to be conducted in the UK?*

Yes

*Is the research based solely upon the following methodologies? Psychological activity, Questionnaires, Measurements of physiological processes, Venepuncture, Collections of body secretions by non-invasive methods, The administration by mouth of foods or nutrients or variation of diet other than the administration of drugs or other food supplements*

Yes

*Research that is based solely upon certain typical methods or paradigms is less problematic from an insurance and risk perspective. Is your research based solely upon one or more of these methodologies? Standard behavioural methods such as questionnaires or interviews, computer-based reaction time measures, standardised tests, eye-tracking, picture-pointing, etc; Measurements of physiological processes such as EEG, MEG, MRI, EMG, heart-rate, GSR (not TMS or tCS as they involve more than simple ‘measurement’); Collections of body secretions by non-invasive methods, venepuncture (taking of a blood sample), or asking participants to consume foods and/or nutrients (not including the use of drugs or other food supplements or caffeine).*

Yes
Appendix B – Bangor University, School of Psychology Ethics Committee Approval

Ethical approval granted for 2017-16070 An Investigation Of Grit And Resilience In Rehabilitation Success Following Acquired Brain Injury

ethics@bangor.ac.uk
Mon 24/07/2017, 09:35
Jenna Elizabeth Evans Todd Jones

Inbox

You forwarded this message on 24/07/2017 10:51

Dear Jenna,

2017-16070 An Investigation Of Grit And Resilience In Rehabilitation Success Following Acquired Brain Injury

Your research proposal number 2017-16070 has been reviewed by the Psychology Ethics and Research Committee and the committee are now able to confirm ethical and governance approval for the above research on the basis described in the application form, protocol and supporting documentation. This approval lasts for a maximum of three years from this date.

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

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

15th July 2017

Dear Sir/Madam

BANGOR UNIVERSITY
AND ALL ITS SUBSIDIARY COMPANIES

We confirm that the above institution is a Member of U.M. Association Limited, and that the following cover is currently in place:

PROFESSIONAL INDEMNITY

Certificate of Entry No. UM026/95
Period of Cover 1 August 2017 to 31 July 2018
Limit of Indemnity £5,000,000 any one claim and in the aggregate except for Pollution where cover is limited to £1,000,000 in the aggregate.
Cover provided by U.M. Association Limited

If you have any queries in respect of the above details, please do not hesitate to contact us.

Yours faithfully

Susan Wilkinson
For U.M. Association Limited
Appendix D – NHS IRAS Research Ethics Committee Form, REC Form

<table>
<thead>
<tr>
<th>NHS REC Form</th>
<th>Reference: 17/es/0118</th>
<th>IRAS Version 5.5.2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Welcome to the Integrated Research Application System</strong></td>
<td></td>
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<tr>
<td><strong>IRAS Project Filter</strong></td>
<td></td>
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<tr>
<td>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.</td>
<td></td>
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</tr>
<tr>
<td><strong>Please enter a short title for this project (maximum 70 characters)</strong></td>
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</tr>
<tr>
<td>Orilt and resilience in rehabilitation following brain injury</td>
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<td></td>
</tr>
<tr>
<td>1. <strong>Is your project research?</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>☐ Yes ☐ No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. <strong>Select one category from the list below:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>☐ Clinical trial of an investigational medicinal product</td>
<td></td>
<td></td>
</tr>
<tr>
<td>☐ Clinical investigation or other study of a medical device</td>
<td></td>
<td></td>
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<tr>
<td>☐ Combined trial of an investigational medicinal product and an investigational medical device</td>
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<tr>
<td>☐ Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice</td>
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<tr>
<td>☐ Basic science study involving procedures with human participants</td>
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<tr>
<td>☐ Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology</td>
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<tr>
<td>☐ Study involving qualitative methods only</td>
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<tr>
<td>☐ Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)</td>
<td></td>
<td></td>
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<tr>
<td>☐ Study limited to working with data (specific project only)</td>
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<tr>
<td>☐ Research tissue bank</td>
<td></td>
<td></td>
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<tr>
<td>☐ Research database</td>
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<tr>
<td>If your work does not fit any of these categories, select the option below:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>☐ Other study</td>
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<tr>
<td>2a. <strong>Please answer the following question(s):</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a) Does the study involve the use of any ionising radiation? ☐ Yes ☐ No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b) Will you be taking new human tissue samples (or other human biological samples)? ☐ Yes ☐ No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c) Will you be using existing human tissue samples (or other human biological samples)? ☐ Yes ☐ No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. <strong>In which countries of the UK will the research sites be located? (Tick all that apply)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>☐ England</td>
<td></td>
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<tr>
<td>☐ Scotland</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date: 03/08/2017</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>
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?

IMPORTANT: If your project is taking place in the NHS and is led from England select IRAS Form. If your project is led from Northern Ireland, Scotland or Wales select NHS/HSC Research and Development Offices’ and/or relevant Research Ethics Committee applications, as appropriate.

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

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

For participating NHS organisations in England different arrangements apply for the provision of site specific information. Refer to IRAS Help for more information.

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

- Yes
- No

8. 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.

6. 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

Date: 03/09/2017
8. 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 is a student project as part of the Doctorate in Clinical Psychology, North Wales Clinical Psychology Programme.
All project procedures will be carried out by the student under the guide of the clinical supervisor (employed by Betsi Cadwaladr University Health Board).

8a. Is the project being undertaken in part fulfillment 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 core team without prior consent at any stage of the project (including identification of potential participants)?

- Yes ☐  No ☐

Date: 03/08/2017  3
NHS REC Form

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

Health Research Authority

Application to NHS/HSC Research Ethics Committee

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

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

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)

Grit and resilience in rehabilitation following brain injury

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

REC Name:
East of Scotland Research Ethics Service REC 1

REC Reference Number: 17/es/0118 Submission date: 03/08/2017

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:
An Investigation Of Grit And Resilience In Rehabilitation Success Following Acquired Brain Injury

A3.1. Educational projects
Name and contact details of student(s):

Student 1

Title Forename/Initials Surname
Dr Jemma E E Todd Jones

Address North Wales Clinical Psychology Programme
42 College Road
Gwynedd

Post Code LL57 2DG
E-mail psp693@bangor.ac.uk
Telephone 07791377124
Fax

Date: 03/08/2017
Give details of the educational course or degree for which this research is being undertaken:
Name and level of course/degree:
Doctorate in Clinical Psychologist (DClinPsy)
Name of educational establishment:
Bangor University

Name and contact details of academic supervisor(s):

Academic supervisor 1
Title Forename/Initials Surname
Dr Rudi Coetzer
Address
North Wales Brain Injury Service
Cowny Bay Hospital
Hesket Road
Post Code LL29 8AY
E-mail Rudi.Coetzer@Wales.NHS.UK
Telephone 01492807770
Fax 01492807770

Academic supervisor 2
Title Forename/Initials Surname
Dr Mike Jackson
Address
North Wales Clinical Psychology Programme
42 College Road, Bangor University
Bangor, Gwynedd
Post Code LL57 2DG
E-mail Mike.Jackson@bangor.ac.uk
Telephone 01248388746
Fax

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

<table>
<thead>
<tr>
<th>Student(s)</th>
<th>Academic supervisor(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Student 1</td>
<td>Dr Rudi Coetzer</td>
</tr>
<tr>
<td></td>
<td>Dr Mike Jackson</td>
</tr>
</tbody>
</table>

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. Who will act as Chief Investigator for this study?

☐ Student
☐ Academic supervisor
☐ Other

Date: 03/06/2017
A3-1. Chief Investigator:

Title Forename/Initials Surname
Dr Jenna E E Todd Jones

Post
Trainee Clinical Psychologist

Qualifications
MSc Clinical Neuropsychology, Bangor University 2010
PhD Experimental Psychology, Bristol University 2016

ORCID ID
0000 0002 6520 9839

Employer
Betsi Cadwaladr University Health Board

Work Address
North Wales Clinical Psychology Programme
School of Psychology, Bangor University
Bangor, Gwynedd

Post Code
LL57 2DG

Work E-mail
psp67@bangor.ac.uk

* Personal E-mail
psp67@bangor.ac.uk

Work Telephone

* Personal Telephone/Mobile 07791377124

Fax

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

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

Title Forename/Initials Surname
Mr Hefin Francis

Address
School of Psychology
Brigantia Building, Penrall Road
Bangor University, Bangor

Post Code
LL57 2AB

E-mail
h.francis@bangor.ac.uk

Telephone
01248383339

Fax
01248382599

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

Applicant/organisation’s own reference number, e.g. R & D (if available):

Sponsor/protocol number:
N/A

Protocol Version:
1

Protocol Date:
24/07/2017

Funder’s reference number:
N/A

Project website:
N/A

Additional reference number(s):

<table>
<thead>
<tr>
<th>Ref. Number</th>
<th>Description</th>
<th>Reference Number</th>
</tr>
</thead>
</table>

Date: 03/08/2017
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.

A6.2. Is this application linked to a previous study or another current application?

☐ Yes  ☐ No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

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

A8-1. 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.

It has been proposed that high levels of trait resilience (Rutter, 2012) can lead to improved rehabilitation (indicated by community integration outcomes) following ABI, although evidence of this in published research is mixed (Dumont, Gervais, Fougeryolas, & Bertrand, 2004; Losol et al., 2015; Lukow et al., 2015; McCauley et al., 2012). Presently no research exists addressing trait grit and outcomes of any kind following ABI (Duckworth & Quinn, 2009).

The current study aims to explore further the potential influence of trait resilience and grit on outcomes following ABI, and contribute to on-going efforts to determine protective and mitigating factors of individuals functioning following ABI. Grit and resilience scales have enormous potential for informing the treatment of ABI. Their simplicity and short completion time lends well to populations who may struggle with concentration or acquired cognitive deficits. Further, grit and resilience scales may be useful tools for assessing the likely trajectory of patient recovery. That is, there is potential value in understanding that low levels of grit or resilience may lead to longer rehabilitation time, or require greater or different input from the treating clinician (Dumont et al., 2004; Lukow et al., 2015; White, Driver, & Warren, 2010).

Patients attending the North Wales Brain Injury Service (NWBIIS) with an ABI that occurred at least one year previously would be eligible to participate. Participants will likely be enrolled in the study for up to 12 months and participation would include completing cognitive tests (paper and pencil type tests designed to measure Intelligence quotient) and questionnaires that should take no more than two hours.

A8-2. Summary of main issues. Please summarise the main ethical, legal, or management issues arising from your study and say how you have addressed them.

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

Design and Procedures:
The study will employ a cross-sectional, correlational design. Correlation coefficients will be calculated to explore associations between personality factors and rehabilitation following acquired brain injury. Dependent variables will be the outcome scores for the measures employed.

Participants will be asked to complete self-report questionnaires pertaining to levels of grit and resilience, as well as reporting basic demographic information including whether they are employed. Participants will also be asked to complete a standardised cognitive assessment to establish their IQ. Measures will be administered in one session (or two at the participant’s request) and will take between 1-2 hours. Participants will be recruited from the North Wales
NHS REC Form Reference: 17/ES/0118 IRAS Version 5.5.2

Brain Injury Service (NWBIS) which is a multidiisciplinary community based outpatient brain injury rehabilitation service.

Recruitment Procedure and Consent:
The Chief Investigator (CI, Jenna Todd Jones) will approach clinicians at NWBIS and present the research proposal. Clinicians will be asked to identify clients on their case load that meet inclusion criteria. Clinicians will not approach clients on their case load whom do not have capacity to provide informed consent. These potential participants will be approached in the first instance by their treating clinician and asked if they would like a participant information sheet and if they consent to the CI contacting them by telephone approximately 1 week later to discuss the research. Participants who agree to be contacted will be given the opportunity to ask any questions about the research and to discuss the study. They will be asked if they would like to participate in the study. Prior to inclusion in the study, each participant will give their fully informed, written consent to participate.

For those who take part in the study, a full debrief at the end of the testing session will be offered and further feedback session outlining the results of the tests if the participant is interested. All participants will receive a newsletter at the end of the study outlining the general findings. The CI will take primary responsibility for recruiting and testing participants when consent has been given. Where possible, testing will take place at the NWBIS but if participants are unable to attend, home visits or using a convenient GP surgery will be offered. Participant travel expenses will be reimbursed when participants are travelling to and from NWBIS for the study.

Risks, Burdens and Benefits:
Potential risks include those related to lone working for the CI who may be required to undertake testing at the participant’s home address. Where possible, lone working will be avoided and it is anticipated that the majority of testing will take place at the NWBIS or GP Surgery. When lone working is necessary, the Betsi Cadwaladr University Health Board Lone Worker Policy will be adhered to.

Treatig clinicians at the NWBIS will be aware of any risks from the client to the CI and as such clients who represent a risk to the CI will not be approached.

The study has been deemed not to present any direct risks but participants will be asked questions about their return to work following their brain injury. Additionally participants may find the cognitive tests challenging and frustrating. If any participant experiences any distress they will be encouraged to speak to their treating clinician at the NWBIS or their GP. In circumstances where it is clear that the participant is experiencing significant distress, with the participant’s consent, the CI will write to their GP via letter.

As participants will be completing a number of questionnaires and tests, any participant may request feedback on their results which will be given by the CI or the supervisor. If there are any concerns, these will be discussed with the participant’s treating clinician at the NWBIS with the participant’s consent to do so. If a participant experiences any distress as a consequence of taking part in the study, the participant will be advised to speak to their treating clinician at the NWBIS or their GP.

Benefits of taking part include contributing to the scientific evidence base and a full debrief on the study and individual tests if requested, also a newsletter detailing the findings of the research. Burdens may include time spent participating in the study, reading the information sheet, the testing itself and talking with the CI.

Confidentiality:
All paper and electronic data will be stored at the NWBIS. Paper data will be stored securely in the client’s file at NWBIS. Electronic data will be stored on a secure NHS networked computer at the NWBIS. Anonymised electronic data will be analysed on a password protected laptop and only made available to the CI and the Academic Supervisor. The CI will comply with BCUHB data protection policy and legislation. At the end of the project (July 2018) all data will remain securely at the NWBIS. All data will be destroyed after a specified time period in line with BCUHB policy. The data will be used for academic research publications in the form of journal articles and conference presentations (all data will be anonymous and presented as a group average). Participants will receive a brief news letter following completion of the research, alternatively they can request individual explanation of the results from the CI. Participant names will only be recorded once for consent purposes, following which, a unique identification number will be assigned and used thereafter and will be used exclusively if referring to specific data in research publications. Additional safeguards include keeping all consent forms and any paper copies of tasks or questionnaires in a locked filing cabinet at the NWBIS. Computer data will be stored anonymously on a password protected computer. All data and consent forms will be retained by the academic supervisor based at NWBIS following completion of the study for a minimum of 5 years, after which they will be safely disposed in line with BCUHB confidential waste policy.

Date: 03/06/2017
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
- Metaanalysis
- Qualitative research
- Questionnaire, interview or observation study
- Randomised controlled trial
- Other (please specify)

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

The main aim of the study is to establish whether grit and resilience (non-cognitive, personality trait-level elements of function) are good predictors of rehabilitation (as measured by community integration) following an acquired brain injury. Presently there is limited available research regarding the potential influence of resilience in relation to neuropsychological rehabilitation success and community integration; none exists regarding trait grit. Grit and resilience scales have enormous potential for informing the treatment of ABI. Accordingly, this study is intended as a pilot proof of concept that the grit and/or resilience measures can be used to determine the likelihood of success in committing to the long-term goal of return-to-work (and other evidence of community integration) in the face of adversity in the form of an acquired brain injury.

Hypothesis 1: high levels of grit are associated with increased rehabilitative success following ABI (as measured by community integration).

Hypothesis 2: high levels of resilience are associated with increased rehabilitative success following ABI (as measured by community integration).

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

Not applicable.

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

Research attempting to predict the likelihood of community integration (including family engagement, social engagement, and return to work) following acquired brain injury (ABI) has demonstrated the influence of age (Lubusko, Moore, Stambrook, & Gill, 1994; Willemse-van Son, Ribbers, Verhagen, & Stam, 2007), gender (Walker, Manutz, Korzuzer, Hart, & Novack, 2006), pre-injury education (Franulic, Carbonell, Pinto, & Sepulveda, 2004), category of employment prior to injury (Andelic, Stevens, Sigurdardottir, Arango-Lasprilla, & Roe, 2012; Fellingham, Baguley, & Crooks, 2001; Lubusko et al., 1994), cognitive and behavioural function (Andelic et al., 2012; Crepeau & Scherzer, 1993; Schreiner, 2000), injury severity (Tsakoskides et al., 2009), and cause of injury (Ketchum et al., 2012). Limited research has demonstrated the influence of personality traits in post-injury community integration outcomes following ABI. More recently several studies have addressed trait resilience, with mixed results; presently no research yet exists addressing trait grit in this population. Dumont et al. found that up to 51% of the variance in social participation following ABI can be accounted for by resiliency factors (2004). Resiliency related coping skills have also

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been found to predict successful role functioning in both the short- and long-term following an ABI (Kendall & Terry, 2008). A qualitative study from Adams and Dahdah (2016) reported spontaneous engagement in coping strategies and adaptation to difficulties in those recovering from ABI, where the authors reported that "the overall impression from the interviews was the presence of resiliency" (p. 233). Perceived self-efficacy has also been found to be linked to social participation in those with non-ABI complex impairments (Bent, Jones, Molloy, Chamberlain, & Tennant, 2001).

Conversely, Losol et al. (2015) found no association between their measure of resilience and the likelihood of return to work (96% of participants returned to work within one year). Nonetheless, participants with high levels of resilience reported improved symptomatology and psychosocial functioning during rehabilitation, which is likely to influence community integration (Similarly to Kreutzer et al., 2016, and White et al., 2010).

The current study aims to explore further the links between resilience and grit personality traits and successful community integration following ABI. These short, simple personality trait scales may enable us to better tailor treatment options for individuals with ABI (Cumont et al., 2004; Lukow et al., 2015; White, Driver, & Warren, 2010).

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.

Participants will be recruited from service users attending the NWBIS for routine outpatient appointments, identified by their clinician as having sustained a traumatic brain injury and who do not meet any of the exclusion criteria.

Clinicians will approach the individuals in the first instance and provide them with some verbal and written information. If the individual is interested, a time will be arranged for the researcher to phone them and to discuss the study further at a time of their convenience.

After the initial phone conversation, participants will be asked to let the researcher know within one week whether they would like to participate. If they would like to continue with the research a time will be made for the participant to attend the NWBIS to complete the testing. If the participant is unable to travel to the NWBIS then the researcher will arrange to meet the participant at their GP surgery or at their home. Travel expenses will be reimbursed when the participant is travelling to complete the testing. Participants should expect to be in the testing session for no more than 2 hours. The session will involve completing short questionnaires and answering demographic questions including whether they have returned to work. If the participant would rather complete the testing over two sessions, that can be arranged.

Once the tests are completed the participant will receive verbal feedback from the researcher on the testing and be offered more comprehensive feedback on the results of the tests at a later date if the participant would like. This can be given over the phone or the researcher can arrange to meet with the participant if they would rather.

Once the research has been written up, the researcher will create a newsletter to circulate to all participants outlining the general findings of the study. It is anticipated that this will be in June 2018.

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?

☐ 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.
After completion of the study the CI will produce a newsletter for all participants which will be reviewed by the university ‘People Panel’ before dissemination.
A17.1. Please list the principal inclusion criteria (list the most important, max 6000 characters).

Approximately 30 participants with a confirmed history of ABI will be prospectively recruited to participate. All participants will be recruited from the NWBIS. Participants who sustained an ABI with a minimum interval of one year following brain injury to exclude those who have only recently sustained injury. Severity of traumatic brain injury will be determined by examining patient's medical file following the Mayo Classification System (Malec et al., 2007).

A17.2. Please list the principal exclusion criteria (list the most important, max 6000 characters).

Patients will be excluded from participating in this study if they meet the following criteria (as determined by the treating clinician and/or patient file): Severe cognitive impairment that would impair their ability to participate Unable to provide informed consent Existing comorbid psychiatric condition Current substance misuse/dependence Brain injury having occurred within the last year At risk of violent behaviour (i.e. those with frontal lobe trauma or history of violent behaviour, determined by treating clinician)

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.

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<th>2</th>
<th>3</th>
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<td>Awareness scale</td>
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<td>Test of premorbid functioning</td>
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<td>Jenna Todd Jones, CI at the NWBIS or clients home/ GP at their request.</td>
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</table>

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

Date: 03/08/2017
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.

While no direct risks are anticipated, the study will take up to about two hours of each participant’s time. There is a small possibility that participants might find some of the tasks more difficult than expected which can sometimes be frustrating or upsetting.

Participants will also be asked to complete a questionnaire including questions about their return to work, which can very occasionally produce distressing feelings.

Clients will be selected by their treating clinicians. The CI will explain each test and questionnaire in detail and clients will be aware that they are free to withdraw at any time without giving a reason. If any distress is caused as a direct result of the study, participants will be encouraged to speak to their treating clinician at the NWBIS or their GP. In extreme cases, the CI would seek the participant’s consent to write directly to their GP.

The recruitment procedure whereby the treating clinicians at the NWBIS identify suitable potential participants from their caseload will prevent unsolicited communication regarding the study and will prevent individuals who are vulnerable or unsuitable being put forward.

Once the testing session has finished with each participant, they will receive a full debrief from the CI and additionally the option for a more extensive feedback about test results and/or a newsletter outlining the main results of the study.

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

☐ Yes  ☐ No

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

Whilst the study is expected not to involve any direct risks to clients, questionnaires will ask directly about return to work following a brain injury. In addition, participants will complete an equivalent of an IQ test and complete personality trait scales and a measure of insight into their current functioning. Clients will be selected by their treating clinicians, minimising the risk of inappropriate participants being put forward. The CI will explain each questionnaire in detail and clients will be aware that they are free to withdraw at any time without giving a reason. If any distress is caused as a direct result of the study, participants will be encouraged to speak to their treating clinician at the NWBIS or their GP. In extreme cases, the CI would seek the participant’s consent to write directly to their GP.

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

Although there are no direct benefits to the individuals taking part in the study, participants will have the knowledge that they are contributing to the scientific evidence base to potentially improve rehabilitation in the future. Participants will be given a full debrief on the study and individual tests if requested. Also a newsletter detailing the findings of the research will be sent out if the participants would like to receive this following the study conclusion, approximately June 2018.

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

Potential risks to the CI include those related to lone working as the CI may be required to undertake testing sessions at the participant’s homes. Where possible this will be avoided and it is anticipated that the majority of testing will take place at the NWBIS or a GP practice local to the participant. Where lone working cannot be avoided, the BCUH Lone Worker Policy will be adhered to. When clinicians approach their clients to participate in the study, they will screen out any clients who may pose a potential risk to the CI.
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).

In the first instance the CI will approach clinicians at NWBIS and present the project and answer any questions they may have. Clinicians will be asked to identify participants who meet the inclusion criteria from their current case load. Potential participants will be approached by their treating clinicians and asked if they would like a study information sheet and if they consent to the CI (Jenna Todd Jones) contacting them approximately one week following the telephone to discuss the study further and at this point potential participants will be asked if they wish to participate in the study. Prior to inclusion in the study, the CI will gain full informed written consent to participate from each participant. Participants will be given the opportunity to discuss the research with the CI and ask any questions they may have. The CI will take responsibility for asking clinicians to identify potential participants and for testing once participants have agreed to take part.

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:
Only members of the participant's clinical care team will have direct access to identifiable personal information in the individual's clinical file. The relevant NWBIS clinician will screen the individual's clinical file to check for eligibility for the study. The treating clinician will then make the first contact with the potential participant to query whether they would be interested in taking part in the research and if so do they consent for the clinician to pass on their contact details to the CI who will contact them to discuss it further. The CI will ONLY contact the potential participants once she has been informed by the treating clinician that the individual is interested to hear more about the research 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

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?

In the first instance the CI will approach clinicians at NWBIS and present the project and answer any questions they may have. Clinicians will be asked to identify participants who meet the inclusion criteria from their current case load. Potential participants will be approached by their treating clinicians and asked if they would like a study information sheet and if they consent to the CI (Jenna Todd Jones) contacting them approximately one week following via the telephone to discuss the study further and at this point potential participants will be asked if they wish to participate in the study. Prior to inclusion in the study, the CI will gain fully informed written consent to participate from each participant. Participants will be given the opportunity to discuss the research with the CI and ask any questions they may have. The CI will take responsibility for asking clinicians to identify potential participants and for testing once participants have agreed to take part. After the testing session, participants will be given the opportunity to discuss the process and ask any questions they may have. Where possible, participants will take part in testing at the NWBIS and travel expenses will be reimbursed. If participants are unable to attend the NWBIS they will be given the option of participating in testing at a local GP or at their home address.

A30-1. Will you obtain informed consent from or on behalf of research participants?

Date: 03/06/2017
NHS REC Form
Reference: 17/ES/0118
IRAS Version 5.5.2

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.

Only adults with the capacity to give informed consent will be approached. Consent will be given directly to the CI (Jenna Todd Jones). Each participant will have a written information sheet accompanied by a verbal explanation of the study and the opportunity to ask any questions they may have. Additionally, the CI will arrange directly with the individual to contact them via phone approximately one week later and ensure they have the CI’s contact details if they would like to make contact.

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

Please enclose a copy of the information sheet(s) and consent form(s).

A30-2. Will you record informed consent (or advice from oncologists) in writing?

☐ Yes ☐ No

A31. How long will you allow potential participants to decide whether or not to take part?

Approximately one week.

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)

Participants deemed not able to provide written informed consent will not be approached to take part in the study. Capacity will be decided upon by the treating clinicians at the NWBII before contact details of those wishing to take part are passed on to the CI.

As the research is taking place in Wales all written documents will be provided bilingually but it will be explained that the CI Jenna Todd Jones is not a Welsh speaker and that all measures are available in English only.

A33-2. What arrangements will you make to comply with the principles of the Welsh Language Act in the provision of information to participants in Wales?

Research documentation (i.e. participant information sheet, consent form, letter sent to participants) will be available bilingually. The battery of measures is only available and validated in English so participants will be made aware that tests and questionnaires will have to be carried out in English in order to maintain validated results. The CI Jenna Todd Jones is not a Welsh speaker so participants will be informed of this.

A36. 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.

Date: 03/08/2017
Further details:
Patients who are deemed unable to provide informed consent will not be approached to take part in the research and as such continued capacity of those who have consented to participate will be assumed.

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

A38. 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
- [x] Use of personal addresses, postcodes, fax numbers, 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:
  - [x] Manual files (includes paper or film)
  - [x] NHS computers
  - [ ] Social Care Service computers
  - [ ] Home or other personal computers
  - [ ] University computers
  - [ ] Private company computers
  - [ ] Laptop computers

Further details:
The CI Jenna Todd Jones will access the client’s medical notes to record details of the brain injury and brain scan findings.

Storage of personal data will be confined to NHS computers and any paper containing personal information will be stored securely in the participant’s clinical file at the NWBIB.

The telephone number of potential participants will be made available to the CI (Jenna Todd Jones) only with the participant’s consent. Home addresses will only be made available to the CI if the participant is unable to travel to the NWBIB or the GP and as such the CI would visit them at home, addresses will only be made available to the CI with the resident’s consent.

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.

Each participant will be given a unique identification number which will be used for all paper and electronic data collected. Paper copies of questionnaires and test sheets will use the unique identification number only and will be...
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.

The research team (i.e., Jenna Todd Jones and Dr. Rudi Coetzee) will have access to participants’ personal data during the study along with each patient’s treating clinician.

### Storage and use of data after the end of the study

A43. How long will personal data be stored or accessed after the study has ended?

- [ ] Less than 3 months
- [ ] 3 – 6 months
- [ ] 6 – 12 months
- [ ] 12 months – 3 years
- [ ] Over 3 years

### INCENTIVES AND PAYMENTS

A48. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

- [ ] Yes
- [ ] No

If Yes, please give details. For monetary payments, indicate how much and on what basis this has been determined. Participants will have their travel expenses to and from the NWBIHB reimbursed. If participants wish to claim for travel expenses, they will be required to give the CI a receipt to allow the CI to reimburse the value of the journey.

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/colleague 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

A48.1. 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

Date: 03/08/2017
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

**A60. Will the research be registered on a public database?**

- [ ] Yes
- [ ] No

Please give details, or justify if not registering the research. The final thesis will be made available in the Bangor University research repository.

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 A6-1.

**A61. How do you intend to report and disseminate the results of the study?** Tick as appropriate:

- [ ] Peer reviewed scientific journal
- [ ] 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)

A newsletter outlining the results of the study will be circulated to participants who took part in the study.

**A62. Will you inform participants of the results?**

- [ ] Yes
- [ ] No

Please give details of how you will inform participants or justify if not doing so. At the end of the study, a participant newsletter will be distributed to participants who took part in the study outlining the main results.

### E. Scientific and Statistical Review

**A64. 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

Date: 03/06/2017
A67. What is the primary outcome measure for the study?

The study is correlational in nature with two hypotheses related to two scales of personality traits. The primary outcome measures are a) the two personality scales examining trait personality post-injury, and b) whether the participant has returned to work.

A68. What are the secondary outcome measures? (if any)

Not applicable.

A69. 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.

Date: 03/06/2017
A80. 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.

Presently it is estimated that a sample of n=30 is a realistic achievement given the time constraints of the project. This project is considered a pilot experiment intended to begin exploration of the influence of grit and resilience in rehabilitation.

A81. Will participants be allocated to groups at random?

- Yes
- No

A82. 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.

Anonymised data will be analysed using SPSS. Correlations will be calculated to investigate associations between measures of personality trait and whether participants have returned to work.

8. MANAGEMENT OF THE RESEARCH

A83. 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.

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<tr>
<th>Title</th>
<th>Forename/Initials</th>
<th>Surname</th>
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<tbody>
<tr>
<td>Dr</td>
<td>Rudi</td>
<td>Coetzer</td>
</tr>
<tr>
<td>Post</td>
<td>Consultant Clinical Neuropsychologist, Head of Service</td>
<td></td>
</tr>
<tr>
<td>Qualifications</td>
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<tr>
<td>Employer</td>
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<tr>
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<td>Jackson</td>
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Date: 03/08/2017
A84. Details of research sponsor(s)

A84.1. Sponsor

Lead Sponsor

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<td>Other social care provider (including voluntary sector or private organisation)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
</tbody>
</table>

If Other, please specify:

Contact person

Name of organisation: Bangor University
Given name: Hefn
Family name: Francis
Address: School of Psychology, Brigantia Building, Penrallt Road, Bangor University
Town/city: Bangor
Post code: LL57 2A8
Country: UNITED KINGDOM
Telephone: 01248388339
Fax: 01248382599
E-mail: h.francis@bangor.ac.uk

Is the sponsor based outside the UK?

○ Yes ○ No

Under the Research Governance Framework for Health and Social Care, a sponsor outside the UK must appoint a legal representative established in the UK. Please consult the guidance notes.

A86. Has external funding for the research been secured?

Date: 03/06/2017
A87. 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 A5-2 how the reasons for the unfavourable opinion have been addressed in this application.

A88-1. Give details of the lead NHS R&D contact for this research:

Title Forename/Initials Surname
Dr Rosella Roberts

Organisation Betsi Cadwaladr University Health Board
Address Clinical Academic Office, Clinical School, Ysbyty Gwynedd, Bangor, Gwynedd
Post Code LL57 2PW
Work Email rossela.roberts@wales.nhs.uk
Telephone 01248384877
Fax 01248384877
Mobile

Details can be obtained from the NHS R&D Forum website: http://www.rdforum.nhs.uk

A88-1. How long do you expect the study to last in the UK?

Planned start date: 01/08/2017
Planned end date: 31/07/2018
Total duration:
Years: 0 Months: 11 Days: 31

A71-2. Where will the research take place? (Tick as appropriate)

☐ England

Date: 03/06/2017
NHS REC Form

Reference: 17/ES/0118

IRAS Version 5.5.2

☑ Wales
☐ Scotland
☐ Northern Ireland
☐ Other countries in European Economic Area

Total UK sites in study

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:

☑ NHS organisations in Wales
☐ NHS organisations in England
☐ 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 (e.g. 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)

Total UK sites in study: 1

A78. Insurance/Indemnity to meet potential legal liabilities

Note: In this question NHS Indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland.

A78-1. 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)

Date: 03/08/2017

22
UMAL Insurance

Please enclose a copy of relevant documents.

A78.2. 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)

UMAL Insurance

Please enclose a copy of relevant documents.

A78.3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/laboratories 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)

Please enclose a copy of relevant documents.

Date: 03/08/2017

23
### PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. For NHS sites, the host organisation is the Trust or Health Board. Where the research site is a primary care site, e.g. GP practice, please insert the host organisation (PCT or Health Board) in the Institution row and insert the research site (e.g. GP practice) in the Department row.

<table>
<thead>
<tr>
<th>Research site</th>
<th>Investigator/ Collaborator/ Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Institution name</td>
<td>Betsi Cadwaladr University Health Board</td>
</tr>
<tr>
<td>Department name</td>
<td>North Wales Brain Injury Service</td>
</tr>
<tr>
<td>Street address</td>
<td>Hesketh Road</td>
</tr>
<tr>
<td>Town/vity</td>
<td>Colwyn Bay</td>
</tr>
<tr>
<td>Post Code</td>
<td>LL29 8AY</td>
</tr>
<tr>
<td>Title</td>
<td>Dr</td>
</tr>
<tr>
<td>First name/ Initials</td>
<td>Rudl</td>
</tr>
<tr>
<td>Surname</td>
<td>Coetzer</td>
</tr>
</tbody>
</table>

Date: 03/08/2017
PART D: Declarations

D1. Declaration by Chief Investigator

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

2. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.

3. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.

4. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.

5. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.

6. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.

7. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.

8. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 1998.

9. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:
   - Will be held by the REC (where applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
   - May be disclosed to the operational managers of review bodies, or the appointing authority for the REC (where applicable), in order to check that the application has been processed correctly or to investigate any complaint.
   - May be seen by auditors appointed to undertake accreditation of RECs (where applicable).
   - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
   - May be sent by email to REC members.

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

11. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after issue of the ethics committee’s final opinion or the withdrawal of the application.

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

NRES would like to include a contact point with the published summary of the study for those wishing to seek further information. We would be grateful if you would indicate one of the contact points below.

☐ Chief Investigator

Date: 03/06/2017
NHS REC Form

Reference:
17/ES/0118

IRAS Version 5.5.2

☐ 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 Jenna Todd Jones on 23/09/2017 08:56.

Job Title/Post: Trainee Clinical Psychologist
Organisation: Betsi Cadwaladr University Health Board
Email: psp6f3@bangor.ac.uk

Date: 03/08/2017
D2. Declaration by the sponsor's representative

If there is more than one sponsor, this declaration should be signed on behalf of the co-sponsors by a representative of the lead sponsor named at A64.1.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.

2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.

3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.

4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.

5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.

6. The duties of sponsors set out in the Research Governance Framework for Health and Social Care will be undertaken in relation to this research.

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 Mr Hefin Francis on 25/09/2017 13:29.

Job Title/Post: School Manager for Psychology

Organisation: Bangor University

Email: h.francis@bangor.ac.uk

Date: 03/08/2017
Declaration for student projects by academic supervisor(s)

1. I have read and approved both the research proposal and this application. I am satisfied that the scientific content of the research is satisfactory for an educational qualification at this level.

2. I undertake to fulfil the responsibilities of the supervisor for this study as set out in the Research Governance Framework for Health and Social Care.

3. I take responsibility for ensuring that this study is conducted in accordance with the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research, in conjunction with clinical supervisors as appropriate.

4. I take responsibility for ensuring that the applicant is up to date and complies with the requirements of the law and relevant guidelines relating to security and confidentiality of patient and other personal data, in conjunction with clinical supervisors as appropriate.

Academic supervisor 1

This section was signed electronically by Dr Mike Jackson on 04/10/2017 09:17.

Job Title/Post: psychologist
Organisation: bcuhb
Email: mike.jackson@wales.nhs.uk

Academic supervisor 2

This section was signed electronically by Dr Rudi Coetzer on 24/09/2017 17:13.

Job Title/Post: Consultant Neuropsychologist
Organisation: North Wales Brain Injury Service, Betsi Cadwaladr University Health Board NHS Wales
Email: Rudi.Coetzer@wales.nhs.uk

Date: 03/08/2017
Appendix E – NHS IRAS Research Ethics Committee Form, Research and Development
NHS R&D Form

☐ 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?

IMPORTANT: If your project is taking place in the NHS and is led from England select 'IRAS Form'. If your project is led from Northern Ireland, Scotland or Wales select 'NHS/HSC Research and Development Offices' and/or relevant Research Ethics Committee applications, as appropriate.

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

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

For participating NHS organisations in England different arrangements apply for the provision of site specific information. Refer to IRAS Help for more information.

6. Will any research sites in this study be NHS organisations?
☐ 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 is a student project as part of the Doctorate in Clinical Psychology, North Wales Clinical Psychology Programme.
   All project procedures will be carried out by the student under the guide of the clinical supervisor (employed by Betsi Cadwaladr University Health Board).

9a. Is the project being undertaken in part fulfillment 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 core team without prior consent at any stage of the project (including identification of potential participants)?
    - Yes
    - No
PART A: Core study information

A1. Full title of the research:
An Investigation Of Grit And Resilience In Rehabilitation Following Acquired Brain Injury

A2-1. Educational projects

Name and contact details of student(s):

Student 1

Title Forename/Initials Surname
Dr. Jenna E E Todd Jones
Address North Wales Clinical Psychology Programme
42 College Road
Gwynedd
Post Code LL57 2DG
E-mail psp6f3@bangor.ac.uk
Telephone 07791377124
Fax

Give details of the educational course or degree for which this research is being undertaken:
Name and level of course/degree:
Doctorate in Clinical Psychologist (DClinPsy)

Name of educational establishment:
Bangor University

Name and contact details of academic supervisor(s):

Academic supervisor 1
Title Forename/Initials Surname
Dr Rudi Coetzee

Address
North Wales Brain Injury Service
Colwyn Bay Hospital
Hesketh Road

Post Code
LL29 5AY
E-mail
Rudi.Coezter@Wales.NHS.UK
Telephone
01492807770
Fax
01492807770

Academic supervisor 2

Title Forename/Initials Surname
Dr Mike Jackson

Address
North Wales Clinical Psychology Programme
42 College Road, Bangor University
Bangor, Gwynedd

Post Code
LL57 2DG
E-mail
Mike.Jackson@bangor.ac.uk
Telephone
01243888476
Fax

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

<table>
<thead>
<tr>
<th>Student(s)</th>
<th>Academic supervisor(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Student 1</td>
<td>Dr Jenna E E Todd Jones</td>
</tr>
</tbody>
</table>

☐ Dr Rudi Coetzee
☐ Dr Mike Jackson

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

A3.2. Who will act as Chief Investigator for this study?

☐ Student
☐ Academic supervisor
☐ Other

A3.1. Chief Investigator:

Title Forename/Initials Surname
Dr Jenna E E Todd Jones

Post
Trainee Clinical Psychologist

Qualifications
BSc Psychology, Bangor University 2009
MSc Clinical Neuropsychology, Bangor University 2010
PhD Experimental Psychology, Bristol University 2016

ORCID ID
0000 0002 6529 9839
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
Mr Hefin Francis

Address
School of Psychology
Brigantia Building, Penrallt Road
Bangor University, Bangor

Post Code LL57 2AS
E-mail h.francis@bangor.ac.uk
Telephone 01248388339
Fax 01248382599

A6-1. Research reference numbers. Please give any relevant references for your study:

Applicant's organisation's own reference number, e.g. R & D (if available): 2017-16070
Sponsor's/protocol number: N/A
Protocol Version: 1
Protocol Date: 24/07/2017
Funder's reference number: N/A
Project website: N/A

Additional reference number(s):

<table>
<thead>
<tr>
<th>Ref Number</th>
<th>Description</th>
<th>Reference Number</th>
</tr>
</thead>
</table>

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.

A6-2. Is this application linked to a previous study or another current application?

☐ Yes ☐ No

Please give brief details and reference numbers.
2. OVERVIEW OF THE RESEARCH

A8.1. 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.

It has been proposed that high levels of trait resilience (Rutter, 2012) can lead to improved rehabilitation (indicated by community integration outcomes) following ABI, although evidence of this in published research is mixed (Dumont, Gervais, Pougetdollais, & Bertrand, 2004; Losol et al., 2015; Lukow et al., 2015; McCauley et al., 2012). Presently no research exists addressing trait grit and outcomes of any kind following ABI (Duckworth & Quinn, 2009).

The current study aims to explore further the potential influence of trait resilience and grit on outcomes following ABI, and contribute to on-going efforts to determine protective and mitigating factors of individuals' functioning following ABI. Grit and resilience scales have enormous potential for informing the treatment of ABI. Their simplicity and short completion time lends well to populations who may struggle with concentration or acquired cognitive deficits. Further, grit and resilience scales may be useful tools for assessing the likely trajectory of patient recovery. That is, there is potential value in understanding that low levels of grit or resilience may lead to longer rehabilitation time, or require greater or different input from the treating clinician (Dumont et al., 2004; Lukow et al., 2015; White, Driver, & Warren, 2010).

Patients attending the North Wales Brain Injury Service (NWBIS) with an ABI that occurred at least one year previously would be eligible to participate. Participants will likely be enrolled in the study for up to 12 months and participation would include completing cognitive tests (paper and pencil type tests designed to measure intelligence quotient) and questionnaires that should take no more than two hours.

A8.2. Summary of main issues. Please summarise the main ethical, legal, or management issues arising from your study and say how you have addressed them.

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

Design and Procedures:
The study will employ a cross-sectional, correlational design. Correlation coefficients will be calculated to explore associations between personality factors and rehabilitation following acquired brain injury. Dependent variables will be the outcome scores for the measures employed.

Participants will be asked to complete self report questionnaires pertaining to levels of grit and resilience, as well as reporting basic demographic information including whether they are employed. Participants will also be asked to complete a standardised cognitive assessment to establish their IQ. Measures will be administered in one session (or two at the participant's request) and will take between 1-2 hours. Participants will be recruited from the North Wales Brain Injury Service (NWBIS) which is a multi disciplinary community based outpatient brain injury rehabilitation service.

Recruitment Procedure and Consent:
The Chief Investigator (CI; Jenna Todd Jones) will approach clinicians at NWBIS and present the research proposal. Clinicians will be asked to identify clients on their case load that meet inclusion criteria. Clinicians will not approach clients on their case load whom do not have capacity to provide informed consent. These potential participants will be approached in the first instance by their treating clinician and asked if they would like a participant information sheet and if they consent to the CI contacting them by telephone approximately 1 week later to discuss the research. Participants who agree to be contacted will be given the opportunity to ask any questions about the research and to discuss the study. They will be asked if they would like to participate in the study. Prior to inclusion in the study, each participant will give their fully informed, written consent to participate.
For those who take part in the study, a full debrief at the end of the testing session will be offered and further feedback session outlining the results of the tests if the participant is interested. All participants will receive a newsletter at the end of the study outlining the general findings. The CI will take primary responsibility for recruiting and testing participants when consent has been given. Where possible, testing will take place at the NWBIS but if participants are unable to attend, home visits or using a convenient GP surgery will be offered. Participant travel expenses will be reimbursed when participants are traveling to and from NWBIS for the study.

Risks, Burdens and Benefits:
Potential risks include those related to lone working for the CI who may be required to undertake testing at the participant’s home address. Where possible, lone working will be avoided and it is anticipated that the majority of testing will take place at the NWBIS or GP Surgery. When lone working is necessary, the Betsi Cadwaladr University Health Board Lone Worker Policy will be adhered to.

Treat clinicians at the NWBIS will be aware of any risks from the client to the CI and as such clients who represent a risk to the CI will not be approached.

The study has been deemed not to present any direct risks but participants will be asked questions about their return to work following their brain injury. Additionally participants may find the cognitive tests challenging and frustrating. If any participant experiences any distress they will be encouraged to speak to their treating clinician at the NWBIS or their GP. In circumstances where it is clear that the participant is experiencing significant distress, with the participant’s consent, the CI will write to their GP via letter.

As participants are completing a number of questionnaires and tests, any participant may request feedback on their results which will be given by the CI or the supervisor. If there are any concerns, these will be discussed with the participant’s treating clinician at the NWBIS with the participant’s consent to do so. If a participant experiences any distress as a consequence of taking part in the study, the participant will be advised to speak to their treating clinician at the NWBIS or their GP.

Benefits of taking part include contributing to the scientific evidence base and a full debrief on the study and individual tests if requested. Also a newsletter detailing the findings of the research.

Burdens may include time spent participating in the study, reading the information sheet, the testing itself and talking with the CI.

Confidentiality:
All paper and electronic data will be stored at the NWBIS. Paper data will be stored securely in the client’s file at NWBIS. Electronic data will be stored on a secure NHS networked computer at the NWBIS. Anonymised electronic data will be analysed on a password protected laptop and only made available to the CI and the Academic Supervisor. The CI will comply with BCUHB data protection policy and legislation. At the end of the project (July 2019) all data will remain securely at the NWBIS. All data will be destroyed after a specified time period in line with BCUHB policy. The data will be used for academic research publications in the form of journal articles and conference presentations (all data will be anonymous and presented as a group average). Participants will receive a brief news letter following completion of the research, alternatively they can request individual explanation of the results from the CI. Participant names will only be recorded once for consent purposes, following which, a unique identification number will be assigned and used thereafter and will be used exclusively if referring to specific data in research publications. Additional safeguards include keeping all consent forms and any paper copies of tasks or questionnaires in a locked filing cabinet at the NWBIS. Computer data will be stored anonymously on a password protected computer. All data and consent forms will be retained by the academic supervisor based at NWBIS following completion of the study for a minimum of 5 years, after which they will be safely disposed in line with BCUHB confidential waste policy.

9. 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
**A10. What is the principal research question/objective? Please put this in language comprehensible to a lay person.**

The main aim of the study is to establish whether grit and resilience (non-cognitive, personality trait-level elements of function) are good predictors of rehabilitation (as measured by community integration) following an acquired brain injury. Presently there is limited available research regarding the potential influence of resilience in relation to neuropsychological rehabilitation success and community integration; none exists regarding trait grit. Grit and resilience scales have enormous potential for informing the treatment of ABI. Accordingly, this study is intended as a pilot proof of concept that the grit and/or resilience measures can be used to determine the likelihood of success in committing to the long-term goal of return-to-work (and other evidence of community integration) in the face of adversity in the form of an acquired brain injury.

Hypothesis 1: high levels of grit are associated with increased rehabilitative success following ABI (as measured by community integration).

Hypothesis 2: high levels of resilience are associated with increased rehabilitative success following ABI (as measured by community integration).

---

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

Not applicable.

---

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

Research attempting to predict the likelihood of community integration (including family engagement, social engagement, and return to work) following acquired brain injury (ABI) has demonstrated the influence of age (Lubusko, Moore, Stambrook, & Gill, 1994; Willemse-van Son, Ribbers, Verhagen, & Stam, 2007), gender (Walker, Marwitz, Kreutzer, Hart, & Novack, 2006), pre-injury education (Franulc, Carbonell, Pinto, & Sepulveda, 2004), category of employment prior to injury (Andelic, Stevens, Gigurardotito, Arango-Lasprilla, & Roe, 2012; Feingham, Baguley, & Crooks, 2001; Lubusko et al., 1994), cognitive and behavioural function (Andelic et al., 2012; Crepeau & Schenzer, 1993; Schreden, 2000), injury severity (Taoussides et al., 2009), and cause of injury (Kelchum et al., 2012).

Limited research has demonstrated the influence of personality traits in post-injury community integration outcomes following ABI. More recently several studies have addressed trait resilience, with mixed results; presently no research yet exists addressing trait grit in this population. Dumont et al. found that up to 51% of the variance in social participation following ABI can be accounted for by resiliency factors (2004). Resiliency related coping skills have also been found to predict successful role functioning in both the short- and long-term following an ABI (Kendall & Terry, 2008). A qualitative study from Adams and Dahdah (2016) reported spontaneous engagement in coping strategies and adaptability in those recovering from ABI, where the authors reported that "the overall impression from the interviews was the presence of resiliency" (p. 233). Perceived self-efficacy has also been found to be linked to social participation in those with non-ABI complex impairments (Bent, Jones, Molloy, Chamberlain, & Tennant, 2001).

Conversely, Losol et al. (2015) found no association between their measure of resilience and the likelihood of return to work (96% of participants returned to work within one year). Nonetheless, participants with high levels of resilience reported improved symptomatology and psychosocial functioning during rehabilitation, which is likely to influence community integration (Smaily to Kreutzer et al., 2016, and White et al., 2010).

The current study aims to explore further the links between resilience and grit personality traits and successful community integration following ABI. These short, simple personality trait scales may enable us to better tailor...
treatment options for individuals with ABI (Dumont et al., 2004; Lukow et al., 2015; White, Driver, & Warren, 2010).

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.

Participants will be recruited from service users attending the NWWBIS for routine outpatient appointments, identified by their clinician as having sustained a traumatic brain injury and who do not meet any of the exclusion criteria.

Clinicians will approach the individuals in the first instance and provide them with some verbal and written information. If the individual is interested, a time will be arranged for the researcher to phone them and to discuss the study further at a time of their convenience.

After the initial phone conversation, participants will be asked to let the researcher know within one week whether they would like to participate. If they would like to continue with the research a time will be made for the participant to attend the NWWBIS to complete the testing. If the participant is unable to travel to the NWWBIS then the researcher will arrange to meet the participant at their GP surgery or at their home. Travel expenses will be reimbursed when the participant is travelling to complete the testing. Participants should expect to be in the testing session for no more than 2 hours. The session will involve completing short questionnaires and answering demographic questions including whether they have returned to work. If the participant would rather complete the testing over two sessions, that can be arranged.

Once the tests are completed the participant will receive verbal feedback from the researcher on the testing and be offered more comprehensive feedback on the results of the tests at a later date if the participant would like. This can be given over the phone or the researcher can arrange to meet with the participant if they would rather.

Once the research has been written up, the researcher will create a newsletter to circulate to all participants outlining the general findings of the study. It is anticipated that this will be in June 2018.

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?

[ ] 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.
After completion of the study the CI will produce a newsletter for all participants which will be reviewed by the university ‘People Panel’ before dissemination.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A16. 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
A17. Please list the principal inclusion criteria (list the most important, max 6000 characters).

Approximately 30 participants with a confirmed history of ABI will be prospectively recruited to participate. All participants will be recruited from the NABIS. Participants who sustained an ABI with a minimum interval of one year following brain injury to exclude those who have only recently sustained injury. Severity of traumatic brain injury will be determined by examining patient’s medical file following the Mayo Classification System (Malec et al., 2007).

A17.2 Please list the principal exclusion criteria (list the most important, max 6000 characters).

Patients will be excluded from participating in this study if they meet the following criteria (as determined by the treating clinician and/or patient file):
- Severe cognitive impairment that would impair their ability to participate
- Unable to provide informed consent
- Existing co-morbid psychiatric condition
- Current substance misuse/dependence
- Brain injury having occurred within the last year
- At risk of violent behaviour (i.e. those with frontal lobe trauma or history of violent behaviour, determined by treating clinician)

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.

<table>
<thead>
<tr>
<th>Intervention or procedure</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial telephone consultation</td>
<td>1</td>
<td>0</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>Seeking consent</td>
<td>1</td>
<td>0</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>Grit scale</td>
<td>1</td>
<td>0</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Resilience scale CD-RISC</td>
<td>1</td>
<td>0</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>Awareness scale</td>
<td>1</td>
<td>0</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Test of premorbid functioning</td>
<td>1</td>
<td>0</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>Montreal cognitive assessment</td>
<td>1</td>
<td>0</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>Participant occupational</td>
<td>1</td>
<td>0</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>information</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Debrief</td>
<td>1</td>
<td>0</td>
<td>15</td>
<td></td>
</tr>
</tbody>
</table>

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

12 months

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.

While no direct risks are anticipated, the study will take up to about two hours of each participant's time. There is a small possibility that participants might find some of the tasks more difficult than expected which can sometimes be frustrating or upsetting.

Participants will also be asked to complete a questionnaire including questions about their return to work, which can very occasionally produce distressing feelings.

Clients will be selected by their treating clinicians. The CI will explain each test and questionnaire in detail and clients will be aware that they are free to withdraw at any time without giving a reason. If any distress is caused as a direct result of the study, participants will be encouraged to speak to their treating clinician at the NWBIS or their GP. In extreme cases, the CI would seek the participant's consent to write directly to their GP.

The recruitment procedure whereby the treating clinicians at the NWBIS identify suitable potential participants from their caseload will prevent unsolicited communication regarding the study and will prevent individuals who are vulnerable or unsuitable being put forward.

Once the testing session has finished with each participant, they will receive a full debrief from the CI and additionally the option for a more extensive feedback about test results and/or a newsletter outlining the main results of the study.

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

Although there are no direct benefits to the individuals taking part in the study, participants will have the knowledge that they are contributing to the scientific evidence base to potentially improve rehabilitation in the future. Participants will be given a full debrief on the study and individual tests if requested. Also, a newsletter detailing the findings of the research will be sent out if the participants would like to receive this following the study conclusion, approximately June 2018.

A28. What are the potential risks for the researchers themselves? (If any)

Potential risks to the CI include those related to lone working as the CI may be required to undertake testing sessions at the participant's homes. Where possible, this will be avoided and it is anticipated that the majority of testing will take place at the NWBIS or a GP practice local to the participant. Where lone working cannot be avoided, the BCUHB Lone Worker Policy will be adhered to. When clinicians approach their clients to participate in the study, they will screen out any clients who may pose a potential risk to the CI.

RECRUITMENT AND INFORMED CONSENT

In this section, we ask you to describe the recruitment procedure 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 out this work 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).

In the first instance, the CI will approach clinicians at NWBIS and present the project and answer any questions they may have. Clinicians will be asked to identify participants who meet the inclusion criteria from their current case load. Potential participants will be approached by their treating clinicians and asked if they would like a study information sheet and if they consent to the CI (Jenna Todd Jones) contacting them approximately one week following via the telephone to discuss the study further and at this point potential participants will be asked if they wish to participate in the study. Prior to inclusion in the study, the CI will gain full informed written consent to participate from each participant. Participants will be given the opportunity to discuss the research with the CI and ask any questions they may have. The CI will take responsibility for asking clinicians to identify potential participants and for testing once participants have agreed to take part.

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:

Only members of the participant's clinical care team will have direct access to identifiable personal information in the individual's clinical file. The relevant NWBIS clinician will screen the individual's clinical file to check for eligibility for the study. The treating clinician will then make the first contact with the potential participant to query whether they would be interested in taking part in the research and if so do they consent for the clinician to pass on their contact details to the CI who will contact them to discuss it further. The CI will ONLY contact the potential participants once she has been...
Informed by the treating clinician that the individual is interested to hear more about the research study.

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 members of the patient's clinical care team will have access to the individual's personal information. The treating clinician will be responsible for first checking the patient's clinical notes to ensure they meet eligibility for the study and to make the initial approach to the patient.

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

- Yes
- No

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?

In the first instance the CI will approach clinicians at NWBIS and present the project and answer any questions they may have. Clinicians will be asked to identify participants who meet the inclusion criteria from their current caseload. Potential participants will be approached by their treating clinicians and asked if they would like a study information sheet and if they consent to the CI (Jenna Todd Jones) contacting them approximately one week following via the telephone to discuss the study further and at this point potential participants will be asked if they wish to participate in the study. Prior to inclusion in the study, the CI will gain fully informed written consent to participate from each participant. Participants will be given the opportunity to discuss the research with the CI and ask any questions they may have. The CI will take responsibility for asking clinicians to identify potential participants and for testing once participants have agreed to take part. After the testing session, participants will be given the opportunity to discuss the process and ask any questions they may have. Where possible, participants will take part in testing at the NWBIS and travel expenses will be reimbursed. If participants are unable to attend the NWBIS they will be given the option of participating in testing at a local GP or at their home address.

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.

Only adults with the capacity to give informed consent will be approached. Consent will be given directly to the CI (Jenna Todd Jones). Each participant will have a written information sheet accompanied by a verbal explanation of the study and the opportunity to ask any questions they may have. Additionally, the CI will arrange directly with the individual to contact them via phone approximately one week later and ensure they have the CI's contact details if they would like to make contact.

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

Please enclose a copy of the information sheet(s) and consent form(s).
A30.2. Will you record informed consent (or advice from consultees) in writing?

- Yes  - No

A31. How long will you allow potential participants to decide whether or not to take part?

Approximately one week.

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)

Participants deemed not able to provide written informed consent will not be approached to take part in the study. Capacity will be decided upon by the treating clinicians at the NWBIS before contact details of those wishing to take part are passed on to the CI.

As the research is taking place in Wales ALL written documents will be provided bilingually but it will be explained that the CI Jenna Todd Jones is not a Welsh Speaker and that all measures are available in English only.

A33.2. What arrangements will you make to comply with the principles of the Welsh Language Act in the provision of information to participants in Wales?

Research documentation (i.e. participant information sheet, consent form, letter sent to participants) will be available bilingually. The battery of measures is only available and validated in English so participants will be made aware that tests and questionnaires will have to be carried out in English in order to maintain validated results. The CI Jenna Todd Jones is not a Welsh speaker so participants will be informed of this.

A36. 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:

Patients who are deemed unable to provide informed consent will not be approached to take part in the research and as such continued capacity of those who have consented to participate will be assumed.

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.

Manage 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
NHS R&D Form

☐ 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, taxes, 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:
The CI Jenna Todd Jones will access the clients medical notes to record details of the brain injury and brain scan findings.

Storage of personal data will confined to NHS computers and any paper containing personal information will be stored securely in the participant's clinical file at the NWBIS.

The telephone number of potential participants will be made available to the CI (Jenna Todd Jones) only with the participant's consent. Home addresses will only be made available to the CI if the participant is unable to travel to the NWBIS or the GP and as such the CI would visit them at home, addresses will only be made available to the CI with the resident's consent.

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

All paper data will be stored at the NWBIS in each participant's file which will be stored in a locked filing cabinet. Raw data will be entered into a computerised statistical package in anonymised form (i.e. using unique identification numbers) on a password protected laptop only available to the CI and the academic supervisor. The CI will comply with Data Protection Legislation. At the end of the project (July 2018), all data (raw and statistical) will remain at the NWBIS. All data will be destroyed after a specified time period in line with BCUHB policies.

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.

Each participant will be given a unique identification number which will be used for all paper and electronic data collected. Paper copies of questionnaires and test sheets will use the unique identification number only and will be stored in a locked filing cabinet in the NWBIS. A record of identification numbers will be kept in a separate locked location at the NWBIS and will only be accessible to the CI and the academic supervisor. Any data that is analysed electronically will be anonymous, using the unique identification number and will contain no personal identification information. Paper data will be retained at the NWBIS and will be destroyed in line with BCUHB policy on data management.

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.

The research team (i.e. Jenna Todd Jones and Dr Rudi Coetzee) will have access to participants' personal data during the study along with each patient's treating clinician.
NHS R&D Form

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?
Data will be analysed on NWBIS premises by the CI and the academic supervisor.

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

Title: Dr Rudi Coetzee
Forename: initials: Surname
Post: Consultant Neuropsychologist, Head of Service
Qualifications: BA (cum laude), BA Hons Clin Psych (cum laude), MA Clin Psych (cum laude), D Clin Psych
Work Address: North Wales Brain Injury Service
                        Colwyn Bay Hospital
                        Hesketh Road
Post Code: LL29 8AY
Work Email: Rud.Coezter@wales.nhs.uk
Work Telephone: 01492807770
Fax: 01492807770

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

A44. For how long will you store research data generated by the study?
Years: 5
Months: 0

A46. 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.
Data will be stored in a locked filing cabinet at the NWBIS. Only the Academic Supervisor based at the NWBIS (Dr Coetzee) will have access to the data. The data will be destroyed after a period of five years in line with BCUHB policy for the safe destruction of paper data.

INCENTIVES AND PAYMENTS

A48. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?
☒ Yes ☐ No
If Yes, please give details. For monetary payments, indicate how much and on what basis this has been determined. Participants will have their travel expenses to and from the NWBSS reimbursed. If participants wish to claim for travel expenses, they will be required to give the CI a receipt to allow the CI to reimburse the value of the journey.

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/colleague 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

A48.1. 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

A60. Will the research be registered on a public database?

☐ Yes  ☐ No

Please give details, or justify if not registering the research. The final thesis will be made available in the Bangor University research repository.

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 A61.

A61. 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)
A newsletter outlining the results of the study will be circulated to participants who took part in the study.

A62. If you will be using identifiable personal data, how will you ensure that anonymity will be maintained when publishing the results?

Results will be analysed at a group level with no reference to individual participants and as such participant data will not be identifiable when being submitted for publication.

A63. Will you inform participants of the results?

- Yes  - No

Please give details of how you will inform participants or justify if not doing so. At the end of the study, a participant newsletter will be distributed to participants who took part in the study outlining the main results.

5. Scientific and Statistical Review

A64. 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.

The scientific quality of the study has been assured by the research team at the North Wales Clinical Psychology Programme and assessed as a suitable study as part of the doctoral programme. The study has also been reviewed by the School of Psychology Ethics Panel, and has received a favourable outcome.

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.

A66. 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.
A57. What is the primary outcome measure for the study?
The study is correlational in nature with two hypotheses related to two scales of personality traits. The primary outcome measures are a) the two personality scales examining trait personality post-injury, and b) whether the participant has returned to work.

A58. What are the secondary outcome measures? (If any)
Not applicable.

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: 30
- Total International sample size (including UK): 0
- Total in European Economic Area: 0
Further details:
The CI will aim to recruit between 30-40 participants.

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.
Presently it is estimated that a sample of n=30 is a realistic achievement given the time constraints of the project. This project is considered a pilot experiment intended to begin exploration of the influence of grit and resilience in rehabilitation.

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.
Anonymised data will be analysed using SPSS. Correlations will be calculated to investigate associations between measures of personality trait and whether participants have returned to work.
A83. 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.

Dr. Rudi Coetzee
Consultant Clinical Neuropsychologist, Head of Service
BA (cum laude), BA Hons Clin PSych (cum laude), MA Clin Psych (cum laude), D Clin Psy.
Betsi Cadwaladr University Health Board
Colwyn Bay Hospital
Hesketth Road
LL29 8AY
01492807770
01492807770
Rudi.Coetzee@wales.nhs.uk

Dr. Mike Jackson
Consultant Clinical Psychologist
BA, D Phil, D Clin Psy.
North Wales Clinical Psychology Programme / Betsi Cadwaladr University Health Board
43 College Road, Bangor University
Bangor, Gwynedd
LL57 2DG
01248388385
01248388385
Mike.Jackson@bangor.ac.uk

A84. Details of research sponsor(s)

A84-1. 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)

Commercial status:
NHS R&D Form

If Other, please specify:

Contact person

Name of organisation Bangor University
Given name Hefin
Family name Francis
Address School of Psychology, Briganta Building, Penrallt Road, Bangor University
Towncity Bangor
Post code LL57 2AS
Country UNITED KINGDOM
Telephone 01248388339
Fax 01248382599
E-mail h.francis@bangor.ac.uk

Is the sponsor based outside the UK?

☐ Yes ☐ No

Under the Research Governance Framework for Health and Social Care, a sponsor outside the UK must appoint a legal representative established in the UK. Please consult the guidance notes.

A86. Has external funding for the research been secured?

☐ Funding secured from one or more funders
☐ External funding application to one or more funders in progress
☒ No application for external funding will be made

What type of research project is this?

☐ Standalone project
☐ Project that is part of a programme grant
☐ Project that is part of a Centre grant
☒ Project that is part of a fellowship/ personal award/ research training award
☐ Other

Other – please state:

A88. Has responsibility for any specific research activities or procedures been delegated to a subcontractor (other than a co-sponsor listed in A84-1)? Please give details of subcontractors if applicable.

☐ Yes ☐ No

A87. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

☐ Yes ☐ No
A68-1. Give details of the lead NHS R&D contact for this research:

Title Forename/initials Surname
Dr Rosella Roberts

Organisation Betsi Cadwaladr University Health Board
Address Clinical Academic Office, Clinical School, Ysbyt Gwynedd
Bangor, Gwynedd

Post Code LL57 2PW
Work Email rosella.roberts@wales.nhs.uk
Telephone 01248384877
Fax 01248384877
Mobile

Details can be obtained from the NHS R&D Forum website: http://www.rdforum.nhs.uk

A68-1. How long do you expect the study to last in the UK?
Planned start date: 01/08/2017
Planned end date: 31/07/2018
Total duration:
Years: 0 Months: 11 Days: 31

A71-1. Is this study?
☑ Single centre
☐ Multicentre

A71-2. Where will the research take place? (Tick as appropriate)
☐ England
☐ Scotland
☑ Wales
☐ Northern Ireland
☐ Other countries in European Economic Area

Total UK sites in study
Does this trial involve countries outside the EU?
☐ Yes ☐ No
NHS R&D Form

☐ NHS organisations in England
☒ 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 (e.g. 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)

Total UK sites in study: 1

A75-1. 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?

Both the North Wales Clinical Psychology Programme and the Bangor School of Psychology Ethics Committee will take a monitoring role regarding this study. The CL Jenna Todd Jones will be required to submit progress reports on a 6 monthly basis until the completion of the study in July 2018.

A78. Insurance/indemnity to meet potential legal liabilities

Note: In this question, NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland.

A78-1. 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)

UMAL Insurance
NHS R&D Form

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)
- [x] Other insurance or indemnity arrangements will apply (give details below)

UMAL Insurance

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.

- [x] 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)

Please enclose a copy of relevant documents.

A76. Could the research lead to the development of a new product/process or the generation of intellectual property?

- [x] 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 NHS sites, the host organisation is the Trust or Health Board. Where the research site is a primary care site, e.g. GP practice, please insert the host organisation (PCT or Health Board) in the institution row and insert the research site (e.g. GP practice) in the Department row.

<table>
<thead>
<tr>
<th>Research site</th>
<th>Investigator/ Collaborator/ Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Institution name</td>
<td>Betis Cadwaladr University Health Board</td>
</tr>
<tr>
<td>Department name</td>
<td>North Wales Brain Injury Service</td>
</tr>
<tr>
<td>Street address</td>
<td>Hesketh Road</td>
</tr>
<tr>
<td>Town/city</td>
<td>Colwyn Bay</td>
</tr>
<tr>
<td>Post Code</td>
<td>LL29 8AY</td>
</tr>
<tr>
<td>Title</td>
<td>Dr</td>
</tr>
<tr>
<td>First name/ Initials</td>
<td>Rudi</td>
</tr>
<tr>
<td>Surname</td>
<td>Coetzee</td>
</tr>
</tbody>
</table>
D1. Declaration by Chief Investigator

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

2. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.

3. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.

4. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.

5. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.

6. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.

7. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.

8. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 1998.

9. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:

   - Will be held by the REC (where applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
   - May be disclosed to the operational managers of review bodies, or the appointing authority for the REC (where applicable), in order to check that the application has been processed correctly or to investigate any complaint.
   - May be seen by auditors appointed to undertake accreditation of RECs (where applicable).
   - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
   - May be sent by email to REC members.

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

11. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

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

NRES would like to include a contact point with the published summary of the study for those wishing to seek further information. We would be grateful if you would indicate one of the contact points below.

☐ Chief Investigator
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.

Signature: ______________________________
Print Name: Jenna Todd Jones
Date: 24/07/2017 (dd/mm/yyyy)
02. 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 A5+1.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.

2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.

3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.

4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.

5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.

6. The duties of sponsors set out in the Research Governance Framework for Health and Social Care will be undertaken in relation to this research.

   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 publicly accessible register in compliance with the HRA registration requirements for the UK, or that any deferral granted by the HRA still applies.

Signature: __________________________________________

Print Name: __________________________________________

Post: ________________________________________________

Organisation: _________________________________________

Date: (dd/mm/yyyy)
D3. Declaration for student projects by academic supervisor(s)

1. I have read and approved both the research proposal and this application. I am satisfied that the scientific content of the research is satisfactory for an educational qualification at this level.

2. I undertake to fulfil the responsibilities of the supervisor for this study as set out in the Research Governance Framework for Health and Social Care.

3. I take responsibility for ensuring that this study is conducted in accordance with the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research, in conjunction with clinical supervisors as appropriate.

4. I take responsibility for ensuring that the applicant is up to date and complies with the requirements of the law and relevant guidelines relating to security and confidentiality of patient and other personal data, in conjunction with clinical supervisors as appropriate.

Academic supervisor 1

Signature: ____________________________________________

Print Name:

Post:

Organisation:

Date: (dd/mm/yyyy)

Academic supervisor 2

Signature: ____________________________________________

Print Name:

Post:

Organisation:

Date: (dd/mm/yyyy)
Appendix F - NHS IRAS Research Ethics Committee Form, Site-Specific Information
3a. In which country of the UK will the lead NHS R&D office be located:

- [ ] England
- [ ] Scotland
- [x] Wales
- [ ] Northern Ireland
- [ ] This study does not involve the NHS

4. Which applications do you require?

**IMPORTANT:** If your project is taking place in the NHS and is led from England select 'IRAS Form'. If your project is led from Northern Ireland, Scotland or Wales select 'NHS/HSC Research and Development Offices' and/or relevant Research Ethics Committee applications, as appropriate.

- [ ] IRAS Form
- [x] NHS/HSC Research and Development Offices
- [ ] Social Care Research Ethics Committee
- [ ] Research Ethics Committee
- [ ] Confidentiality Advisory Group (CAG)
- [ ] National Offender Management Service (NOMS) (Prisons & Probation)

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

For participating NHS organisations in England different arrangements apply for the provision of site specific information. Refer to IRAS Help for more information.

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

- [x] Yes
- [ ] No

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

- [x] Yes
- [ ] No

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

- [x] 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
- [x] 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 is a student project as part of the Doctorate in Clinical Psychology, North Wales Clinical Psychology Programme.
   All project procedures will be carried out by the student under the guide of the clinical supervisor (employed by Bethel Cadwaladr University Health Board).

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 core team without prior consent at any stage of the project (including identification of potential participants)?
    ☐ Yes ☐ No
Site-Specific Information Form (NHS sites)

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

- NHS site
- Non-NHS site

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

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

The data in this box is populated from Part A:

Title of research:
An Investigation Of Grit And Resilience In Rehabilitation Success Following Acquired Brain Injury

Short title: Grit and resilience in rehabilitation following brain injury

Chief Investigator: Title Forename/Initials Surname
Dr E E Todd Jones

Name of NHS Research Ethics Committee to which application for ethical review is being made:
East of Scotland Research Ethics Service REC 1

Project reference number from above REC: 17/SS/0118

1. Give the name of the NHS organisation responsible for this research site
Betsi Cadwaladr University Health Board

1.3. In which country is the research site located?
- England
- Wales
- Scotland
- Northern Ireland

1.4. Is the research site a GP practice or other Primary Care Organisation?
- Yes
- No

2. Who is the Principal Investigator or Local Collaborator for this research at this site?
Select the appropriate title:  
☐ Principal investigator  
☐ Local Collaborator

Title Forename/Initials Surname

Post  
Qualifications  
Organisation  
Work Address

PostCode  
Work E-mail  
Work Telephone  
Mobile  
Fax

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

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

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

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

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

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

<table>
<thead>
<tr>
<th>Location</th>
<th>Activity/Facilities</th>
</tr>
</thead>
</table>

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

6. Does the Principal investigator or any other member of the site research team have any direct personal involvement (e.g. financial, share-holding, personal relationship etc) in the organisation sponsoring or funding the research that may give rise to a possible conflict of interest?  
☐ Yes  ☐ No

7. What is the proposed local start and end date for the research at this site?  
Start date:  
End date:
8-1. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. (These include seeking consent, interviews, non-clinical observations and use of questionnaires.)

Columns 1-4 have been completed with information from A15 as below:

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

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

<table>
<thead>
<tr>
<th>Intervention or procedure</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial telephone consultation</td>
<td>1</td>
<td>0</td>
<td>20</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Seeking consent</td>
<td>1</td>
<td>0</td>
<td>20</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grief scale</td>
<td>1</td>
<td>0</td>
<td>10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Resilience scale CD-RISC</td>
<td>1</td>
<td>0</td>
<td>20</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Awareness scale</td>
<td>1</td>
<td>0</td>
<td>10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test of premorbid functioning</td>
<td>1</td>
<td>0</td>
<td>20</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Montreal cognitive assessment</td>
<td>1</td>
<td>0</td>
<td>20</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Debrief</td>
<td>1</td>
<td>0</td>
<td>15</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participant occupational information</td>
<td>1</td>
<td>0</td>
<td>10</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

☐ Yes  ☐ No

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

Are there any changes other than those noted in the table?
10. How many research participants/samples is it expected will be recruited/obtained from this site?

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

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

<table>
<thead>
<tr>
<th>Name</th>
<th>Expertise/training</th>
</tr>
</thead>
</table>

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

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

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

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

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

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

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

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

21. What external funding will be provided for the research at this site?
   - [ ] Funded by commercial sponsor
   - [ ] Other funding
   - [ ] No external funding

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

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

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

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

Declaration:

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

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

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

Title Forename/Initials Surname
Mr Aaron Pritchard
Work E-mail aaron.pritchard@wales.nhs.uk
Work Telephone 01248 384677

Declaration by Principal Investigator or Local Collaborator

1. The information in this form is accurate to the best of my knowledge and I take full responsibility for it.
2. I undertake to abide by the ethical principles underpinning the World Medical Association’s Declaration of Helsinki and relevant good practice guidelines in the conduct of research.
3. If the research is approved by the main REC and NHS organisation, I undertake to adhere to the study protocol, the terms of the application of which the main REC has given a favourable opinion and the conditions requested by the NHS organisation, and to inform the NHS organisation within local timelines of any subsequent amendments to the protocol.
4. If the research is approved, I undertake to abide by the principles of the Research Governance Framework for Health and Social Care.
5. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to the conduct of research.
6. I undertake to disclose any conflicts of interest that may arise during the course of this research, and take responsibility for ensuring that all staff involved in the research are aware of their responsibilities to disclose conflicts of interest.
7. I understand and agree that study files, documents, research records and data may be subject to inspection by the
NHS organisation, the sponsor or an independent body for monitoring, audit and inspection purposes.

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

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

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

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

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

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

Signature of Principal Investigator or Local Collaborator: ____________________________

Print Name: ____________________________

Date: ____________________________
Appendix G - Research Ethics Committee Amendments and Approval Letter

Dear Dr. Todd Jones,

Study Title:  An Investigation Of Grit And Resilience In Rehabilitation Success Following Acquired Brain Injury

REC reference:  17/ES/0118
Protocol number:  N/A
IRAS project ID:  214855

Thank you for your letter of 04 October 2017, responding to the Committee’s request for further information on the above research and submitting revised documentation.

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

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact hra.studyregistration@nhs.net outlining the reasons for your request.

Confirmation of ethical opinion

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

Conditions of the favourable opinion

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

[If applicable, insert any additional conditions specified by the REC]

Management permission must be obtained from each host organisation prior to the start of the study, as the site concerned.
Review the use of complex terms; for example, acquired brain injury adversity, lead clinician etc

Insert information regarding payment of travel expenses.

The Committee requested that the researcher either use Chief Investigator (CI) or Principal Investigator (PI) for consistency.

Adapt the following paragraph and insert under the heading 'Who has reviewed this study?'

'The East of Scotland Research Ethics Service REC 1, which has responsibility for scrutinising all proposals for medical research on humans, has examined the proposal and has raised no objections from the point of view of research ethics. It is a requirement that your records in this research, together with any relevant medical records, be made available for scrutiny by monitors from << name of sponsor company (if appropriate) >> and NHS <<insert name of Health Board/Trust>>, whose role is to check that research is properly conducted and the interests of those taking part are adequately protected.'

If you would find it helpful to discuss any of the matters raised above or seek further clarification from a member of the Committee, you are welcome to contact Mrs Lorraine Reilly, REC Manager (details at top of letter).

When submitting a response to the Committee, the requested information should be electronically submitted from IRAS. A step-by-step guide on submitting your response to the REC provisional opinion is available on the HRA website using the following link: http://www.hra.nhs.uk/nhs-research-ethics-committee-rec-submitting-response-provisional-opinion/

Please submit revised documentation where appropriate underlining or otherwise highlighting the changes which have been made and giving revised version numbers and dates. You do not have to make any changes to the REC application form unless you have been specifically requested to do so by the REC.

The Committee will confirm the final ethical opinion within a maximum of 60 days from the date of initial receipt of the application, excluding the time taken by you to respond fully to the above points. A response should be submitted by no later than 22 September 2017.

Summary of the discussion at the meeting

Social or scientific value; scientific design and conduct of the study

The Committee asked for clarification as to how the clinical outcomes will be assessed.

You explained that the 50 item questionnaires are specifically designed for people with brain injuries and will be administered in paper form for ease of completion. You went on to say that the study will hopefully show whether the dynamic traits are fixed or whether grit is associated with resilience in clinical service and hopefully over time aid with patient’s treatment.

The Committee requested that copies of all study questionnaires are submitted for review.

The Committee asked whether one interview will be sufficient to answer the study hypothesis.
You replied that you are confident that one interview will be sufficient to answer the research question. You went on to say that the study is to try and understand where people are in terms of their rehabilitation after 12 months.

The Committee was still unclear and asked for further clarification.

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

The Committee asked whether there is a stratification system used to define the different levels of impairment of participants.

You replied that brain injury is heterogeneous and two people could have the same brain injury, but would have different outcomes. You went on to say that the clinician will classify the patient's impairment levels; however, as the study is a pilot there will be no stratifying of participants in the study.

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

The Committee asked for clarification as to the researcher's experience of performing tests on people with brain injuries group.

You replied that you have had significant psychology experience and have undertaken a single case study for your Masters with a participant with short term memory loss. You went on to say that you would be spending your third year of your qualification undertaking clinical training in the Brain Injury Unit that you are recruiting from in the study.

The Committee was satisfied with the response.

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

The Committee asked for clarification as to researcher's experience and qualifications to counsel participants on the results of their brain injury test and what process is in place should they disclose potential danger to themselves or others.

You said as part of her third year training you would be learning to deliver feedback of tests to patients with brain injuries.

The Committee requested that further information is included in the Participant Information Sheet (PIS) of the process in place should the researcher have to break confidentiality if a participant disclosed potential danger to themselves or others.

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

The Committee asked for clarification as to what experience the researcher has in taking consent from a vulnerable group.

You said that during your PhD you had obtained informed consent from hundreds of participants including people with dementia, difficulty with reading and is used to relaying the information sheet and consent form in lay terms to different patient groups.
The Committee requested that the PIS is reviewed for the use of complex terms; for example, acquired brain injury adversity, lead clinician etc was written in lay language.

**Suitability of supporting information**

The Committee requested that information regarding payment of travel expenses is included in the PIS.

The Committee noted that 'I consent to my lead clinician being informed of my participation in this study'; however no letter has been submitted for review.

**Other general comments**

The Committee requested that the researcher either use Chief Investigator (CI) or Principal Investigator (PI) for consistency in the PIS as both terms have been used.

Please contact the REC Manager if you feel that the above summary is not an accurate reflection of the discussion at the meeting.

**Documents reviewed**

The documents reviewed at the meeting were:

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
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<tr>
<td>Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)</td>
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<td>15 July 2017</td>
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<tr>
<td>[Other Email re questionnaires &amp; scales]</td>
<td></td>
<td>03 August 2017</td>
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<td>20 July 2017</td>
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<td>20 July 2017</td>
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<td>Participant information sheet (PIS) [Debrief Information JTJ V1]</td>
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<tr>
<td>Summary CV for supervisor (student research) [ACV Rudi Coetzer 2017]</td>
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<tr>
<td>Validated questionnaire [Grit Scale]</td>
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<tr>
<td>Validated questionnaire [Montreal Cognitive Assessment]</td>
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**Membership of the Committee**

The members of the Committee who were present at the meeting 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.
17/ES/0118

Yours sincerely

[Signature]

pp
Dr Robert Rea
Chair

Email: eosres.tayside@nhs.net

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments.

Copy to: Mr Hefin Francis
Dr Rosella Roberts, Betsi Cadwaladr University Health Board
# East of Scotland Research Ethics Service REC 1
## Attendance at Committee meeting on 18 August 2017

### Committee Members:

<table>
<thead>
<tr>
<th>Name</th>
<th>Profession</th>
<th>Present</th>
<th>Notes</th>
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<tbody>
<tr>
<td>Dr Robert Rea</td>
<td>Business Development Manager</td>
<td>Yes</td>
<td>Chair</td>
</tr>
<tr>
<td>Mr Carlos Widerowitz</td>
<td>Consultant Orthopaedic Surgeon</td>
<td>No</td>
<td>Vice-chair, apologies received</td>
</tr>
<tr>
<td>Mrs Samantha Downie</td>
<td>Specialist Trainee Registrar in Orthopaedics &amp; Trauma</td>
<td>Yes</td>
<td>Alternate Vice-chair</td>
</tr>
<tr>
<td>Dr Clare Clarke</td>
<td>Research Fellow/Physiotherapist</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Mrs Katherine Coll</td>
<td>Trial Manager</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Dr Emma Fletcher</td>
<td>Specialist Registrar in Public Health Medicine</td>
<td>No</td>
<td>Apologies received</td>
</tr>
<tr>
<td>Miss Natalie Grieve</td>
<td>Senior Clinical Scientist</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Dr Sharon King</td>
<td>Tayside Biorepository Manager</td>
<td>Yes</td>
<td></td>
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<tr>
<td>Ms Lisa MacLeod</td>
<td>Specialist Research Clinical Pharmacist</td>
<td>No</td>
<td>Apologies received</td>
</tr>
<tr>
<td>Mr John Macleod</td>
<td>Retired</td>
<td>Yes</td>
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<tr>
<td>Dr Anderson McKendrick</td>
<td>Retired GP</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Mr Adrian Snowball</td>
<td>Retired HR Consultant</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Mrs Hazel Steele</td>
<td>Antimicrobial Pharmacist/Locality Pharmacist</td>
<td>Yes</td>
<td></td>
</tr>
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</table>

### Also in attendance:

<table>
<thead>
<tr>
<th>Name</th>
<th>Position (or reason for attending)</th>
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<tbody>
<tr>
<td>Mrs Caroline Ackland</td>
<td>Scientific Officer/Regional Manager</td>
</tr>
<tr>
<td>Mrs Lorraine Reilly</td>
<td>REC Manager</td>
</tr>
<tr>
<td>Mr Jonathan Deans</td>
<td>Observer</td>
</tr>
<tr>
<td>Miss Emma Wilson</td>
<td>Observer</td>
</tr>
</tbody>
</table>
Appendix H - Participant Consent Form – English

RESEARCH INFORMED CONSENT FORM

Title of Study - Investigating the role of grit and resilience in rehabilitation following Acquired Brain Injury

Principal Investigator – Dr Jenna Todd Jones
psp6f3@bangor.ac.uk

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

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

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

I understand that the Principal Investigator Dr Jenna Todd Jones may access my medical records to gain contact information and/or details of my brain injury.

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

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

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

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

I freely agree to participate in this study.

Signatures:

________________________  ______________________  ______________________
Name of participant (block capitals)  Date  Signature

________________________  ______________________  ______________________
Principal Investigator (block capitals)  Date  Signature

If you would like a copy of this consent form to keep, please ask the researcher.

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

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FFURFLEN CYDSYNIAID GWYBODUS I GYMRYD RHAN MEWN YMCHWIL

Teitl yr astudiaeth - Ymachwilio i swyddogaeth dycnwch a gywtnwch mewn adferiad yn dilyn anaf i’r ymennydd

Prif Ymachwilydd – Dr Jenna Todd Jones psp6f3@bangor.ac.uk

Goruchwyliwr Ymachwil - Dr Rudi Coetzer
Rudi.Coetzer@wales.nhs.uk

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

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

Rwy'n deall y gall y PI Dr Jenna Todd Jones fynd i'm cofnodion meddygol i gael gwybodaeth gyswllt ac/neu fanylion am fy anaf i’r ymennydd.

Rwy'n deall fy mod yn cymryd rhan yn wirfoddol ac y gallaf dynnu’n ôl unrhyw bryd, heb roi rheswm.

Rwy'n deall y caiff fy nata eu trin yn gyfrinachol, ac y bydd unrhyw gyhoeddus sy’n deillio o’r gwaith hwn yn cyfiwyno data nad yw’n datgelu pwy ydwyf.

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

Rwy'n cydsynio i'm prif glinigwr (yr unigolyn sy'n gyfrifol am ofalu amdanaf o fewn Gwasanaeth Anaf i'r Ymennydd Gogledd Cymru) gael gwybod ar lafar fy mod yn cymryd rhan yn yr astudiaeth hon.

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

**Llofnodion:**

<table>
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<tr>
<th>Enw'r sawl sy'n cymryd rhan (priflythrennau)</th>
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<th>Prif Ymchwilydd (priflythrennau)</th>
<th>Dyddiad</th>
<th>Llofnod</th>
</tr>
</thead>
</table>

Os hoffech gael copi o'r ffurflen gydsynio hon, gofynnwch i'r ymchwilydd.

Os ydych chi'n dymuno cwyno am yr astudiaeth, gellwch gyseilltu nali â Thim Pryderon Bwrdd Iechyd Prifysgol Betsi Cadwaladr, Ysbyty Gwynedd, Bangor, Gwynedd, LL57 2PW. E-bost: [ConcernsTeam.bcu@wales.nhs.uk](mailto:ConcernsTeam.bcu@wales.nhs.uk). Ffôn: 01248 384194. Neu Hefin Francis, Ysgol Seicoleg, Adeilad Brigantia. Fforudd Penrallt, Gwynedd LL57 2AS. E-bost: [h.francis@bangor.ac.uk](mailto:h.francis@bangor.ac.uk), Ffôn: 01248 388339

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Investigating the role of grit and resilience in rehabilitation following Acquired Brain Injury

Participant Information Sheet

This information sheet will help you understand why this study is being conducted and what is involved in taking part. Please read this information sheet carefully. You can take your time to read this information and talk to your friends, family, and lead clinician (the individual who is responsible for my care within the North Wales Brain Injury Service) before you make any decisions.

If you have any questions you can talk to your lead clinician. Alternatively you can contact the Principal Investigator (Dr Jenna Todd Jones) or Dr Rudi Coetzee directly:
Dr Jenna Todd Jones – psp6f3@bangor.ac.uk or Telephone: 01248 388365
Dr Rudi Coetzee – Rudi.Coetzee@wales.nhs.uk or Telephone: 01492 807770

PART A

We are asking if you would like to take part in a study to investigate how grit and resilience (personality traits) affect rehabilitation success following an Acquired Brain Injury.

What is an acquired brain injury?
An acquired brain injury is any injury to the brain that occurs after birth, and not as a result of a genetic or developmental disorder.

What are grit and resilience?
Grit is a personality trait that relates to an individual’s commitment to long-term goals in the face of adversity. Adversity can be described as any difficult or stressful situation that a person endures in their life. Resilience is a different personality trait that relates to a positive, adaptive response to adversity that influences an individual’s ability to ‘bounce back’ from stressors, and can produce a ‘steeling’ effect against future events.
Why are we doing this?
Lots of research has been conducted looking into what things affect rehabilitation for those who have suffered different degrees of Acquired Brain Injury. It is hoped that this study may help to provide clinicians and patients with the knowledge and understanding to address crucial underlying factors associated with recovery following Acquired Brain Injury.

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

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

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

What will happen if I take part?
The Principal Investigator will contact you to organise a time and location to meet at your convenience. If you travel to the North Wales Brain Injury Service to participate your travel expense will be reimbursed by providing a receipt to the Principal Investigator. If you are unable to attend the North Wales Brain Injury Service the Principal Investigator will arrange to meet you at a convenient location such as a local GP Surgery, or in your home. Once a time and place is organised, you will meet with the Principal Investigator to complete three short questionnaires and a series of puzzles. The whole process should take no longer than 2 hours. You may bring someone with you to the appointment if you would like. The CI Dr Jenna Todd Jones may access your medical records to gain contact details (e.g. telephone number and/or home address if you are unable to attend NWBIS or your local GP surgery to participate), and to gain information around the nature of your Acquired Brain Injury.
Is there anything to be worried about if I take part?
There are some things that it is important to think about:

1. **The whole process may take up to 2 hours**
   As you are required to answer questions and complete a series of tasks you may feel fatigued during the process. It is important to know that you can take short breaks whenever you choose. You can also choose to stop the process all together without having to explain why.

2. **Some of the questions relate to your rehabilitation, in particular your return to work**
   If you feel distressed by the questions being asked you can choose to stop answering them. You can also highlight your distress with the Principal Investigator who will attempt to address your concerns. You can also choose to stop the process all together without having to explain why.

**What are the possible benefits of taking part?**
We cannot promise that the study will have a direct benefit to you, but you may find the process of taking part in this study enjoyable. You may also find it rewarding to take part in a scientific study which is aimed at improving the understanding and knowledge in this area. It is hoped that this research can add to the scientific literature. This may ultimately help clinicians and those with Acquired Brain Injury to better understand how elements of their personality relate to their recovery.

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

**PART B – Additional Information**

What happens when the study stops?
The whole study is likely to stop in July 2018. If you choose to, you can be sent a summary of the findings when it is finished.
What about if I don’t want to be in the study anymore but I have completed the questionnaire and tasks?
All your data from the study is completely anonymised and cannot be traced back to you. However, should you want your data removed from the study then you can contact the Principal Investigator, Dr Jenna Todd Jones. This decision will have to be made before January 2018 as following this time the data will have been collated and analysed. The anonymised and collated data will be securely held in the North Wales Clinical Psychology Programme for up to five years in accordance with Betsi Cadwaladr University Health Board policy.

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

Who is organising and funding the study?
The study is being performed as part of Dr Jenna Todd Jones’s (Principal Investigator) training to become a Clinical Psychologist. Therefore, the study is organised by the North Wales Clinical Psychology Programme, Bangor University. The study is also organised and supervised through the NHS.

Who has reviewed the study?
The study has been checked and approved by ethics departments in both Bangor University and the NHS Research Ethics Committee. This is to ensure that the research is fair to those who participate in the study. In addition, this study has been checked and approved by The East of Scotland Research Ethics Service REC 1, which has responsibility for scrutinising all proposals for medical research on humans, has examined the proposal and has raised no objections from the point of view of research ethics. It is a requirement that your records in this research, together with any relevant medical records, be made available for scrutiny by monitors from Betsi Cadwaladr University Health Board whose role is to check that research is properly conducted and the interests of those taking part are adequately protected.
Important contact details:
If you wish to make a complaint about the study, you can either contact Betsi Cadwaladr University Health Board Concerns Team, Ysbtyt Gwynedd, Bangor, Gwynedd, LL57 2PW Email: ConcernsTeam.bcu@wales.nhs.uk, Tel: 01248 384194.

Or Hefin Francis, School of Psychology, Adeilad Brigantia, Penrallt Road, Gwynedd LL57 2AS, Email: h.francis@bangor.ac.uk, Tel: 01248 388339

Thank you.

Dr Jenna Todd Jones
Trainee Clinical Psychologist
Betsi Cadwaladr University Health Board
North Wales Clinical Psychology Programme
School of Psychology
Bangor University
Bangor
LL57 2DG
Appendix K - Participant Information Sheet – Welsh

Ymchwilio i swyddogaeth dycnwch a gwytnwch mewn adferiad yn dilyn anaf i'r ymennydd

Taflen wybodaeth i gyfranogwyr

Bydd y daflen wybodaeth hon yn eich helpu i ddeall y rheswm dros wneud yr astudiaeth hon a’r hyn fydd yn digwydd wrth gymryd rhan. Darllenwch y daflen wybodaeth hon yn ofalus. Gellwch gymryd eich amser i ddarlenu y wybodaeth hon a’i thrafod â ffrindiau, teulu a’r prif glinigwr (yr unigolyn sy’n gyfrifol am ofalu amdanoch o fewn Gwasanaeth Anaf i’r Ymennydd Gogledd Cymru) cyn i chi wneud unrhyw benderfyniadau.

Os oes gennych unrhyw gwestiynau, gallwch siarad â’ch prif glinigwr. Fel arall, gellwch gysylltu â’r prif ymchwilydd (Dr Jenna Todd Jones) neu Dr Rudi Coetzer yn uniongyrchol:

Dr Jenna Todd Jones – psp6f3@bangor.ac.uk neu Ffoniwch: 01248 388365
Dr Rudi Coetzer- Rudi.Coetzer@wales.nhs.uk neu Ffoniwch: 01492 807770

RHAN A

Rydym yn gofyn a fydech yn hoffi cymryd rhan mewn astudiaeth sy’n edrych ar sut mae dycnwch a gwytnwch (nodweddiwn personoliaeth) yn efeithio ar Iwyddiant adferiad yn dilyn anaf i’r ymennydd.

Beth yw anaf caffaeledig i’r ymennydd?

Anaf caffaeledig i’r ymennydd yw unrhyw anaf i’r ymennydd sy’n digwydd ar ôl genedigaeth, ac nid o ganlyniad i anhwylder genetig neu ddatblygiadol.

Beth yw dycnwch a gwytnwch?

Dycnwch yw nodweddiwn personoliaeth sy’n ymwyneu â’r ffordd mae unigolyn yn ymwybod i amcanion hir dymor yn wynneb adfyd. Gellir disgrifi adfyd fel unrhyw sefyllfa anodd neu lawno straen y mae rhywun yn ei hwynebu mewn

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bywyd. Mae gwytwnwch yn nodwedd bersonoliaethol wahanol, sy’n ymwneud ag ymateb cadarnhaol i adfyd, sy’n dylanwadu ar allu unigolyn i ‘fownsio’öl’ o sefyllfa o straen a magu ‘caledwch’ wrth wynebu digwyddiadau’r dyfodol.

Pam ydym ni’n gwneud hyn?

Mae llawer o ymchwil wedi’i chynnau sy’n edrych ar pa bethau sy’n effeithio ar adferiad rhai sydd wedi dioddef gwahanol raddau o anaf i’r ymennydd. Gobeithir y bydd yr astudiaeth hon yn helpu i roi gwybodaeth a dealltwriaeth i glinigwyr a chleifion i ymdrin à ffactorau sylfaenol hollbwysig sy’n gysylltiedig ag adferiad yn dilyn anaf i’r ymennydd.

Pam y gofynnwyd imi gymryd rhan?

Mae’r astudiaeth hon yn cael ei gwneud o fewn Gwasanaeth Anaf i’r Ymennydd Gogledd Cymru (NWBIS). Rydym wedi gofyn i chi gymryd rhan yn yr astudiaeth hon oherwydd i chi gael eich cyfeirio at NWBIS yn y gorffennol, neu’n mynd i apwyntiau áno.

Oes rhaid imi gymryd rhan?

Nac oes. Mae cymryd rhan yn yr astudiaeth hon yn holol wirfoddol. Bydd yr astudiaeth hon yn gyfan gwbl ar wahân i’r gofal a dderbyniwch gan NWBIS. Felly, ni fydd unrhyw benderfyniad a wnechw yn effeithio ar y gofal a dderbyniwch.

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

Beth fydd yn digwydd os byddaf yn cymryd rhan?

Bydd yr ymchwiliwyd yn cysylltu â chi i drefnu amser a lleoliad cyfleus i gyfarfod â chi. Os byddwch yn teithio i Wasanaeth Anaf i’r Ymennydd Gogledd Cymru i gymryd rhan, bydd eich costau teithio’i n cael eu had-dalu trwy roi derbynneib i’r prif ymchwilydd. Os na ellwch ddod i Wasanaeth Anaf i’r Ymennydd Gogledd Cymru, bydd y prif ymchwilydd yn trefnu i gyfarfod â chi mewn man cyfleus, megis meddygfa eich meddyg teulu, neu eich cartref. Ar ôl trefnu amser a llæ, byddwch yn cyfarfod â’r prif ymchwilydd i gwbllau’r tri holiadur byr a chyfres o bosau. Ni ddylai’r broses gyfan gymryd mwy na dwy awr. Gellwch ddod â

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rhywun gyda chi i’r cyfarfod os dymunwch. Gall y PI Dr Jenna Todd Jones fynd i’ch cofnodion meddygol i gael manylion cyswilt (e.e. rhif ffôn ac/neu cyfeiriad cartref os na ellwch ddod i NWBIS neu eich meddygfa leol i gymryd rhan), ac i gael gwybodaeth am natur eich anaf i’r ymennydd.

Oes yna unrhyw beth i boeni amdano os bydden i’n cymryd rhan?

Mae yna rai pethau y mae’n bwysig meddwl amdanyn nhw:

1. **Gall y broses gyfan gymryd hyd at ddwy awr.**
   Oherwydd y gofynnir i chi ateb cwestiynau a chwblhau cyfres o dasgau, efallai y byddwch yn teimlo wedi blino yn ystod y broses. Mae’n bwysig gwybod y gellwch gymryd eglwyl fer pryd bynnag yr ydych yn dewis. Gellwch hefyd ddewis rhoi’r gorau i’r broses yn gyfan gwbl heb orfod egluro pam.

2. **Mae rhai o’r cwestiynau’n ymwneud â’ch adferiad, ac yn arbennig dychwelwyd i weithio.**
   Os ydych yn teimlo bod unrhyw rai o’r cwestiynau’n peri gofid ichi, nid oes raid i chi eu hateb. Gellwch hefyd sôn am eich gofid gyda’r prif ymchwilydd a fydd yn ceisio mynd i’r afael â’ch pryderon. Gellwch hefyd ddewis rhoi’r gorau i’r broses yn gyfan gwbl heb orfod egluro pam.

Beth yw manteision posib cymryd rhan?

Ni fedrwn addo y bydd mantais uniongyrchol i chi o’r astudiaeth, ond efallai y byddwch yn gweld cymryd rhan yn yr astudiaeth yn brofiad pleserus. Efallai hefyd y bydd cymryd rhan mewn astudiaeth wyddonol sydd â’r nod o wefalla’r ddealltwriaeth a’r wybodaeth yn y maes hwn yn rhoi bodhath i chi. Gobeithir y bydd yr ymchwili hon yn gallu ychwanegu at ddeunydd darllen gyddonol. Gall hyn yn y pen draw helpu clinigwyr a rhai gyda anaf i’r ymennydd ddeall yn well sut mae elfennau o’u personoliaeth yn gysylltiedig â’u hadferiad.

Os hoffech gael crynodeb o’r canlyniadau, a fyddwch cystal â rhoi gwybod i’r prif ymchwilydd. Ar ôl cwbhlhau’r astudiaeth byddwn yn anfon llythyr atoch yn nodi ein canfyddiadau.
RHAN B - Gwybodaeth Ychwanegol

Beth fydd yn digwydd pan fydd yr astudiaeth yn gorffen?

Bydd yr astudiaeth gyfan yn debygol o ddod i ben ym mis Gorffennaf 2018. Os dewiswch hynny, gellir anfon crynodeb o’r canfyddiadau atoch pan fydd wedi gorffen.

Beth os na fydda’i eisiau bod yn rhan o’r astudiaeth mwyach, ond fy mod i wedi llenwi’r holiadur ac wedi gwneud y tasgau?

Bydd eich holl ddata o’r astudiaeth yn hollol ddienw, ac ni ellir ei olrhain yn ôl i chi. Fodd bynnag, os dymunwch i’ch data gael ei dynnu o’r astudiaeth, yna gellwch gysylltu â’r prif ymchwilydd – Dr Jenna Todd Jones. Bydd yn rhaid i chi benderfynu yng Nghymru cyn Ionawr 2018, oherwydd ar ôl yr amser hwn bydd y data wedi cael ei gasglu a’i ddadansoddi. Bydd y data dienw a gasglwyd yn cael eu cadw’n ddiogel yn Rhaglen Seicoleg Glinigol Gogledd Cymru am hyd at bum mlynedd, yn unol â pholisi Bwrdd Iechyd Prifysgol Betsi Cadwaladr.

Fydd unrhyw un arall yn gwybod fy mod i’n gwneud hyn?

Mae eich rhan yn yr astudiaeth hon yn hollool gyfrinachol. Fodd bynnag, os byddwch yn dweud rhywbeth fydd yn gwneud i ni feddwîl eich bod chi, neu rywun arall, mewn pergyli, byddai’n rhaid i ni rannu’r hyn y gwneithoch ei ddweud wrthym ni gyda’ch prif glinigydd a’ch tîm clinigol (yr unigolion o fewn Gwasanaeth Anaf i’r Ymennydd Gogledd Cymru sy’n gyfrifol am eich gofal) i’w drafod ymhillach, ac o bosib gweithredu ar hynny. Nid yw hynny’n debyg o ddigwydd ond byddem yn rhoi gwybod i chi pe bai’n rhaid i ni wneud hynny.

Pwy sy’n trefnu a chyllido’r astudiaeth?

Mae’r astudiaeth yn cael ei gwneud fel rhan o hyfforddiant Dr Jenna Todd Jones (Prif Ymchwilydd) i fod yn Seicolegdd Clinigol. Trefnir yr astudiaeth felly gan Raglen Seicoleg Glinigol Gogledd Cymru, Prifysgol Bangor. Mae’r astudiaeth hefyd yn cael ei threfnu a’i goruchwylio drwy’r GIG.
Pwy sydd wedi adolygu’r astudiaeth?

Mae’r astudiaeth wedi cael ei hadolygu a’i chymeradwyo gan adranau moeseg ym Mhrifysgol Bangor a chan Bwyllgor Moeseg Ymchwil y Gwasanaeth Iechyd Gwladol. Diben hyn yw sicrhau bod yr ymchwil yn deg i’r rhai sy’n cymryd rhan yn yr astudiaeth. Yn ogystal, mae’r astudiaeth wedi cael ei gwirio a’i chymeradwyo gan The East of Scotland Research Ethics Service REC 1, sydd â chyfrifoledb drwy archwilio pob cynnig i wneud ymchwil feddygol ar bobl. Archwiliwyd y cynnig hwn gan y gwasanaeth ac ni wnaethant wrthwynebu unrhyw beth o safbwynt moeseg ymchwil. Mae’n un o’r gofnion bod eich cofnodion yn yr ymchwil hon, ynghyd ag unrhyw gofnodion meddygol perthnasol, ar gael i’w harchwilio gan fonitoriada o Fwrdd Iechyd Prifysgol Betsi Cadwaladr sydd â’r gwaith o sicrhau bod ymchwil yn cael ei chynnal yn briodol ac y gwarchodir yn digonol fuddiannau’r rhai sy’n cymryd rhan.

Manylion cysylltu pwysig:

Os ydych chi’n dymuno cwyno am yr astudiaeth, gellwch gysylltu â

Thîm Pryderon Bwrdd Iechyd Prifysgol Betsi Cadwaladr, Ysbyty Gwynedd, Bangor, Gwynedd, LL57 2PW

E-bost: ConcernsTeam.bcu@wales.nhs.uk, Tel: 01248 384194, Tel: 01248 384194.

Neu Hefin Francis, Ysgol Seicoleg, Adeilad Brigantia, Ffordd Penrallt, Gwynedd LL57 2AS, E-bost: h.francis@bangor.ac.ukFôn: 01248 388339

Diolch.

Dr Jenna Todd Jones

Seicolegydd Clinigol dan Hyfforddiant

Bwrdd Iechyd Prifysgol Betsi Cadwaladr

Rhapglin Seicoleg Clinigol Gogledd Cymru

Ysgol Seicoleg

Prifysgol Bangor

Bangor

LL57 2DG

22/09/17

Version 3

214855

247
Investigating the role of grit and resilience in rehabilitation following Acquired Brain Injury

Debrief Information

Thank you for taking the time to take part in this research. The information you have provided will help us to gain a better understanding of the relationship between personality traits and how people recover from acquired brain injury. Hopefully this information will help us improve services for people who have sustained an acquired brain injury.

The information you have given will be kept confidential and secure at all times. It will be kept within the North Wales Brain Injury Service for a period of time after which it will be destroyed; this is Betsi Cadwaladr University Health Board policy. The only time we would need to break confidentiality is if you told us something that made us significantly concerned about you or someone else’s safety. In the event of this we will need to share this information with other professionals; we will inform you if this needs to happen.

If you would like to withdraw the information you have provided during the study at any time, you are free to do so and can contact me, the Principal Investigator Dr Jenna Todd Jones, to let me know that this is your wish. You will not need to explain why you would like to withdraw your information.

Should you wish you can let me know now that you would like to receive a newsletter of the results when the research project is complete. This newsletter will include only anonymised information and you will not be identifiable as an individual in the description of what happened. This newsletter will likely arrive some time around June 2018.

If you have concerns about anything that has happened during your participation in this research there are a few different things you can do. You can speak to me as the Principal Investigator directly and I will try my best to answer your questions. You can also speak directly to your treating clinician, or your GP. If you are still unhappy after speaking to
me, your clinician, or GP, and want to make a complaint, you can do this via the Betsi Cadwaladr University Health Board Concerns Team, Ysbyty Gwynedd, Bangor, Gwynedd, LL57 2PW, Email: ConcernsTeam.bcu@wales.nhs.uk, tel: 01248 384194. Or Hefin Francis, School of Psychology, Adelaid Brigantia, Penrallt Road, Gwynedd LL57 2AS, Email: h.francis@bangor.ac.uk, Tel: 01248 388339

Thank you.

Dr Jenna Todd Jones
Trainee Clinical Psychologist
Betsi Cadwaladr University Health Board
North Wales Clinical Psychology Programme
School of Psychology
Bangor University
Bangor
LL57 2DG
Appendix M - Participant Debrief Form – Welsh

Ymchwilio i swyddogaeth dyncwch a gwytnwch mewn adferiad yn dilyn anaf i'r ymennydd

Taflen wybodaeth ddilynol

Diolch yn fawr iawn i chi am roi’r amser i gymryd rhan yn yr ymchwil hon. Bydd y wybodaeth a roesoch yn ein helpu i ddeall yn well y berthynas rhwng nodweddon personoliaeth a sut mae pobl yn gwella ar ôl anaf i’r ymennydd. Gobeithiwn y bydd y wybodaeth hon yn ein helpu i wella gwasanaethau i bobl sydd wedi cael anaf i’r ymennydd.

Caiff y wybodaeth a roddwyd gennych ei chadw’n gyfrinachol a diogel bob amser. Caiff ei chadw o fewn Gwasanaeth Anaf i’r Ymennydd Gogledd Cymru am gyfnod ac yna caiff ei dinistrio; dyna yw polisi Bwrdd Iechyd Prifysgol Betsi Cadwaladr. Yr unig adeg y caiff gwybodaeth ei rhannu yn disgybl, a bydd y wybodaeth hon gyda gweithwyr profesiynol eraill; byddwn yn rhoi gwybod i chi os bydd angen i hynny ddigwydd.

Os hoffech dynnu’n ôl y wybodaeth a roesoch unrhyw bryd yn ystod yr astudiaeth, gellwch wneud hynny drwy gysylltu à mi, yr Prif Ymchwilydd Dr Jenna Todd Jones, a rhoi gwybod i mi am ei dymuniad. Ni fydd raid i chi egluro pam yr hoffech dynnu eich gwybodaeth yn ôl.

Os dymunwch, gellwch roi gwybod i mi’n awr os hoffech dderbyn cyllchlythr o’r canlyniadau pan mae’r project ymchwil wedi’i gwbllau. Bydd y cyllchlythr hwn yn cynnwys gwybodaeth dd-i-enw’r unig ac ni fydd yn bosibl eich adnabod mewn unrhyw ddisgrifiadau o’r hyn a ddigwyddodd. Mae’r cyllchlythr hwn yn debygol o gyrraedd rywbryd tua mis Mehefin 2018.

Os oes gennych unrhyw bryderon yng Nghyrch unrhyw beth a ddigwyddodd wrth i chi gymryd rhan yn yr ymchwil hon, mae yna ychydig bethau y gellwch eu gwneud. Gellwch siarad yn unigonyrchol â mi fel y Prif Ymchwilydd, ac fe wnaf fy nghorau i ateb eich cwestiynau. Gellwch hefyd
siarad yn unigynychol â’r clinigydd sy’n eich trin, neu â’ch meddyg teulu. Os ydych yn dal yn anhapus ar ôl siarad â mi, eich clinigydd, neu feddyg teulu, a’ch bod eisial gwneud cwyn, gellwch wneud hyn drwy Dim Pryderon Bwrdd Iechyd Prifysgol Betsi Cadwaladr, Ysbyty Gwynedd, Bangor, Gwynedd, LL57 2PW. E-bost: ConcernsTeam.bcu@wales.nhs.uk, tel: 01248 384194, Neu Hefin Francis, Ysgol Seicoleg, Adeilad Brigantia, Ffordd Penralt, Gwynedd LL57 2AS, E-bost: h.francis@bangor.ac.uk, Ffôn: 01248 388339

Diolch.

Dr Jenna Todd Jones
Seicoleydd Clinigol dan Hyfforddiant
Bwrdd Iechyd Prifysgol Betsi Cadwaladr
Rhadlen Seicoleg Clinigol Gogledd Cymru
Ysgol Seicoleg
Prifysgol Bangor
Bangor
LL57 2DG
Appendix N - Demographic and Vocational Administered Question Sheet

Investigating the role of grit and resilience in rehabilitation following Acquired Brain Injury

Participant Questions sheet

This next section contains several questions related to your basic information, education, and vocation. Please ask the Principal Investigator to clarify any questions you are unsure of.

1. Age?

2. Gender?

3. What was your highest educational attainment?

4. What was your occupation prior to your brain injury?

5. What was the length of time in this occupation prior to your brain injury?

6. How many years in total have you been in a full-time, paid occupation?

7. Had you intended to return to work following your brain injury?
8. Have you returned to work following your brain injury?
   If yes, please state your occupation

9. Are you participating in voluntary work following your brain injury?
   If yes, please state the nature of the voluntary work

10. Have you joined a training/educational program following your brain injury?
    If yes, please state the nature of the training or educational program

11. Had you previously returned to work but are no longer employed?
    If yes, please state the occupation, length of time in employment, and reasons for ending the employment
Appendix O - Montreal Cognitive Assessment

Montreal Cognitive Assessment (MOCA)
Version 7.1 Original Version

Visuospatial / Executive

Copy cube
Draw clock (Ten past eleven) (3 points)

Points: __/5

Naming


Points: __/3

Memory
Read list of words; subject must repeat them. Do 2 trials, even if 1st trial is successful. Do a recall after 5 minutes.

1st trial
2nd trial

Points: __/2

Attention
Read list of digits (1 digit/sec). Subject has to repeat them in the forward order. Subject has to repeat them in the backward order.

Points: __/2

Serial 7 subtraction starting at 100

Points: __/3

Language
Repeat: I only know that John is the one to help today.

The cat always hid under the couch when dogs were in the room.

Fluency: Name maximum number of words in one minute that begin with the letter F

Points: __/1

Abstraction
Similarity between e.g. banana - orange = fruit

Points: __/2

Delayed Recall
Has to recall words with no cue

Points: __/5

Optional
Category cue
Multiple-choice cue

Points: __/6

Orientation
[ ] Date [ ] Month [ ] Year [ ] Day [ ] Place [ ] City

Points: __/6

Total Points: __/30

© Z.Nasreddine MD www.mocatest.org Normal ≥ 26 / 30

Add 1 point if ≥ 12 yr edu
Appendix P - Awareness Questionnaire

Awareness Questionnaire
Patient Form

Name: ____________________________ Patient #: ____________ Date: ________________

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

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

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

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

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

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

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

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

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

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

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

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

13. How good is your memory for recent events now as compared to before your injury?
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<th>3</th>
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<tbody>
<tr>
<td></td>
<td>much worse</td>
<td>a little worse</td>
<td>about the same</td>
<td>a little better</td>
<td>much better</td>
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14. How good are you at planning things now as compared to before your injury?

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

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

17. How well adjusted emotionally are you now as compared to before your injury?
Awareness Questionnaire
Clinician Form

Clinician Name: ___________________________  Date: ____________

Patient: ___________________________  Patient #: ____________

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<tr>
<td>much worse</td>
<td>a little worse</td>
<td>about the same</td>
<td>a little better</td>
<td>much better</td>
</tr>
</tbody>
</table>

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

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

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

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

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

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

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

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

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

___ 10. How good is the patient at keeping up with the time and date and where he/she is now as compared to before his/her injury?
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<tr>
<td>much</td>
<td>a little</td>
<td>about the same</td>
<td>a little better</td>
<td>much better</td>
<td></td>
</tr>
</tbody>
</table>

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

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

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

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

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

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

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

|   |   |   |   |   |
|---|---|---|---|
| 1 | 2 | 3 | 4 |
| completely | severely | moderately | minimally |

18. To what extent is the patient's accurate self-awareness impaired by his/her brain injury?
## 12-item Grit Scale

**Instructions for taking the grit test:**  
Answer each question honestly, and give yourself the corresponding score for that response. Keep track of your total score in the column on the far right. Your individual grit score will be the average of your responses to each question (somewhere between 1 and 5, with 1 being not at all gritty and 5 being extremely gritty). Tab two in the excel chart provides a scoring “cheat sheet” so you don’t have to do the math.

<table>
<thead>
<tr>
<th>Question</th>
<th>Question Score</th>
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<tbody>
<tr>
<td>1. I have overcome setbacks to conquer an important challenge.</td>
<td>Score</td>
</tr>
<tr>
<td>Very much like me</td>
<td>5</td>
</tr>
<tr>
<td>Mostly like me</td>
<td>4</td>
</tr>
<tr>
<td>Somewhat like me</td>
<td>3</td>
</tr>
<tr>
<td>Not much like me</td>
<td>2</td>
</tr>
<tr>
<td>Not like me at all</td>
<td>1</td>
</tr>
<tr>
<td>2. New ideas and projects sometimes distract me from previous ones.*</td>
<td>Score</td>
</tr>
<tr>
<td>Very much like me</td>
<td>1</td>
</tr>
<tr>
<td>Mostly like me</td>
<td>2</td>
</tr>
<tr>
<td>Somewhat like me</td>
<td>3</td>
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<td>Not much like me</td>
<td>4</td>
</tr>
<tr>
<td>Not like me at all</td>
<td>5</td>
</tr>
<tr>
<td>3. My interests change from year to year.*</td>
<td>Score</td>
</tr>
<tr>
<td>Very much like me</td>
<td>1</td>
</tr>
<tr>
<td>Mostly like me</td>
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<td>Somewhat like me</td>
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<td>Not much like me</td>
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<tr>
<td>Not like me at all</td>
<td>5</td>
</tr>
<tr>
<td>4. Setbacks don’t discourage me.</td>
<td>Score</td>
</tr>
<tr>
<td>Very much like me</td>
<td>5</td>
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<tr>
<td>Mostly like me</td>
<td>4</td>
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<tr>
<td>Somewhat like me</td>
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<tr>
<td>Not much like me</td>
<td>2</td>
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<tr>
<td>Not like me at all</td>
<td>1</td>
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<td>Question</td>
<td>Question Score</td>
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<tr>
<td>5. I have been obsessed with a certain idea or project for a short time but later lost interest.*</td>
<td></td>
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<tr>
<td>Very much like me</td>
<td>1</td>
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<td>Mostly like me</td>
<td>2</td>
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<tr>
<td>Somewhat like me</td>
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<tr>
<td>Not much like me</td>
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</tr>
<tr>
<td>Not like me at all</td>
<td>5</td>
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<tr>
<td>6. I am a hard worker.</td>
<td></td>
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<tr>
<td>Very much like me</td>
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<tr>
<td>Mostly like me</td>
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<tr>
<td>Somewhat like me</td>
<td>3</td>
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<tr>
<td>Not much like me</td>
<td>2</td>
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<tr>
<td>Not like me at all</td>
<td>1</td>
</tr>
<tr>
<td>7. I often set a goal but later choose to pursue a different one.*</td>
<td></td>
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<tr>
<td>Very much like me</td>
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<td>Mostly like me</td>
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<tr>
<td>Somewhat like me</td>
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<tr>
<td>Not much like me</td>
<td>4</td>
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<tr>
<td>Not like me at all</td>
<td>5</td>
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<tr>
<td>8. I have difficulty maintaining my focus on projects that take more than a few months to complete.*</td>
<td></td>
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<tr>
<td>Very much like me</td>
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<tr>
<td>Mostly like me</td>
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<tr>
<td>Somewhat like me</td>
<td>3</td>
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<tr>
<td>Not much like me</td>
<td>4</td>
</tr>
<tr>
<td>Not like me at all</td>
<td>5</td>
</tr>
<tr>
<td>9. I finish whatever I begin.</td>
<td></td>
</tr>
<tr>
<td>Very much like me</td>
<td>5</td>
</tr>
<tr>
<td>Mostly like me</td>
<td>4</td>
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<tr>
<td>Somewhat like me</td>
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<tr>
<td>Not much like me</td>
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<tr>
<td>Not like me at all</td>
<td>1</td>
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</table>
### 12-Item Grit Scale*

<table>
<thead>
<tr>
<th>Question</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>10. I have achieved a goal that took years of work.</strong></td>
<td></td>
</tr>
<tr>
<td>Very much like me</td>
<td>5</td>
</tr>
<tr>
<td>Mostly like me</td>
<td>4</td>
</tr>
<tr>
<td>Somewhat like me</td>
<td>3</td>
</tr>
<tr>
<td>Not much like me</td>
<td>2</td>
</tr>
<tr>
<td>Not like me at all</td>
<td>1</td>
</tr>
<tr>
<td><strong>11. I become interested in new pursuits every few months.</strong></td>
<td></td>
</tr>
<tr>
<td>Very much like me</td>
<td>1</td>
</tr>
<tr>
<td>Mostly like me</td>
<td>2</td>
</tr>
<tr>
<td>Somewhat like me</td>
<td>3</td>
</tr>
<tr>
<td>Not much like me</td>
<td>4</td>
</tr>
<tr>
<td>Not like me at all</td>
<td>5</td>
</tr>
<tr>
<td><strong>12. I am diligent.</strong></td>
<td></td>
</tr>
<tr>
<td>Very much like me</td>
<td>5</td>
</tr>
<tr>
<td>Mostly like me</td>
<td>4</td>
</tr>
<tr>
<td>Somewhat like me</td>
<td>3</td>
</tr>
<tr>
<td>Not much like me</td>
<td>2</td>
</tr>
<tr>
<td>Not like me at all</td>
<td>1</td>
</tr>
</tbody>
</table>
Word Counts

Thesis Abstract
297 words

Chapter 1 - Meta-analysis and systematic literature review
Abstract – 276 words
Main text (excluding tables and figures) – 5139 words
Tables, figures, and references – 4261 words
Total – 9676 words

Chapter 2 - Empirical research paper
Abstract – 164 words
Main text (excluding tables and figures) – 4471 words
Tables, figures, and references – 3362 words
Total – 7997 words

Chapter 3 - Contributions to theory and clinical practice, and reflection
Main text (excluding tables and figures) – 3653 words
Tables, figures, and references – 1898 words
Total – 5551 words

Thesis Total
23521 words