REACT-Recovery Enhancement from Traumatic Brain Injury using Acceptance and Commitment Therapy; A Feasibility Study

& Clinical Research Portfolio

Volume I
(Volume II bound separately)

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Submitted in partial fulfilment of the requirements for the degree of Doctorate in Clinical Psychology (DClinPsy)

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July 2015

Acknowledgements

Firstly I would like to extend a big thanks to my supervisors, Professor Tom McMillan, Dr Hamish McLeod and Dr Ross White for all their ongoing guidance, support and enthusiasm throughout this project, it was very much appreciated. A big thank you to Dr Brian O'Neill, my field supervisor, and Dr Nikki Patterson for your help and support in ensuring this project was possible, without your enthusiasm to trial this treatment the study would never have happened. I would also like to thank Diane Whiting for not only sharing the therapy manual and client workbook she developed so that we could complete our project, but also for her support during the study process. The answers and guidance you gave were really appreciated. Thank you also to the heads of service, Assistant Psychologists and nursing staff at Graham Anderson House, Daniel Yorath House and York House for helping to ensure this project ran smoothly. Huge thanks also to the participants in the study for giving up their time; I would like to dedicate the work to them.

Thank you to my friends and family. My parents, Cathy and Leslie, and my brothers David and Richard, for your continued support from across the pond. Special thanks to my boyfriend Garry for your support particularly in the last few months; you listened to my ramblings, provided me with coffee and cleaned the dishes, I couldn't have asked for more. Lastly I would like to say a big thank you to my proof readers Jane and Tracey, my fellow classmates, but particularly my "other half" Niamh. I could not have done this without you.

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Chapter One: Systematic Review

Prevalence of Head Injury in a Prison Population: A Systematic Review

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Submitted in partial fulfilment of the requirements for the degree of Doctorate in Clinical Psychology. Written in accordance with the guidelines for submission to the Journal Neuropsychological Rehabilitation (Appendix 1.5).

Word count 6103, including abstract and references.

Abstract

Objective:

Following transfer of responsibility of health care for people in prisons in Scotland to the NHS in 2011, there has been growing interest in understanding the service-need for people with head injury (HI). As an initial step, this review systematically assesses the literature on the prevalence of HI in people in prisons and the proportion of these with persisting disability.

Methods:

Searches were carried out using electronic databases (PsycINFO, Cochrane Databases, MEDLINE, EMBASE, Web of Science). Reference lists of two meta-analyses were checked for papers relevant to the prevalence of HI in adult prison populations

Results:

Eight studies were included. They report HI prevalence in samples of prisoners of 25-86%. Quality was rated as low in seven (30-43%) and very-low in one (19%). One study reported upon disabilities associated with HI. Overall, these studies use a range of HI definitions, unrepresentative samples and do not use matched-controls.

Conclusion:

The prevalence of HI in prisoners remains unclear. This is linked to the low quality of study design and methods used. Service need is unclear because few studies consider whether disability has persisted after HI.

Keywords: Systematic Review, Prison, Head Injury, prevalence

Introduction

It is estimated that every year Traumatic Brain Injury (TBI) affects 10 million people throughout the world (Hyder, Wunderlich, Puvanachandra, Gururaj, & Kobusingye, 2007). According to Menon, Schwab, Wright and Maas (2010) "TBI is defined as an alteration in brain function, or other evidence of brain pathology, caused by an external force" (p. 1638), where altered brain function can include loss of consciousness (LOC), retrograde or post-traumatic amnesia, confusion, disorientation or neurological deficit. In a number of cases it can be unclear whether the difficult that has arisen is in fact TBI, particularly if the injury was less severe, consequently the term Head Injury (HI) will be used in place of TBI for the purpose of this paper. Risk for sustaining a HI is linked to lower socioeconomic status (SES), young males and a history of previous HI (McMillan, 2010), a similar cohort to those at increased risk of antisocial behaviour (Miller, 1999). Following HI there can be wide-ranging implications for a person's life (Carroll & Coetzer, 2011). Neurobehavioural and personality changes that are associated with antisocial behaviour are often reported; these include aggression, poor judgement, egocentricity, poor insight, tactlessness and a lack of concern for others (Miller, 1999). Such difficulties, particularly impulsivity, emotional instability and irritability (McAllister, 2008), may give rise to an increased risk of antisocial behaviour; further antagonised by a person with HI's lack of awareness of these changes (McAllister, 2008). HI is reported as ranging from 25-87% among incarcerated samples (Barnfield & Leatham, 1998; de Souza, 2003; Morrell, Merbitz, Shelley & Santosh, 1998; Schofield et al., 2006a; Slaughter, Fann & Ehde, 2003). If such prevalence rates are accurate, they may signify an unmet service-need in prisons.

According to McMillan (2010) the evidence base for the prevalence of HI among adult prison populations is not robust. It is true that existing studies have used several HI definitions, different methods of HI screening and are drawn from a variety of incarcerated samples (Shiroma, Ferguson, & Pickelsimer, 2010); yet no study has systematically investigated the accuracy of this claim. A meta-analysis by Shiroma et al (2010) noted methodological problems in many studies. By conducting sub-group analyses they showed that prevalence rates are associated with methodological differences. They estimated that the prevalence of HI was 60% in offender populations (prison populations, death-row inmates, high security inpatient psychiatric hospitals, sexual offender groups), 68% in a general incarcerated sample (e.g. prison, jail) and 50% if a more conservative definition of HI that requires LOC is used. The studies were not evaluated for quality. A meta-analysis by Farrer and Hedges (2011) sought to compare the prevalence of HI in incarcerated groups with the general population. They reported a higher prevalence of HI in the incarcerated groups (unweighted pooled prevalence of 52%; source studies reported a prevalence of TBI from 10-86%), however the general population samples (prevalence of 2-39%) were not matched for SES and the studies were not rated for quality. The community controls included inappropriate samples such as college students and it was unclear whether gender was controlled for. As HI is more common in males (Corrigan, Selassie, & Orman, 2010), this needed to be controlled for in the comparison group.

Amongst individuals who suffer HI in the general population, over 90% are thought to be mild (Cassidy et al., 2004). The prognosis for those who experience a single incident mild HI tends to be good with most making a full recovery within three-months and

many within days or weeks of the incident (Ettenhofer & Abeles, 2008). When symptoms persist, factors such as psychological distress, pain or compensation/litigation can be relevant (Carroll, Cassidy, Peloso et al., 2004). Therefore, when considering service-need, it is important to take into account the persisting effects of HI rather than simply whether HI has occurred. In the context of this review, insights into service-need are important given the transfer of responsibility for prisoners' healthcare in 2011 from the Scottish Prison Service to the NHS. As the available literature base currently suggests a high prevalence of HI among this population, the needs of people with HI in prison are being considered by both the NHS and the Scottish Parliament (MacAskill, 2014; Scottish Parliament Justice Committee, 2014).

This systematic review assesses the evidence on the prevalence of HI in adult prisoners and from those studies the prevalence of disability arising from HI in prisoners will also be examined.

Method

Search Strategy

Relevant studies were identified by searching the following electronic databases:

- Ovid Medline® In-Process and Other Non-Indexed Citations (1946-31.3.15)
- Ovid EMBASE 1947 – Present, updated daily (1946-31.3.15)
- Ebsco PsycINFO (1987-31.3.15)
- Web of Science (1990-31.3.15)
- Wiley Cochrane Library

The following search criteria were used in text-word searches in the above databases:

((criminal* OR inmate* OR prisoner* OR offender*))

((“Traumatic Brain Injury” OR TBI OR “Head Injur*”))

To denote a Traumatic Brain Injury as a phrase *Traumatic Brain Injury* was used in Cochrane Library and “Traumatic Brain Injury” was used in OVID, Web of Science and EBSCO.

The two text-word searches were combined using the Boolean operator AND. The last search was conducted 31.3.2015. In addition, the reference lists of Shiroma et al’s (2010) and Farrer and Hedges (2011) meta-analyses were searched for further studies of relevance (see Appendix 1.1). Decisions to include or exclude studies were based on selection criteria.

Selection Criteria

Studies obtained by the search were initially screened by titles, and then abstracts before the full article was read and considered using the following criteria:

- Printed in English
- Used an adult prison population (aged 18 and over)
- Specifically identified prevalence of HI

Studies were excluded if they were unpublished dissertations, book chapters, conference abstracts or used a sub-group of offender populations (e.g. high security inpatient psychiatric hospitals, death row inmates, sexual offender groups) or a mixed group of offenders (e.g. prison and police custody).

Duplicates were removed.

Assessment of methodological criteria

The author devised a rating scale to assess study quality and risk of bias. This rating scale modified the framework of the Strengthening the Reporting of Observational Studies in Epidemiology checklist (STROBE; von Elm et al., 2007) for use as a quality-rating tool by including or adapting items to specifically address the research questions (see Appendix 1.2). The structure of the STROBE checklist was adhered to; title/abstract, introduction, methods, statistical methods, results and discussion of each article was assessed. The items were amended in order to assess the quality of each study in relation to the specific research questions asked, rather than assessing the general quality of each study.

The quality rating scale comprised of 32 items with a maximum score of 115 (Appendix 1.2). High quality articles were categorised as those with quality rating scores greater

than 70%; moderate quality 50-69%; low quality 30-49% and very-low quality as less than 30%. Inter-rater reliability was assessed by another Trainee Clinical Psychologist second-rating four articles using the quality-rating tool. Four articles were chosen at random as this number represented 50% of the total number of included papers. There were no differences in the total scores for three, and a difference of four points on one paper (Appendix 1.3). Disagreements were resolved by discussion.

Search Questions

1. To assess the quality of studies reviewing the prevalence of HI in adult prisoners
2. To assess the prevalence of disability arising from HI in adult prisoners

Results

Search Results

After removing duplicates, 728 references were identified. Of these, 675 were deemed ineligible on the basis of title and a further 38 on the basis of abstract. Fifteen articles were read in full. Of these, seven were excluded as they included non-prison participants. Overall, eight studies were included which identified the prevalence of HI in adults in prison (see Figure 1).

Two of these eight studies reported behavioural or neuropsychological symptoms arising from HIs and one further study discussed on-going disabilities, but did not report disability prevalence (Table 1).

Methodological Quality Rating

The quality of the studies ranged between 19% and 53%. Seven papers were rated as low quality (Bogner & Corrigan, 2009; Barnfield & Leathem, 1998; Colantonio et al., 2014; Ferguson, Pickelsimer, Corrigan, Bogner, & Wald, 2012; Morrell et al., 1998; Ray, Sapp, & Kincaid, 2014; Williams et al., 2010) and one as very-low quality (Templer et al., 1992).

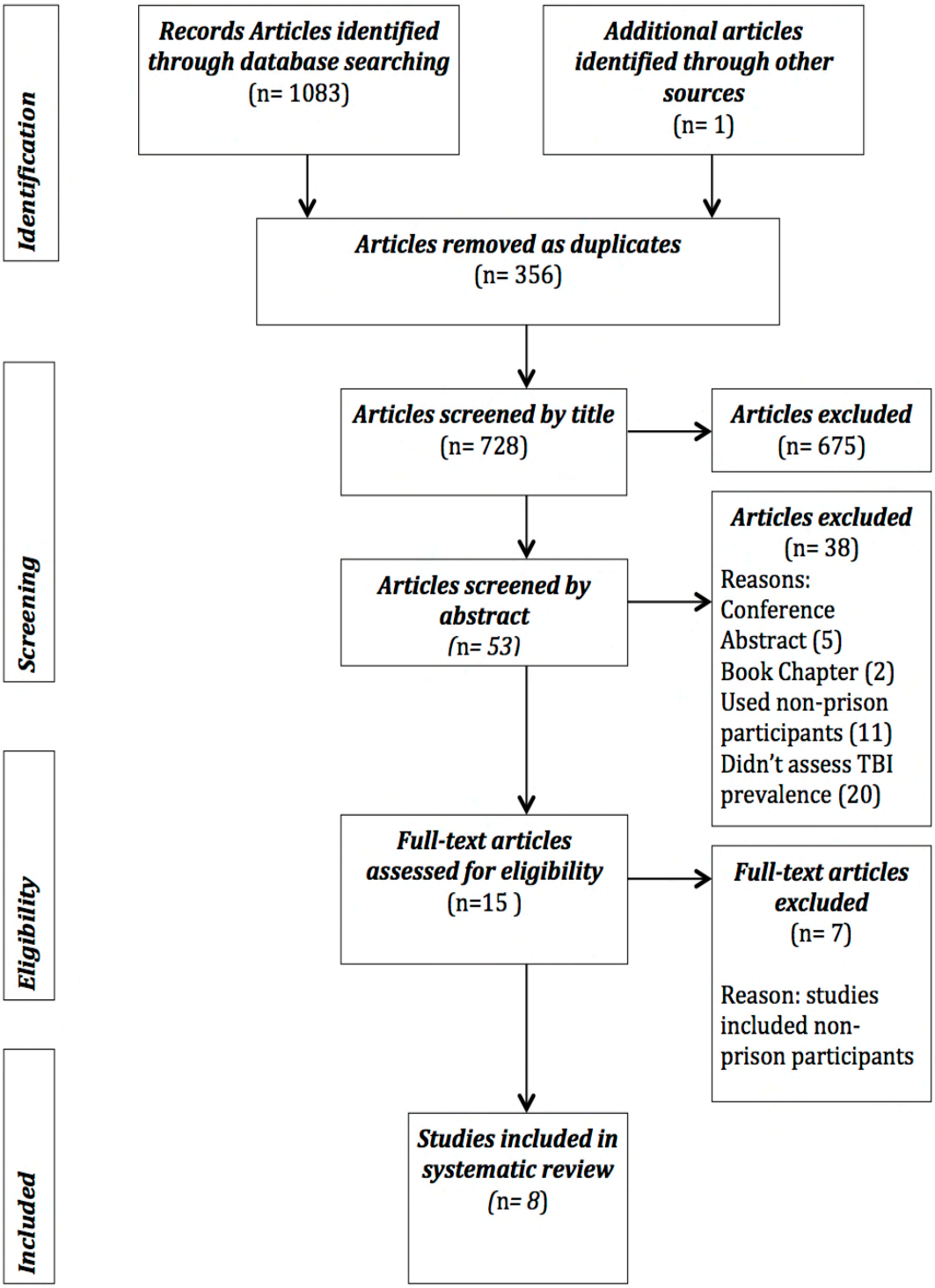

Figure 1. Flow chart detailing included/excluded studies

Table 1.
Data extraction table

Authors, Year	**Source population (#M, #F)**	**HI measure**	**HI definition**	**HI disability outcome measured**	**HI severity**	**Rates of Neuropsychological /behavioural symptoms reported**	**Prevalence of HI in Non-prison Control group reported; Controls were:**	**Total Prevalence of HI in prison population**		**Total Prevalence of HI in comparison group**		**Quality score**
								n	**(%)**	**n**	**(%)**	**(%)**
(Barnfield & Leathem, 1998)	NZ (188M)	Self report questionnaire	Any HI	Yes	LOC duration combined with number of HIs	No	No	n/a	86	n/a	n/a	41
(Bogner & Corrigan, 2009)	USA (105M); (105F)	Validated structured Interview	All injuries requiring medical attention or injury to the head or neck that resulted in altered consciousness	No	LOC duration	No	No	164	78	n/a	n/a	30
(Colantonio et al., 2014)	Canada (131M; 104F)	Self report, interview	Any HI	No	LOC duration	No	No	102	43	n/a	n/a	38

(Ferguson, Pickelsimer, Corrigan, Bogner, & Wald, 2012)	USA (320M; 216F)	Validated structured interview	Injuries requiring medical attention or injury to the head/neck resulting in altered consciousness	No	LOC duration	Yes	No	? M ? F	65 72	n/a	n/a	41
(Morrell et al., 1998)	USA (1000?)	Structured interview	Any HI	No	LOC duration	Yes	No	249	25	n/a	n/a	43
(Ray, Sapp, & Kincaid, 2014)	USA (831M)	Validated structured interview	All injuries requiring medical attention or injury to the head or neck that resulted in altered consciousness	No	LOC duration	No	No	297	36	n/a	n/a	39

(Templer et al., 1992)	USA (1055; 322 prison participants)	Self report questionnaire	Any HI with LOC	No	Not reported	No	Yes 1. Fresno State University Introductory Psychology students 2. Fresno City College students 3. Fresno State University college football players 4. California School of Professional Psychology	322	36	Cntrl1 Cntrl2 Cntrl3 Cntrl4	41M 23F 18M 22F 26M 32M 1F	19	
(Williams et al., 2010)	UK (196M)	Self report questionnaire	Any HI	No	LOC duration	No	No	119	65	n/a	n/a	31	

Abbreviations: Aus, Australia; Cntrl, control; F, Females; LOC, Loss of Consciousness; M, males; HI, Head Injury; UK, United Kingdom, USA, United States of America; ?, unknown

Low Quality Articles

Morrell et al. (1998) – 43%

This study reported the prevalence and effects of HI in a male prison sample (N=1000), consecutively admitted to an unreported number of prisons in a US Midwestern state. No details were provided in relation to the broader prison population or the recruitment time-period, and it is unclear whether the sample is representative of the population of these prisons. A brief structured interview assessed whether participants ever had a "head injury" before asking about hospitalisation, duration of LOC and long-term consequences. Results indicated that 25% of the sample reported a HI. Severity of HI was stratified by LOC duration, no LOC (24%), LOC of one minute or less (7%), 1-5 minutes (26%), 5-30 minutes (15%), ½-2 hours (13%), 2-6 hours (2%), 6-12 hours (2%), 12 hours-2 days (5%) or more than 2 days (4%). No rationale was given for these categories. If considering prevalence in terms of the more widely accepted categories of mild (LoC< 30 minutes) and moderate-severe (LoC> 30 minutes; Carroll, Cassidy, Holm, Kraus & Coronado, 2004) they are 48% and 26% respectively. At least one residual symptom was reported in 20% of those with a HI of any severity. Learning and memory difficulties were reported in 11% of the head-injured prisoners, 10% reported behavioural changes, 7% reported injury-related dizziness and 6% coordination difficulties and speech problems. How such symptoms impacted their daily lives in terms of on going disability is not described, nor is there a matched-population comparison. Morrell et al. (1998) note that the research is limited by the use of self-report measures but suggest that if one in four prisoners report a HI then further research into behavioural interventions for this group is warranted, despite not identifying the behavioural problems elicited.

Fergusson et al. (2012) – 41%

This study reported rates of HI amongst a US sample of prisoners in 30 prisons in South Carolina who were released during the data collection period or had lifetime or death sentences. To assess HI a customised version of the Ohio State University Traumatic Brain Injury Identification Method (OSU-TBI-ID; Bogner & Corrigan, 2009) was used. Results of the study indicated that test/retest reliability ranged from acceptable to high and the measure had good predictive validity. The authors caution that the findings may not generalise outwith or within South Carolina because of exclusion criteria, such as arrests outside of South Carolina, being younger than 18 years, and having difficulty understanding informed consent. Participants were asked if they experienced any injury requiring medical attention (whether or not they obtained it) before asking whether they had experienced injury to the head or neck resulting in altered consciousness. Severity of HI was classified as HI with LOC (altered conscious, <5 minutes, <30 minutes, >30 minutes). Results indicated that 65% of male and 72% of female prisoners reported at least one HI, see table 2 for details.

Table 2.

Prevalence of HI

	Males		Females	
	Release	Life/Death	Release	Life/Death
HI with LOC	42%	50%	50%	33%
Repeat HI	35%	42%	43%	49%
Repeat HI with LOC	15%	23%	20%	12%
HI on-going symptoms	35%	42%	55%	58%

The number of persistent symptoms reported increased with HI severity. The most common persistent symptom for both genders was headaches (males 59%; females 66%). Dizziness and balance problems were commonly endorsed by women (50%) and feeling slowed down (42%) and vision problems (44%) were commonly endorsed by men. Of the 431 participants 29% of male releases, 41% of male non-releases, 47% of female releases and 25% of female non-releases reported that family or friends said they "acted differently" post HI.

Although rates of persisting symptoms are reported, no details are provided about the prevalence of disability among the prison sample. No control group is used and the use of a specific geographical cohort limits generalisability of the findings.

Barnfield & Leathem (1998) – 41%

This study investigated the rates and effects of HI, in a sample of prisoners (N=118) in one prison in New Zealand. Fifty-percent of the initial participant pool (N=360) were unavailable due to risk issues and other commitments. HI was assessed using a non-validated questionnaire designed for the study. No demographic details are provided for the overall prison population. In addition to general questions about the occurrence of 'head injuries', whether they experienced LOC and duration of LOC, selected questions from the Patient Competency Rating Scale (PCRS; Prigatano, 1986) and Cognitive Failures Questionnaire (Broadbent, Cooper, Fitzgerald, & Parkes, 1982) were combined and reworded to simplify the language. This 'Problem Rating Scale' was used to ascertain the nature of everyday difficulties experienced by those who sustained a HI and shown to have good internal consistency (r=0.93).

HI was reported by 86% of the sample. The authors developed a method of classifying severity for the study that combines total duration of LOC and the number of HIs reported. Their severity definitions were not validated and described by the authors as having "arbitrary cut-off points" (Barnfield & Leathem, 1998, p.462). For these reasons the data cannot be seen as reliable. Frequency of HI by severity was reported as 41% mild, 29% moderate and 11% severe TBI. The mean scores on the PCRS indicated that the participants reported mild impairments in memory, socialisation and impulse control.

The authors reported that the prevalence noted in the sample suggests a disproportionately high occurrence of HI in the prison population. They suggest that a general population comparison group would be important in future research. They also suggest that there is a need for a new HI severity classification system that considers both the number and severity of TBI sustained.

Ray et al. (2014) – 39%

This study examined the prevalence of HI among male prisoners in US Indiana State (number of prisons recruited is not reported) using a short version of the OSU-TBI-ID. The tool has good reliability and predictive validity (Bogner & Corrigan, 2009). Participants (N=831) were recruited from prison entrants within a data collection period of 28-days, no details were provided about the wider prison population. The self-report interview examined whether prisoners had sustained an injury to the head or neck resulting in altered consciousness. Severity was determined by estimating duration of

LOC. 'Possible' (6%) or mild (20%) HI was defined as being dazed, or having a 'brief' lapse in memory or LOC, and moderate (6%) or severe (4%) as LOC for more than 30 minutes. Overall, 36% reported a HI. This study did not compare results to the general population and did not report on-going neurological symptoms or disability. The authors are cautious in interpreting their findings given the focus on males in a single US state.

Colantonio et al. (2014) – 38%

This study examined the prevalence of HI in a sample of men and women in four prisons in Ontario. There was a 72% recruitment rate (N=235) among those invited. No information is provided about overall populations in the included prisons, and it is unclear whether the sample is representative. Recruitment procedures varied at each institution, but all were based on a random sample of newly admitted prisoners over a three-month period. Each prisoner was asked two questons about their history of HI 'have you ever had an injury to the head, which knocked you out or at least left you dazed, confused or disoriented? And 'how many injuries like this have you had over your lifetime?'. If they reported a history of HI, follow-up questions regarding LOC duration were asked. Severity was defined as mild (LOC of 30 minutes or less) or moderate to severe (LOC of 30 minutes or more) and were based on the American Congress of Rehabilitation Medicine's definition of mild HI (1993). HI was reported in 43%. In 34% HIs were mild and in 33% moderate to severe. When divided into gender 37% of females and 50% of males reported having a HI. They conclude that there is a need to screen for HI in correctional programmes using a validated questionnaire such as the OSU-HI-ID that would provide a more detailed HI history than gathered in their

study. They report that screening could help tailor rehabilitation approaches; however they provide no data on neurological symptoms or associated disability.

Williams et al. (2010) – 31%

This study aimed to establish the prevalence of HI in a sample of male adult prisoners in one prison in the UK. Of the 453 prisoners approached 43% participated (N=196); no details are provided about those who did not participate. A self-report questionnaire was used to determine HI and severity was determined by LOC duration (mild=no LOC or less than 10 minutes; moderate=10minutes to 6 hours; severe=more than 6 hours). According to this severity definition, self-report of HI occurred in 65% (16% moderate-severe and 48% mild HI). Sixty-percent of those with mild HI reported more than one mild HI. The authors did not evaluate neuropsychological effects or disability. They suggest that future research should examine HI severity and associated deficits and conclude that HI appears to be a key factor to be addressed in offender rehabilitation programmes.

Bogner & Corrigan, (2009) – 30%

The primary purpose of this paper is to assess the reliability and predictive validity of the OSU-TBI-ID in prisoners. The study used this structured self-report interview measure to assess the prevalence, severity and effects of HI in a convenience sample of male and female prisoners in US Ohio State. They asked if prisoners had experienced any injury requiring medical attention prior to examination and if they experienced an injury to the head or neck resulting in altered consciousness. They found that 78% of the sample reported a HI. Severity was defined by length of LOC with 93% mild (LOC

<30 minutes). Episodes of multiple mild HIs were counted as one injury. Multiple moderate or severe HIs were reported in 3% of the sample.

Very-low Quality Articles

Templer et al. (1992) – 19%

This study sought to explore the prevalence of HI which received no medical attention in California among male prisoners and four control groups of University students (California School of Professional Psychology, Fresno City College students, Fresno State University college football players and Fresno State University Introductory Psychology students). No rationale was given for choosing these samples. All participants were administered a brief questionnaire to ascertain whether they ever had a HI with LOC. No details were provided about the wider prison population. Results indicated that 36% of male prisoners reported one or more HIs compared to 41% of male controls, however no inferential statistics were conducted comparing the prison to control samples. In addition, 47% of the prisoner group reported permanent "lasting effects" from HI compared to 5-25% of the controls. Further details about what constituted "lasting effects" were not provided. The study is limited by the lack of detail provided and the inappropriateness of the control groups.

Discussion

Increasing expenditure on psychological therapies in prison is being considered in the UK and evaluating the evidence base for need is important (Williams, 2012). Following an event organised by the British Psychological Society that looked at the issues of HI and offending behaviour and the current challenges in identifying and treating prisoners with HI, a parliamentary initiative to investigate the needs of people with HI in Scottish prisons was developed. In a meeting of the brain injury and criminal justice system group the need for a comprehensive epidemiological study assessing TBI prevalence in Scottish prisons was noted as an important starting point (Scottish Parliament Justice Committee, 2014). Prior to starting this however, there is a need to know how TBI has been assessed in previous studies and whether these studies were of good quality. The eight studies included in the review were published between 1992-2014. The low quality of the studies reflects methodological weaknesses and it is difficult to reach firm conclusions with regard to the questions posed.

What is the prevalence of HI in prisoners?

Despite narrowing the focus of the review by omitting studies that used a single sub-group of offender populations (e.g. death row only, sexual offenders etc.), prevalence of HI ranged from 25-86%. Two meta-analyses (Farrer & Hedges, 2011; Shiroma et al., 2010) to date have investigated HI prevalence among incarcerated samples, but neither assessed the quality of the design used. As reported by Crombie and Davies (2009) meta-analyses are "fundamentally limited by the quality of the underlying studies" (p.7). Although both meta-analyses attempted to control for heterogeneity in methodology by using a random-effects model, when heterogeneity is great it is often

inappropriate to calculate a summary measure, particularly if relying on papers of low quality (Crombie & Davies, 2009).

The variability in the definitions of HI used by the studies is likely to contribute to the wide range in prevalence reported. A good prognosis is expected after mild HI, which typically comprises 90% of the HI population. In considering service-need, the identification of moderate and severe HI prevalence therefore seems important. Despite the fact that severity is reported in seven studies and was primarily based on LOC duration only (six studies), few used recognised cut-offs to stratify severity and none obtained corroboration (e.g. from hospital records). In four studies where severity of HI could be calculated to be LOC of more or less than 30 minutes (see table 3), a wide range in prevalence of moderate-severe HI remained (7-37%). One study (that was published as several papers) was not included in this review due to their use of a mixed group (custody and prison sample; Perkes, Schofield, Butler & Hollis 2011; Schofield et al., 2006a; Schofield et al., 2006b; Schofield, Butler, Hollis & D'Este, 2011). This study compared the prevalence of HI to a sample of community controls matched for SES. They reported that HI (with or without LOC) was significantly more common in the custody/prison group (82% vs. 72%). The occurrence in the control group was surprisingly high, as was the higher percentage of controls (14% V 9%) reporting moderate-severe HI. It should be noted that 62% of the prison sample did not know the length of LOC after their most recent HI in this study.

The eight studies were conducted in only five Western countries; five studies were conducted in the US and one each in New Zealand, UK, Canada and Australia. The generalisability of the prevalence rates among the wider prison population consequently remains unclear.

Table 3.

Severity prevalence based on LOC duration where calculation was possible.

	Morrell et al. (1998)	**Ray et al. (2014)**	**Colantonio et al. (2014)**		**Bogner& Corrigan (2009**
Gender	Unknown	M	M	F	M+F
LOC < 30 minutes	48%	20%	34%	34%	93%
LOC > 30 minutes	26%	12%	33%	37%	7%
Quality Rating	43%	39%	38%		30%

Abbreviation: M=male; F=female; LOC=loss of consciousness; <=less than; >=more than

What is the prevalence of disability arising from HI in prisoners?

Although the majority of studies considered disability outcome to be an important factor to assess, it was rarely investigated. Barnfield and Leathem (1998) found that the prisoner/HI group reported persistent symptoms using the amended PCRS. They did not provide details on the prevalence of the problems or on any disabling consequences. Given that the evidence base is restricted to this single study of low quality, it is difficult to form firm conclusions regarding potential service-need. Alternative explanations for the origin of these complaints, which are not considered and are particularly relevant to those with mild HI, include malingering (Mittenberg, Patton,

Canyock, & Condit, 2002), the presence of a psychosomatic disorder or beliefs that a negative event leads to a negative outcome (Mittenberg, DiGiulio, Perrin, & Bass, 1992).

Prevalence in Juvenile Offenders

A recent systematic review on HI in juvenile offenders (Hughes et al., 2015) concluded that given the heterogeneity of research designs in published studies it is not possible to calculate a robust estimate. Such methodological issues between the reviewed studies include varying definitions of HI, HI assessed by different measures and variation in populations recruited. It would seem that the limitations within the youth literature parallel the limitations in the adult literature.

At present there is no agreed guidance on the screening of HI among adult prison populations. In the corresponding child literature, there are several position papers proposing the need for early intervention and routine assessments (British Psychological Society, 2015; Hughes, Williams, Chitsabean, Davies & Mounce, 2012; Williams, 2012). In screening the youth population and developing further protocols for screening the adult population, clinicians need to accurately determine any on-going disability emanating from HI, that suggests a treatment need. Ultimately however, developing proactive strategies to prevent HIs may be the most cost-effective strategy.

Strengths and limitations of the current review

In order to control for a limitation reported by Shiroma et al., (2011) this study explored the prevalence of HI and disability among prison populations only. It was hoped that

this would help control for some of the variance associated with examining studies which used single sub-groups of offenders (e.g. sex offenders).

While the quality rating scale developed specifically for this systematic review was based on a validated measure (von Elm et al., 2007), its validity has not been established.

Future research

There is a need to use a standard definition of HI and HI severity, incorporating matched-controls and studies need to carefully reflect prevalence in prison populations or clearly identified representative samples. This would facilitate comparisons between studies. There is also a need to obtain corroboration from medical records, at least for moderate to severe HI, where hospital admission is likely.

As was noted in much of the research, future studies need to use validated assessments of disability for HI that do not entirely rely on self-report in order to develop a greater understanding of HI severity, any persisting neuropsychological/behavioural symptoms and the resulting disability outcome. This is required in order to estimate service-need.

Furthermore very limited information is known about rates of HI among female prisoners, so increased research among this gender group is required.

Conclusion

This is the first study to assess the quality of the literature on HI prevalence among adult prisoners. While studies often state that HI is common among this population, the methodological limitations of the studies mean that the quality of evidence is low. Most studies report that the prevalence of HI in prisons reflects a need for HI rehabilitation, but few provide evidence to support this, and none adequately establish a link between self-report of HI and associated disability requiring intervention. To do this, and simultaneously improve study quality, homogeneity in research design is required. If this is achieved, it will help ascertain the clinical-need of this population.

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Chapter 2: Major Research Project

REACT-Recovery Enhancement from Traumatic Brain Injury using Acceptance and Commitment Therapy; A Feasibility Study

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Submitted in partial fulfilment of the requirements for the degree of Doctorate in Clinical Psychology. Written in accordance with the guidelines for submission to the Journal Neuropsychological Rehabilitation (Appendix 1.5).

Word count 6463, including abstract and references.

Plain English Summary

What is Traumatic Brain Injury?

Traumatic Brain Injury (TBI) is a head injury that occurs after a blow or trauma to the head, often experienced after an assault or road traffic accident. TBI is often associated with depression and anxiety. People with severe TBI (sTBI) are particularly at risk of these mental health difficulties. Psychological therapies may help treat these difficulties, however, at present there is little evidence available to support the use of psychological treatments with this population.

What is Acceptance and Commitment Therapy (ACT)?

ACT was developed to help people manage distress. The main goal of ACT is to support the individual to live a life that is important and meaningful to them while accepting the distress that inevitably goes with living. There is limited evidence to suggest that ACT is effective in helping people who have sTBI.

Current Study

This study considers the feasibility of carrying out a larger scale study into the usefulness of ACT with people with sTBI. Prior to conducting a clinical trial, feasibility studies are recommended to assess whether the therapy is acceptable to those with sTBI. The present study aims to do this by:

- Reporting on any missing data

- Assessing participant views on the ACT treatment
- Exploring how useful the treatment measures were

- Reporting on how many people were recruited and dropped out
- Assessing what treatment as usual (TAU; the typical treatment offered to those attending BIRT) was in each group

This was achieved by recruiting participants from the Brain Injury Rehabilitation Trust (BIRT) to two groups. One group received TAU. The other group received six weeks of ACT in addition to TAU (ACT/TAU). Groups were compared using self-report questionnaires before and after treatment that assessed:

- The ability to think flexibly
- Levels of distress
- Self-awareness
- Motivation to participate in rehabilitation
- Participant views of the ACT treatment.

Results

Seventeen participants completed the assessments before and after treatment, four people dropped-out of the study. The majority of participants (77%) found ACT at least 'a little' helpful. Scores on the self-report questionnaires changed for 88% of participants from before to after treatment; 47% of these changes indicated

improvements. Distress scores as measured by the Hospital Anxiety and Depression Scale (HADS), suggested that 35% of people were not distressed at the start of treatment. Both ACT/TAU and TAU groups received similar TAU.

Conclusion

Participants' ratings of ACT as at least 'a little' helpful, together with low dropout rates, suggests that most participants were accepting of the treatment. The changes across treatment in some participants, suggests that the measures were able to explore the effect of ACT. The HADS, however, may not be a suitable measure for this population, as it was unable to pick-up on the participant's level of distress at the start of treatment. In order to recruit more people future research should recruit from more units and extend the recruitment periods. This will allow for future studies to determine whether the treatment is effective.

Abstract

Introduction: Adjustment to disability is considered key in recovery from severe traumatic brain injury (sTBI). Acceptance and Commitment Therapy (ACT) focuses on improving psychological flexibility, which facilitates adjustment after traumatic events and in doing so may improve adjustment.

Objectives: To investigate acceptability and feasibility of ACT for people with sTBI undergoing inpatient neurorehabilitation.

Method: Participants in ACT/TAU (N=9) and TAU (N=8) groups completed assessments. The outcome measures were the Hospital Anxiety and Depression Scale (HADS), the Awareness Questionnaire (AQ) and process measures of psychological flexibility and treatment engagement motivation. All measures were given pre- and post-intervention.

Results: Groups did not differ significantly in terms of TAU received. Treatment acceptability varied, but 77% reported ACT was at least 'a little' helpful. HADS baseline scores were within sub-clinical range for 35% of participants. Reliable Change Index scores indicated desired change on the HADS in 24% of participants. Desired change on the AQ was found in 5% of participants.

Conclusion: The acceptability of ACT to participants varied, nevertheless retention rates were high. Treatment signals were obtained for 24% of participants on the HADS and this may in part reflect the non-clinical scores at baseline. Amendments to methods for future studies are proposed.

Keywords: TBI, ACT, traumatic brain injury, feasibility

Introduction

Traumatic Brain Injury (TBI) is a public health problem associated with long-term psychological consequences including depression and anxiety (McAllister, 2008). A key factor in recovery is adjustment to the effects of injury (McMillan, 2013). Psychological intervention may facilitate adjustment, however, little research has evaluated interventions with this population (SIGN, 2013). Further research into the use of psychological therapy in rehabilitation could play an important role in developing ways to treat emotional disturbance.

Current literature base

The research evidence for the use of psychological therapy with severe TBI (sTBI) is sparse, and methodologically weak (SIGN, 2013), despite research noting that incorporating psychological health into rehabilitation services is important (Khan-Bourne & Browne, 2003). The reasons for poor progress in treatment development have likely been two-fold. Firstly, conducting research with a heterogeneous TBI population is difficult. McMillan (2013) reviewed the methodological issues and concluded that high dropout, use of unrepresentative samples and presence of confounding variables mean it is difficult to predict outcome. Secondly, developing treatments adaptable to TBI sequelae is also difficult. TBI gives rise to deficits in problem solving, cognitive-flexibility, attention, memory and information processing (McAllister, 2008), which may mean individuals have reduced capacity to partake in psychological therapies designed for non-brain injury services.

The psychological therapy research evidence available tends to focus on Cognitive Behavioural Therapy (CBT). Despite the vast evidence base for CBT in treating anxiety and depression in the general population (Linde et al., 2015; Hofmann, Asnaani, Vonk, Sawyer & Fang, 2012), in a recent meta-analysis there were only six randomised controlled trials and two group comparison studies which assessed the effectiveness of CBT in treating people with TBI (Waldron et al., 2013). Given the cognitive deficits displayed by those with sTBI, the use of CBT has been criticised (Anson & Ponsford, 2006). CBT requires engagement in cognitive restructuring, and this involves challenging unhelpful thought processes, which may be difficult given the cognitive impairments often present after TBI (Anson & Ponsford, 2006). As Kashdan and Rottenberg (2010) noted, "devoting finite attention resources and energy to regulating emotions…"steals" time and effort from other strivings" (p.866). A further issue is that published studies have primarily recruited participants with mild-moderate TBI (SIGN, 2013), and findings may not generalise to those with sTBI. Consequently, no specific psychological therapy could be recommended for those with sTBI in the SIGN 130 guidelines (2013). It is clear that further research evaluating the use of psychological therapies with this population is needed.

Acceptance and Commitment Therapy (ACT)

One emerging "third wave behavioural" therapy is ACT (Cullen, 2008). The main aim is not to improve mood (although this is often an outcome) but instead emphasis is placed on improving a patient's ability to accept difficulties in the service of pursuing valued life goals (Harris, 2006). This is known as psychological flexibility. Kashdan and Rottenberg (2010) reviewed the interaction between psychological flexibility and

health and concluded that unlike static approaches that focus on the removal of negative emotions, approaches that focus on psychological flexibility allow for greater adjustment after traumatic events. ACT helps patients to understand that efforts to control emotions can paradoxically maintain problems. Therefore, rather than focusing on regulating emotions through cognitive challenging, as is the case in CBT, ACT focuses on learning to accept difficulties so the main focus can remain on living a valued life. This may be more acceptable to people with sTBI who likely have reduced attentional capacities. Although cognitive flexibility may be a component of psychological flexibility (impaired in sTBI), Whiting, Deane, Simpson, McLeod and Ciarrochi (2015) concluded that it is not a pre-requisite.

ACT and sTBI

Published work on the use of ACT with adult patients who have a brain injury is limited to theoretical reviews and position papers. Kangas and McDonald (2011) propose that ACT could help distressed patients with Acquired Brain Injury (ABI) to live a valued life by accepting the presence of their neurological deficits. Through "self-as-context" and "acceptance" principles these researchers propose that patients with ABI could develop increased self-awareness, a key to positive rehabilitation outcome (McMillan, 2013). Soo, Tate and Lane-Brown (2011) similarly argued for the use of ACT for ABI based on findings that the acceptance of difficulties after ABI promotes the re-construction of self-concept. Unlike CBT, ACT's approach to cognitive defusion does not require intellectualising; instead it uses more concrete processes, which may be more amenable to the individual's capabilities (Whiting, Deane, Simpson et al., 2015). These propositions have yet to be tested in a clinical trial context.

Current research

In summary, it is proposed that there is a need to develop interventions that promote adjustment to TBI. The existing published reviews (Soo et al., 2011) and treatment protocols (Whiting, Simpson, McLeod, Deane & Ciarrochi, 2013) provide a theoretical and practical starting point for this work. As a first step a feasibility study is required.

In line with the Medical Research Council Complex Interventions Framework (MRC, 2008), this group-comparison study examined the feasibility of ACT for sTBI, with the aim of using the information gained to develop a future intervention trial. A second Doctorate in Clinical Psychology (DClinPsy) study with which it was paired (see Appendix 2.1) used focus groups to assess the study protocol. The aims of the present study were:

1. To investigate the availability of data (i.e. whether patients and staff could complete measures, whether relevant demographic data was available, what neuropsychological data was available)
2. To investigate the acceptability of ACT to people with sTBI
3. To explore treatment signals in potential treatment measures
4. To determine rates of patient recruitment and retention
5. To characterise Treatment As Usual (TAU) against which an ACT intervention could be compared

Methods

Ethical Approval

Approval was obtained from West of Scotland Research Ethics Committee and Brain Injury Rehabilitation Trust (BIRT) Ethics Committee (Appendix 2.2-2.3).

Design

The study is a prospective feasibility trial of an ACT intervention for use in inpatient neurorehabilitation for people with sTBI. This design reflects strategies that could be used in cluster-randomised trials. The ACT manual was based on a published protocol being tested with outpatients with TBI (Whiting et al., 2013).

Treatment Units and Participants

Participants were recruited from three BIRT units. All units have comparable service-user profiles, based on data collected by BIRT, and have the same core philosophy following a holistic, non-medical model structure for rehabilitation (Wood & McMillan, 2001). The ACT/TAU (treatment) group was recruited from one unit in order to minimise unintended leakage of treatment principles or practices across groups, the

TAU (comparison) group was recruited from the remaining two units. Care staff (i.e. Nurses, Assistant Psychologists, Support Workers) were recruited from each unit.

Eligibility Criteria

Inclusion criteria for patient participants were (Appendix 2.4): (a) aged over 18 years; (b) had capacity to give consent to participate in research; (c) had sufficient cognitive capacity and English language skills to complete questionnaires; (d) had a sTBI[1] assessed by clinicians at BIRT; (e) exhibited psychological distress or behavioural disability assessed by clinicians at BIRT; (f) were likely able to complete the study (i.e. did not have an agreed discharge date within eight weeks); (g) did not exhibit current severe challenging behaviour (impulsivity, disinhibition and/or aggression) that would put the researcher or participant at risk or prevent study participation.

Inclusion criteria for care staff who were asked to complete the Awareness Questionnaire-Clinician Form were: (a) worked directly with the patient; and (b) had commenced employment at BIRT prior to first assessment.

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[1]TBI severity was classified by satisfying at least one of the following criteria: (a) score of less than 9 on the Glasgow Coma Scale at time of injury (Teasdale & Jennett, 1974);

Recruitment and Research Procedures

Recruitment took place between January and June 2015 during which 24 individuals met the inclusion criteria (ACT/TAU, N=14; TAU, N=10). In total 17 patient participants completed all assessments (ACT/TAU N=9; TAU N=8). Figure 1 details the recruitment flowchart.

All participants recruited (patients and staff) who met inclusion criteria were provided an information sheet and given at least 24 hours to consider participation (Appendix 2.5-2.8). Once researchers (CM; NoM) obtained consent (Appendix 2.9-2.11), baseline measures (time 1) were completed with patients and staff. The same measures were completed post-treatment (time 2); the ACT/TAU group completed an additional satisfaction questionnaire. Two rounds of ACT treatment were provided. During the first round two Clinical Psychologists each ran a group (February-March). During the second round one Clinical Psychologist ran a group (April-June). The same procedure (Figure 2) was followed in each round. Participants who attended five or more of the six sessions were deemed to have completed treatment.

Demographic characteristics.

Demographic and background data were obtained at baseline from patient files. These were: (a) gender; (b) age; (c) best level of occupational attainment; (d) Socio-economic status (SES) (e) Time since TBI; (f) Time since admission to neurorehabilitation; (g) Disability severity assessed by the Glasgow Outcome at Discharge Scale (GODS; McMillan, Weir, Ireland & Stewart, 2013); (h) Cognitive data from routine assessments in the neurorehabilitation units comprised of the Wechsler Test of Pre-morbid

Functioning (TOPF; Wechsler, 2011), Wechsler Adult Intelligence Scale-IV (Wechsler, 2008) subtests: Similarities, Block Design, Coding.

SES was estimated from the Scottish Index of Multiple Deprivation (SIMD; The Scottish Government, 2012) and the English Index of Multiple Deprivation (EIMD; Department for Communities and Local Government, 2011). Direct comparisons between these cannot be made, as the factors used to develop the ratings differ. In order to give an estimation of relative deprivation experienced, the study reported SES ratings within the respective population quintiles.

Measures

Process Measures

These are mediator variables by which ACT operates (Whiting et al 2013). Two process measures were chosen, from Whiting et al (2013).

1. The Acceptance and Action Questionnaire-Acquired Brain Injury (AAQ-ABI; Sylvester, 2011; Appendix 2.12)

The AAQ-ABI is a 15-item questionnaire measuring psychological flexibility. It uses the Likert scale in the revised AAQ-II (Bond et al., 2011), but incorporates simplified language to aid comprehension. It was initially used in a study with paediatric brain injury (Sylvester, 2011). Towards the end of this study validation of a 9-item version of AAQ-ABI was published (α = .89; Whiting, Deane, Ciarrochi, McLeod & Simpson, 2015, appendix 2.13). This validation enabled calculation of reliable change index (RCI) scores, and hence, the short form was used in analyses.

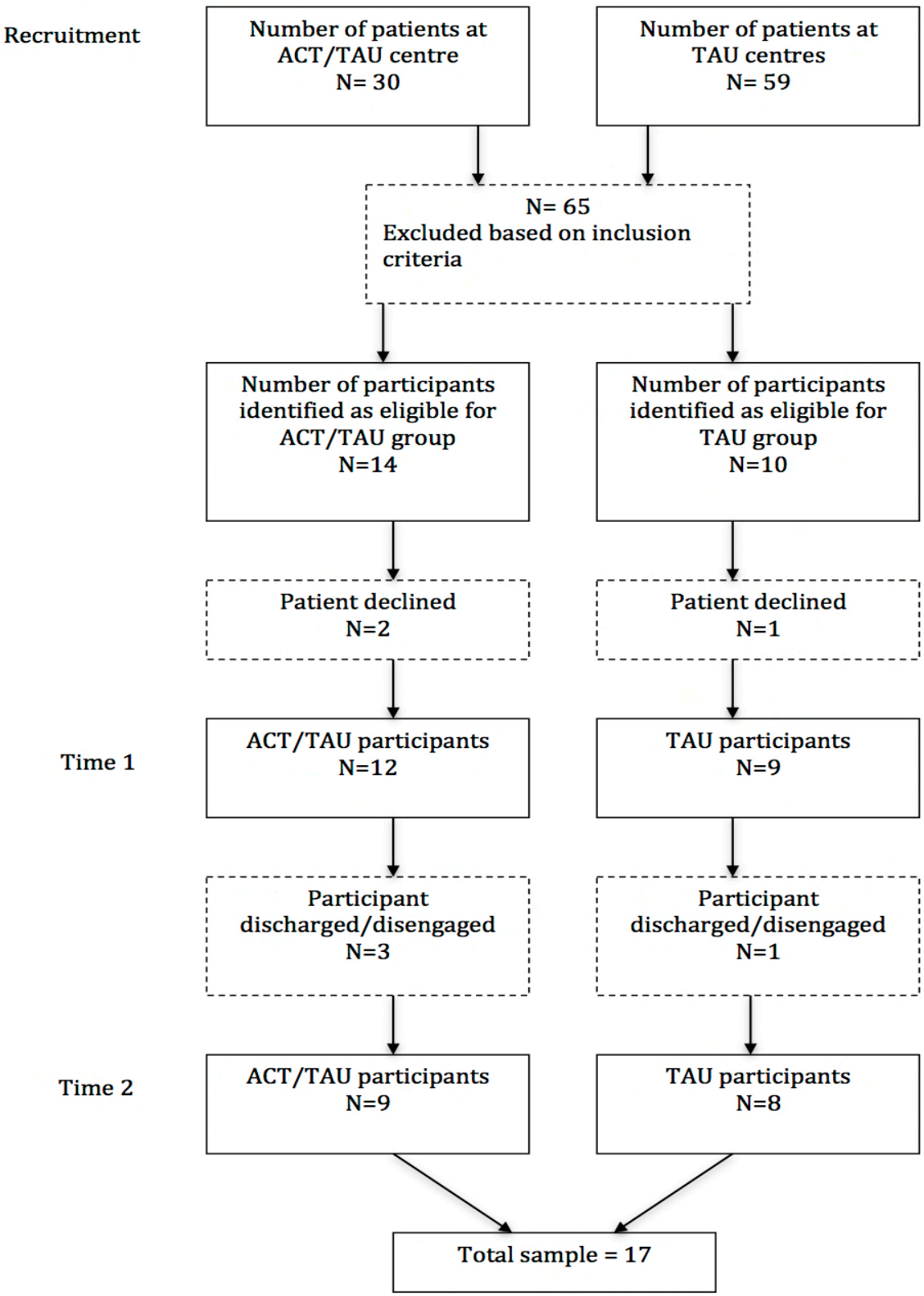

Figure 1. Recruitment Flowchart

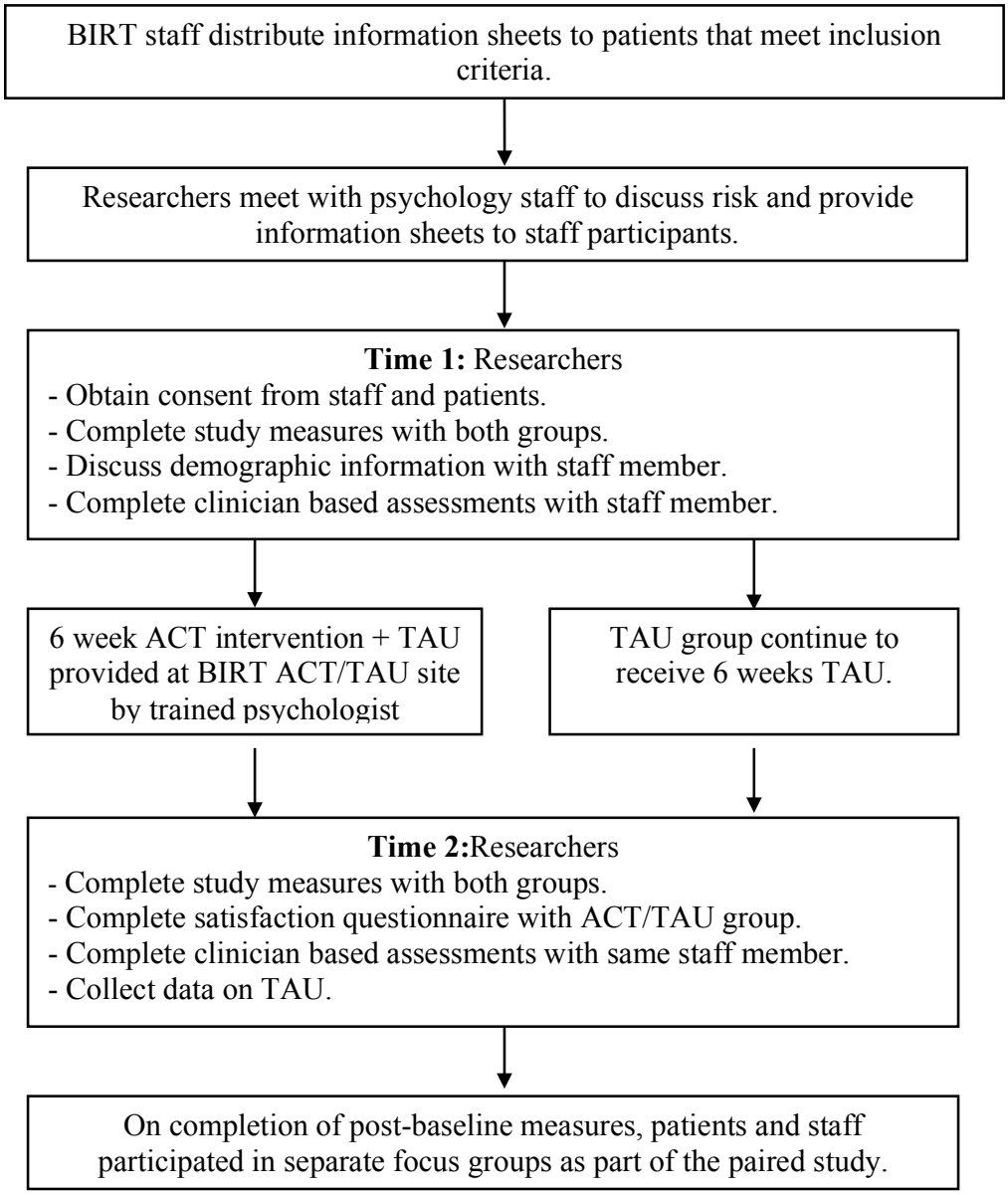

Figure 2. Research procedure

2. Motivation for traumatic brain injury rehabilitation questionnaire (MOT-Q; Chervinsky et al, 1998; Appendix 2.14)

Items included in this questionnaire assess factors that facilitate or block motivation to engage in rehabilitation. These include denial of illness, anger, compliance with treatment, and medical information seeking behaviour. Chervinsky et al, 1998 reported this scale as having good reliability (α=0.91).

Participant Satisfaction: The Satisfaction Questionnaire (Appendix 2.15): was developed by the author for the study to determine whether ACT was deemed acceptable to patients. The questionnaire contains three statements related to how they found the ACT group. Each asks the participant to rate how true they believe the statement to be on a likert scale of 0-4.

Outcome Measures:

Two outcome measures proposed by Whiting et al., (2013) were used.

1. Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983; Appendix 2.16)

The HADS was used to assess depression and anxiety. People with adjustment difficulties after TBI are more likely to have anxiety and depressive symptoms (Kashdan & Rottenberg, 2010). The 14-item scale has good internal consistency (α=0.94) and is a reliable measure of post-ABI distress (Whelan-Goodinson, Ponsford & Schonberger, 2009).

2. The Awareness Questionnaire (AQ; Sherer, 2004; Appendices 2.17-2.18)

The AQ was used to assess self-awareness after TBI. Increased self-awareness has been indicated as key in rehabilitation outcome (McMillan, 2013). This 17-item questionnaire was designed for people with TBI. Patient and clinician versions were administered. In order to obtain a self-awareness score, the total score for the clinician is substracted from the total score for the patient. A larger difference indicates greater

impairment. The AQ is reported to have good internal consistency (α=0.88; Sherer, Bergloff et al., 1998) and validity (Sherer, Boake et al., 1998).

The intervention

Training in ACT

Training was provided to researchers (CM, NoM) and psychologists at BIRT. A trained ACT clinician (RW) provided the training over 1.5 days (11 hours in total), addressing the ACT model and how this can be adapted for individuals with sTBI. The training was based on the protocol published by Whiting et al. (2013) that focused on three phases:

- Phase 1. Socialisation to the model, assessment and formulation
- Phase 2. Progressing with the ACT intervention
- Phase 3. Looking beyond the ACT intervention

The ACT trainer supervised trial therapists. This included monitoring of adherence to the protocol and the therapeutic principles of ACT ensuring the approach provided was consistent with the model. Two supervision sessions were provided to both Clinical Psychologists (2.3.2015, 16.3.2015). Details relating to deviations from the treatment manual were obtained through focus groups and are reported in the second DClinPsy paired study.

ACT Treatment Protocol

The ACT protocol used by Whiting et al., (2013) comprised of six two-hour sessions provided over six-weeks and a one-month follow-up. In the current study, the treatment was provided in an inpatient setting, and the follow-up session was not as relevant, as it was believed the setting would provide support to practice skills. The six core processes

of ACT were incorporated into each two-hour session. Each session included: review of homework and the previous session, introduction of the new topic and setting new homework. Each group consisted of four patient participants and one (of the two) trained therapist (see Appendix 2.19).

Treatment as Usual (TAU)

This was provided to both groups. At BIRT, TAU for mental health problems includes a patient-centred goal planning system that is linked to community reintegration and based on a holistic rehabilitation model (Wood & McMillan, 2001). In order to characterise TAU for both groups researchers (CM; NOM) used patient casefiles to ascertain the treatment and medications provided during the eight-week assessment period.

Treatment Adherence

Therapist adherence to the treatment protocol affects the validity of a study and the inferences that can be drawn (Perepletchikova, Treat & Kazdin, 2007). Adherence in this study was guided by principles drawn from the Implementation of Treatment Integrity Procedures Scale (ITIPS; as described in Perepletchikova et al., 2007) and was used to assess trial implementation quality (see Table 1).

Table 1.

Treatment Fidelity Monitoring Framework Based on ITIPS Guidelines

ITIPS guideline	**Implemented in this study**
Definition of Treatment Adherence	Description provided in protocol

provided	
Provision of Treatment manual	Therapist trained to use provided manual
Therapist training	Training provided and description of training provided in protocol
Supervision of therapist	Supervision provided and description of supervision provided in protocol
Assessment of Treatment Adherence	Completed in Supervision and through subjective measures (focus group) as part of the paired D.Clin.Psy study.

Sample size

As there are no data available to estimate sample size with respect to this intervention, the sample size estimation was based on Lancaster, Dodds and Williamson (2004) who recommend an overall sample size of 30 for pilot studies. Moreover as an aim of the study was to ascertain how many people could be approached, consented and retained, setting an a priori sample size was not desirable.

Analysis

Statistical analysis was undertaken using IBM SPSS version 22. Demographic data are presented as measures of central tendency (median) or frequency (percentages). As assumptions of normal distribution and homogeneity of variance were violated, Mann-Whitney *U* tests, in addition to Fisher's exact test were used to explore differences between-groups on demographic variables.

Acceptability of ACT: Frequency data from the satisfaction questionnaire were presented using descriptive statistics (percentages).

Sensitivity to change in therapeutic measures: Descriptive statistics (mean, standard deviations) are presented on each measure for participants who completed assessments at both time points (N=17).

Sensitivity analysis was conducted to test for clinically significant change for each participant on the outcome measures (HADS and AQ) and the process measures (AAQ-ABI (9-item); MOTQ). Jacobson and Truax (1991) report that clinical significance is achieved if changes in scores meet the following criteria:

1. Reliable according to the *Reliable Change Index* (RCI; <-1.96 or > 1.96)
2. They should transition from being above clinical cut-off at baseline to below clinical cut-off at post-baseline[2]

The RCI determines whether the magnitude of change for a participant is statistically reliable. Calculations were based on estimates of internal reliability (see appendix 2.20; Evans, Margison, & Barkham, 1998):

- HADS-Anxiety (HADS-A): Whelan-Goodinson et al., (2009; α=0.92)

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[2]MOT-Q scores should transition from being below clinical cut-off at baseline to above clinical cut-off at post-baseline.

- HADS-Depression (HADS-D): Whelan-Goodinson et al., (2009; α=0.88)
- AQ: Sherer et al., (1998; α=0.88)
- AAQ-ABI 9-item: (Whiting, Deane, Ciarrochi et al., 2015; α = .89)
- MOT-Q: Chervinsky et al., (1998; α=0.91)

Jacobson and Truax (1991) suggest three formulae to determine clinical cut-off scores, all of which assume normality of distribution (appendix 2.19). Data were assessed by histograms and p-p plots and found to be non-normally distributed. Given this violation of normality cut-off scores could not be calculated from data obtained in the sTBI samples. Instead consideration is given to published cut-offs for the outcome measures and these were available for the HADS only (Bjelland, Dahl, Haug & Neckelmann, 2002).

Recruitment and Retention: Descriptive analysis was used to obtain frequency data related to recruitment and dropout rates.

TAU: Descriptive statistics were used to obtain frequency data and Fisher's exact test was used to examine group differences.

Results

Aim 1: Availability of data

Missing data

The AQ clinician-form was not completed with one participant, as the clinician did not have adequate information about the participant prior to TBI. For an additional

participant, a missing answer on the AQ was substituted with the average score for that participant. Raw neuropsychological data (collected routinely by the units) could not be located for six participants (see table 2); further subtest data was not collected with three participants.

Demographic variables (See table 2)

As the demographic data violated parametric assumptions non-parametric tests were used. There were no significant differences between groups for age at TBI, time since admission or time since TBI. The ACT/TAU group (*Mdn*= 43) was significantly older than the TAU group (*Mdn = 30; U* = 15.00, z = -2.78, p = <.05, r = 0.60). A 3x2 Fisher's exact test was used to compare the levels of occupation attainment. A 6x2 Fisher's exact test was used to compare the levels of the GODS. Both tests produced no significant differences. The GODS indicated that all participants were severely disabled as a result of the TBI.

Table 2.

Participant Characteristics for overall sample (N=21) at baseline

		ACT/TAU	TAU	Significance tests
		N (%)	*N (%)*	Fisher's Exact Test
Gender	Male	11 (92)	9 (100)	
	Female	1 (8)	0 (0)	
Highest level of occupation attainment	Unemployed	1 (8)	3 (33)	
	Unskilled/Semi-Skilled	4 (34)	5 (56)	
	Skilled-professional	7 (58)	1 (11)	.094
Deprivation	1st Quintile	5 (42)	0 (0)	
	2nd Quintile	4 (33)	2 (29)	

	3rd Quintile	0 (0)	4 (57)	
	4th Quintile	2 (17)	1 (14)	
	5th Quintile	1 (8)	0 (0)	
Glasgow Outcome at Discharge Scale	Lower severe	8 (67)	8 (89)	
	Upper severe	4 (33)	1 (11)	
	Lower moderate	0 (0)	0 (0)	
	Upper moderate	0 (0)	0 (0)	
	Lower good	0 (0)	0 (0)	
	Upper good	0 (0)	0 (0)	.338
		Mdn (N)	*Mdn (N)*	*p*-value*
Age (years)		43 (12)	30 (9)	.004*
Age at TBI (years)		40 (12)	25 (9)	.219
Time since TBI (months)		23 (12)	27 (9)	.917
Time since admission (months)		12 (12)	8 (9)	.382
Estimate of premorbid full scale IQ (FSIQ)		75 (10)	89 (2)	1.000
Similarities scaled score		7 (12)	7 (2)	.549
Block-design scaled score		7 (11)	11 (2)	.749
Coding scaled score		4 (11)	10 (3)	.225

* Significant difference, $p<.05$

Aim 2: Acceptability of ACT

Following ACT completion all ACT/TAU participants were asked to complete a short satisfaction questionnaire (see table 3).

Table 3.

Results of satisfaction questionnaire

		ACT/TAU
		N (%)
I found the group helpful	Not at all	2 (22)
	A little true	3 (33)
	True	0 (0)
	Pretty true	1 (11)
	Very true	3 (33)
I would recommend this group	Not at all	3 (33)
	A little true	2 (22)
	True	0 (0)
	Pretty true	1 (11)
	Very true	3 (33)

I found the group distressing	Not at all	5 (56)
	A little true	2 (22)
	True	1 (11)
	Pretty true	1 (11)
	Very true	0 (0)

Aim 3: Treatment signals (See table 4):

a. Process Measures

The AAQ-ABI 9-item version was sensitive to change in 9/17 participants. Three ACT/TAU participants and two TAU participants exhibited significantly improved psychological flexibility. A further three ACT/TAU and one TAU participant exhibited significantly deteriorated psychological flexibility.

On the MOT-Q process measure two ACT/TAU participants and one TAU participant exhibited significant deterioration in motivation. Two further TAU participants exhibited significantly improved motivation.

b. Outcome Measures

On the HADS a score of 8 or above indicates the clinical presence of depression or anxiety (Bjelland et al., 2002). Forty-one percent (33% of ACT/TAU group; 50% of TAU group) of participants scored 7 or less on the HADS-A scale and 65% (56% of ACT/TAU group; 75% of TAU group) scored 7 or less on the HADS-D scale. Sixty-five percent of all participants obtained a score within the clinical range at baseline on the HADS-A and/or the HADS-D. On the HADS-A subscale 29% were mild, 18% moderate and 12% severely distressed. On the HADS-D subscale 47% were mild and 0% were moderate or severely distressed.

Table 4.

Reliable Change scores

Measure	Rel	Mean	SD	ACT/TAU1			ACT/TAU 2			ACT/TAU 3			ACT/TAU 4			ACT/TAU 5			ACT/TAU 6		
				Pre	Post	RCI	Pre	Post	RCI	Pre	Post	RCI	Pre	Post	RCI	Pre	Post	RCI	Pre	Post	RCI
Primary Outcome measures: Psychological Distress																					
HADS-A	0.92	8.38	5.22	10	9	-0.48	21	21	0	7	8	0.48	9	15	**2.87***	1	1	0	0	0	0
HADS-D	0.88	6.10	3.53	12	11	-0.58	9	9	0	6	3	-1.73	11	18	**4.05***	2	0	-1.16	6	1	**-2.89***
AQ	0.88	12.95	13.88	11	18	1.03	30	32	0.29	26	19	-1.03	5	-14	**-2.79***	23	27	0.59	16	14	-0.29
Process Measures:																					
AAQ-ABI	0.92	12.71	8.71	14	24	**4.07***	29	21	**-3.25***	14	9	**-2.44***	12	12	0	0	4	1.62	10	3	**-2.84***
MOT-Q	0.91	18.71	21.46	22	33	1.21	38	53	1.65	11	7	-0.44	33	12	**-2.31***	38	11	**-2.96***	-29	-17	1.32
Measure	Rel	Mean	SD	ACT/TAU 7			ACT/TAU8			ACT/TAU 9			TAU1			TAU 2			TAU 3		
				Pre	Post	RCI	Pre	Post	RCI	Pre	Post	RCI	Pre	Post	RCI	Pre	Post	RCI	Pre	Post	RCI
Primary Outcome measures: Psychological Distress																					
HADS-A	0.92	8.38	5.22	13	9	-1.92	16	13	-1.44	10	4	**-2.87***	2	4	0.96	13	15	0.96	6	4	-0.96
HADS-D	0.88	6.10	3.53	5	7	1.16	3	4	0.58	9	0	**-5.20***	1	0	-0.58	5	5	0	0	0	0
AQ	0.88	12.95	13.88	11	13	0.29	-8	3	1.62	17	20	0.44	14	28	**2.06***	-6	-10	-0.59	14	17	0.44
Process Measures:																					

AAQ-ABI	0.92	12.71	8.71	8	17	**3.66***	17	15	0.81	1	9	**3.25***	6	4	-0.81	27	18	**-3.66***	2	4	0.81
MOT-Q	0.91	18.71	21.46	5	11	0.66	39	34	-0.55	4	11	0.77	30	10	**-2.20***	49	45	-0.44	10	47	**4.06***
Measure	Rel	Mean	SD	TAU 4			TAU 5			TAU 6			TAU 7			TAU 8					
				Pre	Post	RCI	Pre	Post	RCI	Pre	Post	RCI	Pre	Post	RCI	Pre	Post	RCI			
Primary Outcome measures: Psychological Distress																					
HADS-A	0.92	8.38	5.22	6	10	1.92	9	2	**-3.35***	13	16	1.44	3	5	0.96	8	6	-0.96			
HADS-D	0.88	6.10	3.53	8	10	1.16	7	3	**-2.31***	7	4	-1.73	4	3	-0.58	10	13	1.73			
AQ	0.88	12.95	13.88	-10	-5	0.74	38	31	-1.03	-	-	-	29	23	-0.88	-2	15	1.62			
Process Measures:																					
AAQ-ABI	0.92	12.71	8.71	17	19	0.41	20	17	-1.22	13	22	**3.66***	4	8	1.63	22	15	**-2.85***			
MOT-Q	0.91	18.71	21.46	15	26	1.21	0	5	0.55	39	35	-0.44	21	43	**2.41***	-5	-14	-0.99			

Notes. Rel = Reliability was taken from TBI populations for the calculation of RCI. Mean and SD were calculated from the ACT/TAU and TAU data. Higher MOT-Q scores indicate improved motivation. Lowered HADS indicate improved mood, lowered AAQ-ABI indicates lowered psychological inflexibility and lowered AQ indicates improved self-awareness. * < -1.96 or > 1.96 significant at 0.05.

On the HADS-A, two ACT/TAU participants and one TAU participant improved significantly. A further ACT/TAU participant deteriorated significantly. On the HADS-D one ACT/TAU participant and one TAU participant improved significantly on depression scores. An additional ACT/TAU participant deteriorated significantly.

On the AQ one ACT/TAU participant improved significantly in self-awareness and one TAU participant deteriorated significantly.

Aim 4: Recruitment and Retention

During the 6-month recruitment period, 89 participants were available to participate. Of these, 24 (27%) met inclusion criteria and 21 (88%) consented to participate. Of those that consented 80% (N=17) completed post-baseline assessments. Of those who dropped-out (N=4; 19%) three were discharged earlier than planned and could not take part in the study for practical reasons and one (5%) withdrew from the study after session three. Of those who completed ACT one missed half a session and four missed one session (Table 5).

Table 5.

Attendance across sessions within each treatment group

Session	1	2	3	4	5	6
ACT Group 1	4/4*	3/3	2/3 full session; 1/3½ session	2/3	3/3	3/3
ACT Group 2	4/4	3/4	4/4	3/3**	3/3	3/3
ACT Group 3	4/4	4/4	4/4	3/3**	3/3	2/3

* Participant was discharged from service
** One participant dropped out after session 3

Aim 5: Comparison of TAU intervention given (see table 6)

Fisher's exact test indicated no significant differences between groups in the receipt of 'psychological therapy' (1:1/group therapy; $p = 1.000$), other multidisciplinary therapies (Occupational/speech and language/Physiotherapy) or 'psychotropic medication' (anti-depressants/anti-anxiolytic/anti-psychotic; $p = .335$).

Table 6.

Treatment as Usual provided to each group

	ACT/TAU	TAU
	N (%)	*N* (%)
1:1 Psychological therapy	8 (89)	7 (88)
Group psychological therapy	0 (0)	3 (38)
Occupational Therapy	9 (100)	7 (88)
Speech & Language Therapy	6 (67)	2 (25)
Physiotherapy	6 (67)	4 (50)
Anti-depressant medication	3 (33)	3 (38)
Anti-anxiolytic medication	4 (44)	1 (13)
Anti-psychotic medication	4 (44)	2 (25)

Discussion

This feasibility study examined the use of ACT in people with sTBI. The results suggest that although ACT acceptability varied, it was deemed to be at least "a little" helpful by the majority (77%; N= 7/9) of ACT/TAU participants and although some amount of distress was reported by 44% of participants, no participant rated ACT as 'very distressing'. This finding is strengthened by the high retention rates, with only four participants (N=3 in ACT/TAU group) dropping-out of the study, and only one because of reluctance to continue with ACT.

Measures

The GODS indicated that participants were all severely disabled. This suggests that appropriate participants were recruited, and that those with severe disabilities were willing to attend and persist with psychological treatment. HADS scores suggest that participants were mostly in the sub-clinical range for distress at baseline compared to normative cut-off scores (Bjelland et al., 2002). Although 65% scored above the cut-off of 7 on either HADS subscale; on HADS-A subscale only 30% scored in the moderate or severe ranges for distress and none scored in this range on HADS-D subscale, suggesting that anxiety or depression were not perceived to be major problems by most participants. This together with a potentially modest scope for improvement on the HADS may at least in part explain why the sensitivity analysis showed significant change on the HADS in few participants. The HADS might not be the most useful outcome measure in an inpatient sTBI group in future research on ACT.

On the AQ significant improvement was observed in one ACT/TAU participant and significant deterioration in one TAU participant. Change on the AAQ-ABI 9-item measure was found for 53% of the overall sample; five participants (3 in ACT-TAU; 2 in TAU) indicated improved psychological flexibility. Change on the MOT-Q was found in two TAU participants, indicating improved motivation, in one and reduced motivation in the other. These measures were sensitive enough to assess significant change in 82% of participants, but the desired direction in only 41%. Clearly, definitive conclusions regarding the appropriateness of the process and outcome measures cannot be made. However, given the information available it would seem that the measures used were sensitive enough to detect improvements and deteriorations across time in this population. Although the aim of the study was not to assess treatment effectiveness it is important to consider that the treatment may not have been effective, as significant positive changes were not reported by all of the ACT/TAU participants. This should be explored more definitely in future studies.

Units and recruitment

The units recruited to the study were comparable. Significant group differences were not found in the severity of disability, the frequency of psychotropic medications prescribed or psychological therapy provided. This supports the view that the same rehabilitation structure is followed across units.

Over half of the sample (N=14) were recruited from one unit. In hypothesising the reasons for this it may be the case that some units have a client-base that better fit criteria or perhaps, more worryingly, different sites might have adopted different

interpretations of the inclusion criteria. Twenty-one participants were recruited within the 6-month period. This gives a framework for the number of units and duration of recruitment required to achieve sample size targets.

Limitations

The sample is unlikely to be representative of the sTBI population, as all participants were male (although most sTBI's are male) and the sample was recruited from inpatient programmes, which may differ from community samples. The units recruiting for this study were not randomly assigned to treatment. Further to this, obtaining neuropsychological data proved difficult, as one unit was unable to locate the raw data and the same test-battery was not routinely completed with every patient, and as a result a baseline of neuropsychological ability was not possible. Multiple deprivation indexes differ in Scotland and England and could not be compared. Finally, the Acceptability Questionnaire is not validated and as all measures were self-report, they were open to response bias.

Implications for future research

This feasibility study examined the use of ACT for people with sTBI. It was informed by the MRC (2008) guidelines on developing complex interventions, which suggest that a number of studies may be required to refine the design prior to developing a full-scale evaluation. Further feasibility and pilot studies are needed. Future research should seek to assess the feasibility of an alternative measure of adjustment to replace the HADS (which was used as a proxy measure). The validated 9-item version of the AAQ-ABI should be used (Whiting, Deane, Ciarrochi et al., 2015). Moreover as some clinicians

reported that they lacked adequate information to complete the AQ-clinician form, the AQ-family/significant-other form should be used. As it was difficult to obtain consistent neuropsychological data at baseline, a cognitive screening measure such as the RBANS (Repeatable battery for the assessment of Neuropsychological Status; Randolph, Tierney, Mohr & Chase, 1998) should be incorporated into the study, so that participants can be compared more easily.

Recruitment targets need to reconsider the recruitment period and number of units involved. A recruiter liaison employed from BIRT could help ensure recruitment consistency across units.

Conclusion

In overview, the majority of participants were willing to take part in ACT, but the benefit of ACT was unclear. Future studies need to address the issues highlighted in order to obtain a more definite conclusion about the usefulness of ACT in facilitating adjustment after sTBI. Further feasibility and pilot studies will support the refinement of methods for future evaluation.

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Chapter 3: Advanced Clinical Practice I:

Reflective Critical Account (Abstract Only)

"Challenges in Supervision: What has it taught me?"

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Abstract

The role of psychologists is changing; more and more we are being called upon to use our professional skills in order to meet the therapeutic needs of many. Supervisory skills in particular are essential in the modern NHS where a skills mix is being turned to in order to provide mental health care in Scotland. Supervision, however, is not a simple process and according to Roth and Fonagy (2008) is a collaborative relationship, which is part of the therapist's training. The basic building block for supervision is the supervisory alliance and if not cared for, can have an impact on learning. During doctoral training the role of supervision is particular pertinent, not only does it serve to equip trainees with skills but it is within this relationship that the trainee's competencies are assessed. The Integrated Developmental Model (Stolenberg & Delworth, 1987) puts forward a framework for understanding the development of therapists in training. This three phase developmental outlook offers a coherent model that maps well onto the years of the doctoral course, offering an insight for trainees and supervisors alike. This reflection serves to address the role of supervision and what happens when ruptures occur. It offers a chance for learning through reflection using the What? Model (Driscoll, 1994), allowing me to address what supervisor I wish to be in the future.

Chapter 4: Advanced Clinical Practice II

Reflective Critical Account (Abstract Only)

"Do MDTs exist in mental health care; or is it just a name game?"

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Submitted in partial fulfilment of the requirements for the degree of Doctorate in Clinical Psychology.

Abstract

Multidisciplinary teams appear to be the gold standard of mental health provision. Research has shown that whilst people report team working to be enjoyable (Healthcare commission, 2006), it was noted by many that their 'team' did not meet the criteria to be described as such. This discrepancy between name and definition was noted in the BPS guidelines (2007) on 'working psychologically in teams' as a potential risk. It noted that 'nominal' teams, those that are teams in name only, can lead to increased psychological distress and clinician error (Carter & West, 1999). If MDTs are going to exert positive benefits then they will have to be team by name and by definition. In order to achieve this clinicians within the team need to ensure MDT working is put into practice. This reflection serves to examine the author's developmental experience of MDT working. It reflects on how desires to work within an MDT grew throughout training and seeks to understand why different experiences often occur. From this a personal plan for further development is suggested.

Systematic Review Appendices

Appendix 1.1. Search Strategy

The researcher developed the search strategy after discussions with a librarian at the University of Glasgow and her research supervisor. Search terms were identified through reading related articles and agreed with the research supervisor prior to running the final search in the chosen databases. Inclusion and exclusion criteria were adhered to when deciding what studies to include or exclude.

Appendix 1.2 Quality Rating Scale

Table 1.

Amended STROBE rating scale adapted for the purpose of the current systematic review.

Rating Scale for papers estimating the prevalence of HI amongst prison populations			
Author and title of article:			
		Item	Score
1	**Title/Abstract**	Does title, abstract and/or keywords suggest the use of a population/prospective design (assess the prison population in a specific time window; score 3) **OR** cross-sectional or case-control design (score 2) **OR** prevalence study not in specific time window (score 1).	/3
2		Does the abstract provide a balanced summary that includes research question, short description of methods, results and conclusions?	/1
3	**Introduction**	Does the introduction explain the scientific background and rationale?	/1
4		Does the introduction state the research questions and aims (e.g. estimating the prevalence of HI in prisons)	/1
5	**Methods** *Setting*	Setting: Are the settings and location where data were collected specified (Score 1) **AND** were relevant dates provided (e.g. data collection, recruitment periods; Score 1)?	/2
6		Study population: Are eligibility criteria specified?	/2
7	*Participants*	Participant recruitment: Sample included entire prison population (score 4**) OR** a reasonable estimate of the entire prison population (score 2) **OR** unclear due to provision of limited information (score 0)?	/4
8		Representative: Is the sample representative of the population?	/6

9		Control sample used: Does the study use a matched-control group (score 6); **OR** non-matched control group (score 4); **OR** a reported and cited frequency of HI in the general population (e.g. a frequency reported in a previous study) (score 2); **OR** no control (score 0)?	/6
10	*Test methods*	Variables used: Is a definition of HI provided (score 2)? Is the definition recognised by a consensus body (score 6)?	/6
11		Is a definition of the category boundaries for HI severity reported (i.e. mild, moderate, severe or LOC, LOC>30minsetc) (score 2)? **OR** Was the method of definition validated (score 4)? **OR** Was the category breakdown recognised by a consensus body (Score 6)?	/6
12		Is a description of the methods of assessing for HI provided?	/1
13		Does the method of assessing for the occurrence of HI rely on 1-3 self-report questions or telephone interview (score 1); **OR** hospital data only (score 2); **OR** structured or in-depth interview (score 3); **OR** validated questionnaire (score 4) validated questionnaire or interview including neuropsychological /behavioural assessment and/or hospital	/6
14		Disability: is a valid tool for assessing disability for head injury used?	/6
15	*Selection Bias*	Were participants recruited by individuals not affiliated to the research (score 2); **AND** recruited using standardised procedure (score 2). If unclear score 0.	/4
16	*Design Bias*	Was the data collected by trained individuals (score 2) **AND** collected in a standardised way (score 2) **AND** was any subjective data corroborated by further evidence (score 2)? If unclear score 0.	/6
17	*Interviewer Bias*	Were the assessors blind to the purpose of the study (score 2). If unclear score 0.	/2
18	*Recall Bias*	Were participants blind to the study aim (score 2)? If unclear score 0.	/2

19	**Statistical Methods**	Described all statistical methods used (score 1)**,** were the statistical methods used appropriate (score 4)?	/4
20		Did the statistical analysis control for any possible confounding variables in the prevalence rate?	/2
21		Explained reasons for and how missing variables were handled?	/1
22	**Results**	Participants: Are the number of individuals at each stage of the study reported (Score 1) **AND** are reasons for non-participation provided (score 1)?	/2
23		Descriptive Data: Are demographic characteristics (score 1), **AND** confounding variables (score 1) reported?	/2
24		Gender: Is gender breakdown reported?	/1
25		Outcome Data: Frequency of HI provided?	/4
26		Rates of different severities of HIs provided?	/4
27		Rates of neurobehavioral/psychological symptoms provided?	/4
28		Rates of ongoing disability provided?	/4
29		Does the study summarise the key results with reference to the study objectives?	/1
30	**Discussion**	Interpretation: Does the study caution the interpretation of the findings?	/1
31		Generalisability: Are the study results generalisable to other settings (consider study setting, the characteristics of the participants, the exposures examined, the outcomes assessed, missing data etc.)?	/4
32	**Conclusions**	Is the stated prevalence of HI in prisons justified on the basis of the data presented?	/6
		Total Score/Percentage	/105

Appendix 1.3. Table of inter-rater reliability

	Morrell et al. (1998)		*Ray et al. (2014)*		*Bogner & Corrigan (2009)*		*Templer et al. (1992)*	
	Rater 1	Rater 2	Rater 1	Rater 2	Rater 1	Rater 2	Rater 1	Rater 2
1	2	2	2	2	0	0	1	1
2	1	1	1	1	1	1	0	0
3	1	1	1	1	1	1	0	0
4	1	1	1	1	1	1	1	1
5	1	1	2	2	1	1	1	1
6	2	2	2	2	2	2	0	0
7	2	2	0	0	0	0	0	0
8	0	0	0	0	0	0	0	0
9	0	0	0	0	0	0	4	4
10	2	2	2	2	2	2	2	2
11	2	2	2	2	0	0	0	0
12	1	1	1	1	1	1	1	1
13	3	3	4	4	4	4	1	1
14	0	0	0	0	0	0	0	0
15	4	4	2	2	4	4	2	2
16	2	2	2	2	4	4	0	0
17	0	0	0	0	0	0	0	0
18	0	0	0	0	0	0	0	0
19	4	4	4	4	4	4	0	0
20	0	0	0	0	0	0	0	0
21	1	1	1	1	1	1	0	0
22	1	1	0	0	***1***	***2***	0	0
23	1	1	2	2	***1***	***2***	1	1
24	0	0	1	1	1	1	1	1

25	4	4	4	4	1	1	4	4
26	4	4	4	4	0	0	0	0
27	4	4	0	0	0	0	0	0
28	0	0	0	0	0	0	0	0
29	1	1	1	1	1	1	1	1
30	1	1	1	1	1	1	0	0
31	0	0	0	0	0	0	0	0
32	0	0	0	0	0	0	0	0
Total	45	45	40	40	32	34	20	20
Rating	43%	43%	38%	38%	30%	32%	19%	19%

Appendix 1.4. Methodological Quality Rating

Question	Max score	Fergusson et al. (2012)	Morrell et al. (1998)	Ray et al. (2014)	Barnfield &Leathem (1998)	Bogner& Corrigan (2009)	Williams et al. (2010)	Colantonio et al. (2014)	Templer et al. (1992)
Does title, abstract and/or keywords suggest the use of a population/prospective design (assess the prison population in a specific time window; score 3) cross-sectional or case-control design (score 2), prevalence study not in specific time window (score 1).	3	2	2	2	1	0	2	2	1
Does the abstract provide a balanced summary that includes research question, short description of methods, results and conclusions?	1	1	1	1	1	1	1	1	0
Does the introduction explain the scientific background and rationale?	1	1	1	1	1	1	1	1	0
Does the introduction state the research questions and aims (e.g. estimating the prevalence of HI in prisons)	1	1	1	1	1	1	1	1	1
Setting: Are the settings and location where data were collected specified (Score 1) and were relevant dates provided (e.g. data collection, recruitment periods; Score 1)?	2	2	1	2	1	1	2	2	1
Study population: Are eligibility criteria specified?	2	2	2	2	2	2	2	2	0
Participant recruitment: Sample included entire prison population (score 4) or a reasonable estimate of the entire prison population (score 2) or unclear due to provision of limited information (score 0)?	4	0	2	0	2	0	2	0	0
Representative: Is the sample representative of the population?	6	0	0	0	0	0	0	0	0
Control sample used: Does the study use a matched-control group (score 6); non-matched control group (score 4); a reported and cited frequency of HI in the	6	0	0	0	0	0	0	0	4

general population (e.g. a frequency reported in a previous study) (score 2); no control (score 0)?									
Variables used: Is a definition of HI provided (score 2)? Is the definition cited as being recognised by a consensus body (score 6)?	6	2	2	2	2	2	2	2	2
Is a definition of the category boundaries for HI severity reported (i.e. mild, moderate, severe or LOC, LOC>30minsetc) (score 2)? Was the method of definition validated (score 4)? Was the category breakdown recognised accurately by a consensus body (Score 6)?	6	2	2	2	2	0	2	6	0
Is a description of the methods of assessing for HI provided?	1	1	1	1	1	1	1	1	1
Does the method of assessing for the occurrence of HI rely on 1-3 self-report questions or telephone interview (score 1); hospital data only (score 2); structured or in-depth interview (score 4); validated questionnaire or interview including neuropsychological/behavioural assessment and/or hospital data (score 6)?	6	4	3	4	1	4	1	1	1
Disability: is a valid tool for assessing disability for head injury used?	6	0	0	0	6	0	0	0	0
Were participants recruited by individuals not affiliated to the research (score 2); and recruited using standardised procedure (score 2) or unclear (score 0)?	4	0	4	2	2	4	0	2	2
Was the data collected by trained individuals (score 2), in a standardised way (score 2) or unclear (score 0); and was any subjective data corroborated by further evidence (score 2)?	6	4	2	2	4	4	0	4	0
Were the assessors blind to the purpose of the study	2	0	0	0	0	0	0	0	0

(score 2) or unclear (score 0)?									
Were participants blind to the study aim (score 2) or unclear (score 0)?	2	0	0	0	0	0	0	0	0
Described all statistical methods used (score 1), were the statistical methods used appropriate (score 4)?	4	4	4	4	4	4	4	1	0
Did the statistical analysis control for any possible confounding variables?	2	0	0	0	0	0	0	0	0
Explained reasons for and how missing variables were handled?	1	0	1	1	1	1	0	1	0
Participants: Are the number of individuals at each stage of the study reported (Score 1) and are reasons for non-participation provided (score 1)?	2	1	1	0	1	1	0	1	0
Descriptive Data: Are demographic characteristics (score 1), confounding variables (score 1) reported?	2	1	1	2	1	1	1	2	1
Gender: Is gender breakdown reported?	1	1	0	1	0	1	1	1	1
Outcome Data: Frequency of HI provided?	4	4	4	4	4	1	4	4	4
Rates of different severities of HIs provided?	4	4	4	4	4	0	4	4	0
Rates of neurobehavioral/psychological symptoms provided?	4	4	4	0	0	0	0	0	0
Rates of ongoing disability provided?	4	0	0	0	0	0	0	0	0
Does the study summarise the key results with reference to the study objectives?	1	1	1	1	1	1	1	1	1
Interpretation: Does the study caution the interpretation of the findings?	1	1	1	1	0	1	1	0	0
Generalisability: Are the study results generalisable to other settings (consider study setting, the characteristics of the participants, the exposures examined, the outcomes assessed, missing data etc.)?	4	0	0	0	0	0	0	0	0
Is the stated prevalence of HI in prisons justified on the basis of the data presented?	6	0	0	0	0	0	0	0	0

	Total							
	105	43	45	40	43	32	33	40	20
		41%	43%	39%	41%	30%	31%	38%	19%

Appendix 1.5. Author guidelines for submission to Neuropsychological Rehabilitation

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Major Research Project Appendices

Appendix 2.1 Details of the two studies involved in this pilot/feasibility research

This pilot study, involving the administration of ACT to patients with sTBI, was split into two studies. The first study aimed to investigate the acceptability of ACT to people with sTBI, to explore treatment signals in potential treatment measures, to determine rates of patient recruitment and retention, to characterise treatment as usual against which an ACT intervention could be compared and investigate the availability of data. This required the administration of study measures at two time points to both the treatment and comparison arm. This study was conducted by Claire Moynan, Trainee Clinical Psychologist (CM).

The second part of this pilot study aimed to assess the suitability, feasibility and acceptability of the study protocol in order to make recommendations to improve the quality and efficiency of a larger study. This involved conducting focus groups and administering questionnaires to inpatients and staff involved in implementation of the study protocol. This study was conducted by Niamh O'Meara, Trainee Clinical Psychologist (NOM).

Details of the study aims are:

Aim	**Method**	**Researcher**
Applicability of inclusion/exclusion criteria	Provide staff assessing eligibility with a list of inclusion and exclusion, with a tick sheet allowing them to indicate what criteria were met/not met. Discuss in Focus group with staff.	NoM

Recruitment procedure. Suitability of information sheets and consent form and experience of being approached	Feedback from all participants in focus groups (ACT facilitators, staff and BIRT clients)	NoM
Participant flow, Recruitment, consent and retention rate	Observe and document at each stage of the process the number of participants that: 1. Are eligible 2. Consent to participate 3. Dropout 4. Complete study protocol	NoM; CM
Missing data	Discuss the availability of data and explore reasons/solutions for missing data	CM
Testing of outcome measures: - Treatment signals - Comprehensible - Appropriate - Well defined - Presented consistently	Test for clinically significant change scores Feedback from patient focus group and staff focus group at Graham Anderson House (Intervention group) Observations during testing.	CM; NoM
Randomisation	Administer short questionnaire for participants in comparison group eliciting views with regard having been assigned to comparison group.	NoM
Staff training	Administer SAFE questionnaire to clinicians involved in administration and discuss in focus group.	NoM
Acceptability of intervention	Focus groups discussion Completion of Satisfaction Questionnaire. Drop-out rates	NoM, CM
Selection of most appropriate outcome measure	Focus group discussion Elicit opinions with regard the most clinically significant outcome. Review data	NoM; CM

Management of ethical issues	Proposed guidelines for detecting and reporting serious adverse events. Focus group feedback for clinicians with regards its use. Observe and document any adverse event which occurred	NoM
Barriers to treatment	Administer SAFE questionnaire to those involved in training	NoM
Determine what TAU looks like	Assess treatments received as part of TAU.	CM

Both researchers were involved in data collection i.e. administration of outcome measures and questionnaires and facilitation of focus groups. NOM and CM each administered treatment measures to half the participants in both groups.

Appendix 2.2 Letter of University ethical approval

WoSRES
West of Scotland Research Ethics Service

NHS
Greater Glasgow and Clyde

Dr Hamish McLeod
Programme Director for Doctorate in Clinical Psychology and Senior Lecturer
University of Glasgow
Mental Health and Wellbeing 1st Floor Admin Building
Gartnavel Royal Hospital
Glasgow
G12 0XH

West of Scotland REC 1
Ground Floor - Tennent Building
Western Infirmary
38 Church Street
Glasgow
G11 6NT

Date 22 January 2015
Direct line 0141 211 6270
E-mail WoSREC1@ggc.scot.nhs.uk

Dear Dr McLeod

Study title: **This piece of research will comprise of two pilot studies entitled: REACT – Recovery Enhancement from TBI using ACT; A Pilot Study.**
REC reference: **14/WS/1152**
IRAS project ID: **154505**

Thank you for your letter of 19 December 2014 (received initially on 06January 2015), 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 favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager, Evelyn Jackson, wosrec4@ggc.scot.nhs.uk. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Confirmation of ethical opinion

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

Conditions of the favourable opinion

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

Appendix 2.3 Letter of BIRT Ethical Approval

Graham Anderson House
1161 Springburn Road
Glasgow
G21 1UU
Tel: 0141 4046060
Fax: 0141 5573536
Email: gahadmin@thedtgroup.org

BIRT
Brain Injury
Rehabilitation Trust
The Disabilities Trust

Liz Jamieson
REC 3
Ground Floor, The Tennent Institute
Western Infirmary
38 Church Street
Glasgow
G11 6NT

27 October 2014

Dear Ms Jamieson

Re: Research Ethics Application: REACT; Recovery Enhancement from TBI using ACT, a pilot study

I have reviewed the submitted research proposal and endorse its aims, methods and analysis. Acceptance and commitment therapy, as an example of third wave therapies, holds promise in the treatment of people with brain injury and adjustment disorder and we endorse its investigation.

[redacted]

Susan Copstick
Clinical Director

Appendix 2.4 Inclusion criteria checklist

REACT –Recovery Enhancement from TBI using ACT. A pilot study.

Date: 12/11/2014
Version number: 1

RECRUITMENT FORM

This form is for clinicians' use only and will only be seen by research team if informed consent has been given.

Please tick as appropriate for this potential participant.

This potential participant:

Is aged 18 or over ☐

Has capacity to give consent to participate in the study ☐

Has sufficient cognitive capacity to complete study questionnaires and capacity to participate in discussions as part of the ACT intervention. ☐

Has an acceptable level of English language skills which will allow completion of validated questionnaires ☐

Exhibits psychological distress or behavioural dysfunction that is deemed to warrant treatment ☐

This potential Participant does not:

Have an agreed discharge date within the following eight weeks ☐

Have current difficulties with regard managing challenging behaviour such as impulsivity, verbal or physical aggressiveness which could impair meaningful participation in treatment. ☐

Appendix 2.5 Information sheet for patient participants at intervention site

REACT – Recovery Enhancement from TBI using ACT; A Pilot Study.

Version Number: 1
Date: 11/11/2014

Contact details: Niamh O'Meara Claire Moynan
Email: n.o'meara.1@research.gla.ac.uk c.moynan.1@research.gla.ac.uk

Information Sheet for Care Staff at Treatment Group

You are being invited to take part in focus group as part of our research study. Please take time to read this information. Please ask us if there is anything that is not clear or if you would like more information.

Who is conducting the research?

This study is being carried out by Niamh O'Meara and Claire Moynan and is being supervised by Dr Hamish McLeod and Professor Tom McMillan (University of Glasgow).

What is the purpose of the study?

This study will be part of a larger piece of research assessing whether Acceptance and Commitment Therapy (ACT) would be a helpful intervention for persons adapting to life following a brain injury. This study is a "pilot study" which means that we are carrying out the present study in order to assess how future studies could be improved.

This study will also be submitted as part of the main researcher' (Claire Moynan and Niamh O'Meara) portfolio for part completion of the Doctorate in Clinical Psychology.

Do I have to take part?

It is up to you to decide. We will describe the study and go through this information sheet, which we will then give to you. You will be asked to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving reason.

What does the taking part involve for the service users?

Service users who meet inclusion criteria will be invited to take part in a six week Acceptance and Commitment Therapy (ACT) Intervention. The main goal of ACT is to help people make room for experiencing painful thoughts and feelings as opposed to trying to get rid of these difficult experiences. In doing so it is proposed that people will have more energy to carry out

activities that are meaningful to them. The psychologists who will deliver the training are part of the existing psychology team at BIRT.

Service users taking part will be asked to complete questionnaires on two occasions; before the first therapy session and after the final therapy session, following which they will be invited to attend a small focus group. The purpose of this group is to seek feedback from service users about being involved in the study.

Service users in BIRT centres in England will also be invited to take part in the study. Participants in England will not receive ACT intervention but will act as a comparison group in this pilot study.

What does taking part involve for you?
Taking part would involve attending a focus group once the ACT intervention has completed and all questionnaires have been collected from the relevant service users. The purpose of this focus group is to seek your opinion on matters relating to the study, for example your perspective of service user involvement in the study. The session will be recorded and facilitated by both Claire and Niamh. The focus group session will be approximately one hour long. If you choose to participate you may also be asked to complete a short questionnaire, which should take no longer than 10 minutes, at two time points (pre and post intervention). This questionnaire will ask questions relating to inpatients' self-awareness. You will be approached to complete questionnaires based on your knowledge of working with that service user and availability. You may also be asked to participate in collecting demographic details for clients and discussing risk factors with the researchers.

What happens to information from the focus groups?
Your identity and personal information will be completely confidential and known only to the researcher. The information obtained will remain confidential and stored within a locked filing cabinet at the University of Glasgow and would only be accessed by others in the event of an audit. Data collected will be anonymised and unique codes will be used as identifiers. The data are held in accordance with the Data Protection Act, which means that we keep it safely and cannot reveal it to other people without your permission. The final report of the results of this study will be submitted for review to Glasgow University as a doctoral thesis and following this may be published in a scientific journal.

What are the possible effects on you?
The focus group may or may not elicit an emotional reaction for you. Should you experience a negative emotional reaction you will be offered the opportunity to discuss this with us following the group and we would encourage you to seek support from a colleague or a member of the psychology team.

What are the possible benefits of taking part?
By taking part in this research you will be providing valuable information on the development of a psychological therapy that could potentially improve rehabilitation interventions for people who have experienced a head injury.

Who has reviewed the study?
This study has been reviewed by the West of Scotland Research Ethics Committee.

If you have any further questions?

We will give you a copy of the information sheet and signed consent form to keep. If you would like more information about the study and wish to speak to someone not closely linked to the study, please contact **Dr Sue Turnbull, Research Tutor, University of Glasgow, email: s.turnbull@clinmed.gla.ac.uk, Tel no: 0141 211 3927.**

If you have a complaint about any aspect of the study?
If you are unhappy about any aspect of the study and wish to make a complaint, please contact the researcher in the first instance but the normal NHS complaint mechanism is also available to you.

Contact details:

Main Researchers (Trainee Clinical psychologists):

Niamh O'Meara
University of Glasgow
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1055 Great Western Road
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Claire Moynan
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Research Supervisors:

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Dr Hamish McLeod
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Thank you for taking the time to read this information sheet.

Appendix 2.6 Information sheet for patient participants at control site

REACT – Recovery Enhancement from TBI using ACT; A Pilot Study.

Version number: 1
Date: 12/11/2014

Contact details: Niamh O'Meara
University of Glasgow
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Claire Moynan
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Information Sheet for Clients in Comparison Group

You are being invited to take part in a research study. Before you decide whether or not you would like to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read this information carefully and discuss it with others if you wish. Please contact us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. You do not have to make an immediate decision.

Who is conducting the research?

This study is being carried out by Niamh O'Meara and Claire Moynan and is being supervised by Dr Hamish McLeod and Professor Tom McMillan (University of Glasgow).

What is the purpose of the study?

This study will be part of a larger piece of research assessing whether Acceptance and Commitment Therapy (ACT) would be a helpful intervention for persons adapting to life following a brain injury. This study is a "pilot study" which means that we will also be looking at how to improve future studies. Agreeing to participate in this study does not mean that you will be obliged to partake in any future studies. This study will also be submitted as part of the main researcher's (Claire Moynan and Niamh O'Meara) portfolio for part completion of the Doctorate in Clinical Psychology.

Do I have to take part?

No it is your decision to take part. A member of the psychology team who is involved in this research will go through this information sheet with you and answer any questions; they will

then give you a copy of the information sheet. Should you choose to meet with us (Niamh or Claire) to hear more about the study, we will answer any further questions. If that point you choose to take part we will ask you to sign a consent form. You are free to drop out at any time, without giving reason. This would not affect the standard of care you receive or your future treatment. If you do withdraw from the study you will still have the opportunity to attend a focus group. This will allow you to discuss any difficulties you encountered, but you are free to choose not to attend this group also.

What does taking part involve?

One of the aims of our study is to assess whether there is a difference in outcome (e.g. levels of depression and anxiety) in service users receiving the ACT intervention (Intervention group) and services users who do not receive the intervention (Comparison group). Should you choose to take part in this study you will be assigned to the comparison group i.e. You will not be involved in the ACT intervention; you will receive treatment as usual. Your participation in the study will involve completing questionnaires on two occasions. The questionnaires will take approximately 40 minutes to complete. There will be a six week period in between completing the questionnaires; this is so we can compare the measures with service users who are receiving the ACT intervention in the same time period. Service users who will receive the intervention will be based at a BIRT unit in Glasgow, the reason choosing Glasgow as the intervention site is because the main researchers are also based in Glasgow. After completing the questionnaires you will be invited to attend a small focus group with others who were also involved in the study. The purpose of this group is to get your thoughts and opinions about your participation. The focus group will last no longer than one hour. The focus group will be recorded so that the information provided by can be analysed at a later date.

Should you choose to take part we would also ask that we access your medical records in order to gather details about your head injury. Furthermore details of your involvement in the study will be included in your medical file.

What happens to the information?

Your identity will be protected and all personal information will be completely confidential known only to the researcher and the people organising the study. The information obtained will be stored in a locked filing cabinet at the University of Glasgow and would only be accessed by others in the event of an audit to make sure the study is being conducted correctly. Data collected will be anonymised and unique codes will be used as identifiers. The data are held in accordance with the Data Protection Act, which means that we cannot reveal it to other people without your permission. The final report of the results of this study will be submitted for review to Glasgow University as a doctoral thesis and following this may be published in a scientific journal. If you chose to participate, you will be given the opportunity to receive a summary sheet detailing the key results of the study.

Will you inform my care team at BIRT?

With your permission, a careplan outlining your participation in the study will be shared with your care team. If you would like to see an example of the careplan please just ask the

researcher. Additionally if you tell us that you or someone else is at harm we will need to contact your care team at BIRT and the appropriate authorities to ensure the safety of you and the public.

What are the possible effects on you?
Should you experience a negative emotional reaction when completing the questionnaire or should you experience strong emotions during the focus group, you will be offered the opportunity to discuss this with the researcher or a member of your care staff.

What are the possible benefits of taking part?
By taking part in this research you will be providing valuable information on the development of a psychological therapy. This could improve rehabilitation interventions for people who have experienced a head injury.

Who has reviewed the study?
This study has been reviewed by the West of Scotland Research Ethics Committee.

If you have any further questions?
If you would like more information about the study and wish to speak to someone not closely linked to the study, please contact Dr Sue Turnbull, Research Tutor, University of Glasgow, email: s.turnbull@clinmed.gla.ac.uk, Tel no: 0141 211 3927.

If you have a complaint about any aspect of the study?
If you are unhappy about any aspect of the study and wish to make a complaint, please contact the researcher in the first instance but the normal NHS complaint mechanism is also available to you.

Contact details:
Research Supervisors:

Professor Tom McMillan
University of Glasgow
Institute of Health and Wellbeing
1055 Great Western Road
Glasgow G12 0XH
Thomas.McMillan@glasgow.ac.uk

Dr Hamish McLeod
University of Glasgow
Institute of Health and Wellbeing
1055 Great Western Road
Glasgow G12 0XH
Hamish.McLeod@glasgow.ac.uk

Thank you for taking the time to read this information sheet.

Appendix 2.7 Information sheet for staff at intervention site

REACT – Recovery Enhancement from TBI using ACT; A Pilot Study.

Version Number: 1
Date: 11/11/2014

Contact details: Niamh O'Meara Claire Moynan
Email: n.o'meara.1@research.gla.ac.uk c.moynan.1@research.gla.ac.uk

Information Sheet for Care Staff at Treatment Group

You are being invited to take part in focus group as part of our research study. Please take time to read this information. Please ask us if there is anything that is not clear or if you would like more information.

Who is conducting the research?

This study is being carried out by Niamh O'Meara and Claire Moynan and is being supervised by Dr Hamish McLeod and Professor Tom McMillan (University of Glasgow).

What is the purpose of the study?

This study will be part of a larger piece of research assessing whether Acceptance and Commitment Therapy (ACT) would be a helpful intervention for persons adapting to life following a brain injury. This study is a "pilot study" which means that we are carrying out the present study in order to assess how future studies could be improved.
This study will also be submitted as part of the main researcher' (Claire Moynan and Niamh O'Meara) portfolio for part completion of the Doctorate in Clinical Psychology.

Do I have to take part?

It is up to you to decide. We will describe the study and go through this information sheet, which we will then give to you. You will be asked to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving reason.

What does the taking part involve for the service users?

Service users who meet inclusion criteria will be invited to take part in a six week Acceptance and Commitment Therapy (ACT) Intervention. The main goal of ACT is to help people make room for experiencing painful thoughts and feelings as opposed to trying to get rid of these difficult experiences. In doing so it is proposed that people will have more energy to carry out

activities that are meaningful to them. The psychologists who will deliver the training are part of the existing psychology team at BIRT.

Service users taking part will be asked to complete questionnaires on two occasions; before the first therapy session and after the final therapy session, following which they will be invited to attend a small focus group. The purpose of this group is to seek feedback from service users about being involved in the study.

Service users in BIRT centres in England will also be invited to take part in the study. Participants in England will not receive ACT intervention but will act as a comparison group in this pilot study.

What does taking part involve for you?
Taking part would involve attending a focus group once the ACT intervention has completed and all questionnaires have been collected from the relevant service users. The purpose of this focus group is to seek your opinion on matters relating to the study, for example your perspective of service user involvement in the study.
The session will be recorded and facilitated by both Claire and Niamh. The focus group session will be approximately one hour long.

If you choose to participate you may also be asked to complete a short questionnaire, which should take no longer than 10 minutes, at two time points (pre and post intervention). This questionnaire will ask questions relating to inpatients' self-awareness. You will be approached to complete questionnaires based on your knowledge of working with that service user and availability. You may also be asked to participate in collecting demographic details for clients and discussing risk factors with the researchers.

What happens to information from the focus groups?
Your identity and personal information will be completely confidential and known only to the researcher. The information obtained will remain confidential and stored within a locked filing cabinet at the University of Glasgow and would only be accessed by others in the event of an audit. Data collected will be anonymised and unique codes will be used as identifiers. The data are held in accordance with the Data Protection Act, which means that we keep it safely and cannot reveal it to other people without your permission. The final report of the results of this study will be submitted for review to Glasgow University as a doctoral thesis and following this may be published in a scientific journal.

What are the possible effects on you?
The focus group may or may not elicit an emotional reaction for you. Should you experience a negative emotional reaction you will be offered the opportunity to discuss this with us following the group and we would encourage you to seek support from a colleague or a member of the psychology team.

What are the possible benefits of taking part?

By taking part in this research you will be providing valuable information on the development of a psychological therapy that could potentially improve rehabilitation interventions for people who have experienced a head injury.

Who has reviewed the study?
This study has been reviewed by the West of Scotland Research Ethics Committee.

If you have any further questions?
We will give you a copy of the information sheet and signed consent form to keep. If you would like more information about the study and wish to speak to someone not closely linked to the study, please contact **Dr Sue Turnbull, Research Tutor, University of Glasgow, email: s.turnbull@clinmed.gla.ac.uk, Tel no: 0141 211 3927.**

If you have a complaint about any aspect of the study?
If you are unhappy about any aspect of the study and wish to make a complaint, please contact the researcher in the first instance but the normal NHS complaint mechanism is also available to you.

Contact details:
Main Researchers (Trainee Clinical psychologists):

Niamh O'Meara
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n.o'meara.1@research.gla.ac.uk

Claire Moynan
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Thank you for taking the time to read this information sheet.

Appendix 2.8 Information sheet for staff at control site

REACT – Recovery Enhancement from TBI using ACT; A Pilot Study.

Version Number: 1
Date: 11/10/2014

Contact details: Niamh O'Meara Claire Moynan
Email: n.o'meara.1@research.gla.ac.uk c.moynan.1@research.gla.ac.uk

Information Sheet for Care Staff in Comparison Group

You are being invited to take part in focus group as part of our research study. Please take time to read this information. Please ask us if there is anything that is not clear or if you would like more information.

Who is conducting the research?

This study is being carried out by Niamh O'Meara and Claire Moynan and is being supervised by Dr Hamish McLeod and Professor Tom McMillan (University of Glasgow).

What is the purpose of the study?

This study will be part of a larger piece of research assessing whether Acceptance and Commitment Therapy (ACT) would be a helpful intervention for persons adapting to life following a brain injury. This study is a "pilot study" which means that we are carrying out the present study in order to assess how future studies could be improved.
This study will also be submitted as part of the main researcher' (Claire Moynan and Niamh O'Meara) portfolio for part completion of the Doctorate in Clinical Psychology.

Do I have to take part?

It is up to you to decide. We will describe the study and go through this information sheet, which we will then give to you. You will be asked to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving reason.

What does the taking part involve for the service users?

Service users who meet inclusion criteria will be invited to take part in a six week Acceptance and Commitment Therapy (ACT) Intervention. The main goal of ACT is to help people make room for experiencing painful thoughts and feelings as opposed to trying to get rid of these

difficult experiences. In doing so it is proposed that people will have more energy to carry out activities that are meaningful to them. The psychologists who will deliver the training are part of the existing psychology team at BIRT.

Service users taking part will be asked to complete questionnaires on two occasions; before the first therapy session and after the final therapy session, following which they will be invited to attend a small focus group. The purpose of this group is to seek feedback from service users about being involved in the study.

Service users in BIRT centres in England will also be invited to take part in the study. Participants in England will not receive ACT intervention but will act as a comparison group in this pilot study.

What does taking part involve for you?
If you choose to participate you may also be asked to complete a short questionnaire, which should take no longer than 10 minutes, at two time points (pre and post intervention). This questionnaire will ask questions relating to inpatients' self-awareness. You will be approached to complete questionnaires based on your knowledge of working with that service user and availability. You may also be asked to participate in collecting demographic details for clients and discussing risk factors with the researchers.

What happens to information from the focus groups?
Your identity and personal information will be completely confidential and known only to the researcher. The information obtained will remain confidential and stored within a locked filing cabinet at the University of Glasgow and would only be accessed by others in the event of an audit. Data collected will be anonymised and unique codes will be used as identifiers. The data are held in accordance with the Data Protection Act, which means that we keep it safely and cannot reveal it to other people without your permission. The final report of the results of this study will be submitted for review to Glasgow University as a doctoral thesis and following this may be published in a scientific journal.

What are the possible effects on you?
The questionnaire will focus on questions related to the service-user. Although unlikely to elicit an adverse emotional reaction for you, should you experience this you will be offered the opportunity to discuss this with us, and we would encourage you to seek support from a colleague or a member of the psychology team.

What are the possible benefits of taking part?
By taking part in this research you will be providing valuable information on the development of a psychological therapy that could potentially improve rehabilitation interventions for people who have experienced a head injury.

Who has reviewed the study?
This study has been reviewed by the West of Scotland Research Ethics Committee.

If you have any further questions?

We will give you a copy of the information sheet and signed consent form to keep. If you would like more information about the study and wish to speak to someone not closely linked to the study, please contact **Dr Sue Turnbull, Research Tutor, University of Glasgow, email: s.turnbull@clinmed.gla.ac.uk, Tel no: 0141 211 3927.**

If you have a complaint about any aspect of the study?
If you are unhappy about any aspect of the study and wish to make a complaint, please contact the researcher in the first instance but the normal NHS complaint mechanism is also available to you.

Contact details:

Main Researchers (Trainee Clinical psychologists):

Niamh O'Meara
University of Glasgow
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Claire Moynan
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Research Supervisors:

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Dr Hamish McLeod
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1055 Great Western Road
Glasgow G12 0XH
Hamish.McLeod@glasgow.ac.uk

Thank you for taking the time to read this information sheet.

Appendix 2.9 Consent form for patients

Consent Form for clients

REACT – Recovery Enhancement from TBI using ACT; A Pilot Study.

Version Number: 1
Date: 11/11/2014

Contact details: Niamh O'Meara
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Institute of Health and Wellbeing
1055 Great Western Road
Glasgow G12 0XH
Email: n.o'meara.1@research.gla.ac.uk

Claire Moynan
University of Glasgow
Institute of Health and Wellbeing
1055 Great Western Road
Glasgow G12 0XH
c.moynan.1@research.gla.ac.uk

Please initial the BOX

I confirm that I have read and understand the client information sheet version 1 dated _____ for the above study. ☐

I confirm that the researcher has answered any queries to my satisfaction. ☐

I understand that my participation is voluntary and that I am free to withdraw from the study at any time, without having to give a reason and without any consequences. ☐

I consent to medical records in relation to head injury being accessed for the purposes of the study. ☐

I give my permission for audio recording of the Focus Group I will attend ☐

I understand that any information recorded in the investigation will remain confidential and no information that identifies me will be made publicly available. ☐

I give permission for my care team to be informed that I am taking part in the study. ☐

I give permission for researchers to inform clinicians at BIRT and appropriate authorities if I should disclose that I or someone else is at harm. ☐

I consent to being a participant in the project. ☐

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Name of Participant	Date	Signature
---	---	---
Name of Witness	Date	Signature

1 copy to patient, 1 copy to researcher, 1 original for the patient's notes

Appendix 2.10 Consent form for care staff at intervention site.

Consent Form for Care Staff at intervention centre

REACT – Recovery Enhancement from TBI using ACT; A Pilot Study.

Version number: 1
Date: 11/11/2014

Contact details: Niamh O'Meara
University of Glasgow
Institute of Health and Wellbeing
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Email: n.o'meara.1@research.gla.ac.uk

Claire Moynan
University of Glasgow
Institute of Health and Wellbeing
1055 Great Western Road
Glasgow G12 0XH
c.moynan.1@research.gla.ac.uk

Please initial the BOX

I confirm that I have read and understand the information sheet for care staff at treatment site, version number 1, dated _____ for the above study. ☐

I confirm that the researcher has answered any queries to my satisfaction. ☐

I understand that my participation is voluntary and that I am free to withdraw from the project at any time, without having to give a reason and without any consequences. ☐

I understand that any information recorded in the investigation will remain confidential and no information that identifies me will be made publicly available. ☐

I consent to audio recording of the focus group ☐

I consent to being a participant in this research. ☐

| --- | --- | --- |
Name of Participant	Date	Signature
Name of Witness	Date	Signature

1 copy to staff, 1 copy to researcher

Appendix 2.11 Consent form for patients at control site.

Consent Form for Care Staff at Comparison Centre

REACT – Recovery Enhancement from TBI using ACT; A Pilot Study.

Version number: 1
Date: 11/11/2014

Contact details: Niamh O'Meara
University of Glasgow
Institute of Health and Wellbeing
1055 Great Western Road
Glasgow G12 0XH
Email: n.o'meara.1@research.gla.ac.uk

Claire Moynan
University of Glasgow
Institute of Health and Wellbeing
1055 Great Western Road
Glasgow G12 0XH
c.moynan.1@research.gla.ac.uk

Please initial the BOX

I confirm that I have read and understand the information sheet for care staff at comparison centre, version number 1, dated _____ for the above study. ☐

I confirm that the researcher has answered any queries to my satisfaction. ☐

I understand that my participation is voluntary and that I am free to withdraw from the project at any time, without having to give a reason and without any consequences. ☐

I understand that any information recorded in the investigation will remain confidential and no information that identifies me will be made publicly available. ☐

I consent to being a participant in this research. ☐

----------	----------	----------
Name of Participant	Date	Signature
----------	----------	----------
Name of Witness	Date	Signature

1 copy to staff, 1 copy to researcher

Appendix 2.12 AAQ-ABI, 15-item version

Acceptance and Action Questionnaire—Acquired Brain Injury (AAQ-ABI)

Read each sentence. Then, circle a number between 0-4 that tells how true each sentence is for you.

1. I do things I care about even when I feel upset about my brain injury.

0	1	2	3	4
Not at all true	A little true	Pretty true	True	Very true

2. I hate how my brain injury makes me feel about myself.

0	1	2	3	4
Not at all true	A little true	Pretty true	True	Very true

3. I need to get rid of my anxiety about my brain injury.

0	1	2	3	4
Not at all true	A little true	Pretty true	True	Very true

4. I stop doing things when I feel scared about my brain injury.

0	1	2	3	4
Not at all true	A little true	Pretty true	True	Very true

5. My brain injury defines me.

0	1	2	3	4
Not at all true	A little true	Pretty true	True	Very true

6. I am moving forward with my life.

0	1	2	3	4
Not at all true	A little true	Pretty true	True	Very true

7. It is OK for me to feel different after my brain injury.

0	1	2	3	4
Not at all true	A little true	Pretty true	True	Very true

8. I would give up important things in my life if I could make the brain injury go away.

0	1	2	3	4
Not at all true	A little true	Pretty true	True	Very true

9. My worries and fears about my brain injury are true.

0	1	2	3	4
Not at all true	A little true	Pretty true	True	Very true

10. I try not to think about having a brain injury.

0	1	2	3	4
Not at all true	A little true	Pretty true	True	Very true

11. Other people make it hard for me to accept myself.

0	1	2	3	4
Not at all true	A little true	Pretty true	True	Very true

12. I don't need to be ashamed of my brain injury.

0	1	2	3	4
Not at all true	A little true	Pretty true	True	Very true

13. I often pretend that I don't have a brain injury.

0	1	2	3	4
Not at all true	A little true	Pretty true	True	Very true

14. Most people are doing better than me.

0	1	2	3	4
Not at all true	A little true	Pretty true	True	Very true

15. Even with my brain injury, I can do good work.

0	1	2	3	4
Not at all true	A little true	Pretty true	True	Very true

Appendix 2.13 AAQ-ABI 9-item version

Acceptance and Action Questionnaire
Acquired Brain Injury (AAQ-ABI)

Read each sentence. Then, circle a number between 0-4 that tells how true each sentence is for you

	Not at all true	A little true	Pretty true	True	Very True
1. I hate how my brain injury makes me feel about myself	0	1	2	3	4
2. I need to get rid of my anxiety about my brain injury	0	1	2	3	4
3. I stop doing things when I feel scared about my brain injury	0	1	2	3	4
4. My brain injury defines me as a person	0	1	2	3	4
5. I am moving forward with my life	0	1	2	3	4
6. I would give up important things in my life if I could make the brain injury go away	0	1	2	3	4
7. My worries and fears about my brain injury are true	0	1	2	3	4
8. Other people make it hard for me to accept myself	0	1	2	3	4
9. Most people are doing better than me	0	1	2	3	4

111112

Appendix 2.14 MOTQ

MOT-Q

Motivation for Traumatic Brain Injury Rehabilitation Questionnaire

Defense and Veterans Head Injury Program, Walter Reed Army Medical Center, Bldg. 7, Rm. 224, Washington, D.C. 20307
(202) 782-7281, FAX (202) 782-4400

Participant code: _____

_____/_____/_____
Today'sDate (Mo/Day/Yr)

Please rate your agreement with the following statements by placing an X in an appropriate square.

Rehabilitation programs are designed to help injured persons recover from their illness. Rehabilitation includes: physical therapy, speech therapy, counseling or psychotherapy, occupational therapy, vocational services, and cognitive therapy.

		Strongly Disagree	Disagree Somewhat	Undecided	Agree Somewhat	Strongly Agree	For Office Use Only LD	IR	LA	RH
1	If it was recommended, I would see a rehabilitation therapist.	-2	-1	0	1	2				
2	Given a choice I would spend more time in therapy.	-2	-1	0	1	2				
3	Rehabilitation will probably help me.	-2	-1	0	1	2				
4	Rehabilitation is very useful.	-2	-1	0	1	2				
5	At first I had some problems, but I'm fine now.	2	1	0	-1	-2				
6	I'm better now than I ever was.	2	1	0	-1	-2				
7	Rehabilitation therapists can't help me with my problems.	2	1	0	-1	-2				
8	Rehabilitation has nothing to do with my needs.	2	1	0	-1	-2				
9	I have always had the problems I'm having now.	2	1	0	-1	-2				
10	I have some problems, but I'm doing fine.	2	1	0	-1	-2				
11	Rehabilitation therapists would probably treat me like a child.	2	1	0	-1	-2				
12	I'm very excited about getting treatment as soon as possible.	-2	-1	0	1	2				
13	There is nothing wrong with me.	2	1	0	-1	-2				
14	I'll be the same if I get treatment or not.	2	1	0	-1	-2				
15	Therapists would have me do things that are irrelevant.	2	1	0	-1	-2				
16	The head injury had minimal effect on my abilities.	2	1	0	-1	-2				
17	Rehabilitation is useful, but I don't think I need it.	2	1	0	-1	-2				
For Office Use Only	Subtotal Page 1									

Appendix 2.15 Satisfaction Questionnaire

Participant Satisfaction with ACT Treatment

Project Title: REACT – Recovery Enhancement from TBI using ACT; A Pilot Study.

Version Number: 1

Date: 24th October 2014

Client Code:

Please rate on a scale from 0 to 4 that tells how true each sentence is for you.

I found this group helpful:

0	1	2	3	4
Not at all true	A little true	Pretty true	True	Very true

I would recommend this group to others:

0	1	2	3	4
Not at all true	A little true	Pretty true	True	Very true

Attending this group was highly distressing:

0	1	2	3	4
Not at all true	A little true	Pretty true	True	Very true

Appendix 2.16 HADS

Hospital Anxiety and Depression Score (HADS)

This questionnaire helps your physician to know how you are feeling. Read every sentence. Place an "X" on the answer that best describes how you have been feeling during the LAST WEEK. You do not have to think too much to answer. In this questionnaire, spontaneous answers are more important

A	**I feel tense or 'wound up':**	
	Most of the time	3
	A lot of the time	2
	From time to time (occ.)	1
	Not at all	0
D	**I still enjoy the things I used to enjoy:**	
	Definitely as much	0
	Not quite as much	1
	Only a little	2
	Hardly at all	3
A	**I get a sort of frightened feeling as if something awful is about to happen:**	
	Very definitely and quite badly	3
	Yes, but not too badly	2
	A little, but it doesn't worry me	1
	Not at all	0
D	**I can laugh and see the funny side of things:**	
	As much as I always could	0
	Not quite so much now	1
	Definitely not so much now	2
	Not at all	3
A	**Worrying thoughts go through my mind:**	
	A great deal of the time	3
	A lot of the time	2
	From time to time, but not often	1
	Only occasionally	0
D	**I feel cheerful:**	
	Not at all	3
	Not often	2
	Sometimes	1
	Most of the time	0
A	**I can sit at ease and feel relaxed:**	
	Definitely	0
	Usually	1
	Not often	2
	Not at all	3

D	**I feel as if I am slowed down:**	
	Nearly all the time	3
	Very often	2
	Sometimes	1
	Not at all	0
A	**I get a sort of frightened feeling like "butterflies" in the stomach:**	
	Not at all	0
	Occasionally	1
	Quite often	2
	Very often	3
D	**I have lost interest in my appearance:**	
	Definitely	3
	I don't take as much care as I should	2
	I may not take quite as much care	1
	I take just as much care	0
A	**I feel restless as I have to be on the move:**	
	Very much indeed	3
	Quite a lot	2
	Not very much	1
	Not at all	0
D	**I look forward with enjoyment to things:**	
	As much as I ever did	0
	Rather less than I used to	1
	Definitely less than I used to	2
	Hardly at all	3
A	**I get sudden feelings of panic:**	
	Very often indeed	3
	Quite often	2
	Not very often	1
	Not at all	0
D	**I can enjoy a good book or radio/TV program:**	
	Often	0
	Sometimes	1
	Not often	2
	Very seldom	3

Appendix 2.17 Awareness Questionnaire: Patient-form

Awareness Questionnaire
Patient Form

Participant Code: _____

Date: _____

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Appendix 2.18 Awareness Questionnaire: Clinician-form

Awareness Questionnaire
Clinician Form

Participant Code: _____

Date: _____

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

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

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

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

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

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

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

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

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

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

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

Appendix 2.19 ACT treatment as provided in this study

The Intervention:
- 6 weekly 2-hour sessions

Aims of Group:
- Assisting in the rehabilitation process.
- Helping with emotional difficulties since the injury.
- Learning some strategies to help service users progress.
- Working together in a supportive environment and respecting others in the group.
- Helping service users to live the best life they can in spite of what has happened.
- Focused on what service users want, what they value and what they want to achieve in their life.
- Helping to put the service user back in the driver's seat, empowering and enabling them to think about where they might want to go.

Session 1:Introduction to the group
- Introductions & name tags
- Brief mindfulness exercise
- Group guidelines including confidentiality
- Icebreaker activity (pair/share – where to with rehabilitation?)
- Reason for attending – Group aims – Program outline

<u>Confronting the agenda</u>
- Facilitate individual stories: A)Event B)Feelings C) Thoughts D) What I've done to feel better.
- Workability of strategies to reduce distress (15-mins) – Breathing mindfulness activity (10-mins)

<u>Homework</u>
- Introduce concept of homework
- Complete monitoring during the week of any event when they became distressed: 1) what happened, 2) what were they thinking about, and 3) what they did to feel better e.g. yell at someone, go to your room.
- Homework contract

Session 2: Control is part of the problem
- Mindfulness activity (5 mins)
- Review homework
- Review previous session
- Control is the problem (15 mins) – Normalcy of control/chocolate cake exercise –

<u>Human suffering</u>
- Exercise: Let suffering get close (10 mins)
- Exercise: Passengers on the Bus

Homework: Valued activity
- write value on a card and the barriers on the other side. Carry the card for a week. Notice if you can complete valued activity in spite of barriers
- Homework contract

Session 3- Acceptance and Defusion
- Brief mindfulness exercise (5mins)
- Review homework
- Review previous session

Acceptance and Defusion:
- Defusion exercise – The power of language: milk milk milk (10 mins)
- Physicalise the thought: 'Imagine holding a thought in your hands in front of you....' (15 mins)
- Don't get eaten machine (20 mins)
- Education: the mind is like a salesman

Homework – Physicalising thoughts
- Homework contract

Session 4
- Mindfulness exercise (5mins)
- Review homework (10mins)
- Review previous session (5mins)

The observing self:
- Separating self from thoughts/feelings/actions
- 4 circles
- Exercise: Observer (15 mins)
- The Observing Self (20 mins)
- Chessboard Metaphor
- Mindful walking / mindful eating of sultana

Homework – Listing to mindfulness CD
- 3 times over the next week/Drinking tea or coffee mindfully.
- Homework contract
- Weekly diary

Session 5
- Mindfulness activity (5 mins)
- Review homework
- Review previous session

Introduction of values:
- Like a lighthouse guiding us.
- Difference between goals (something you succeed or fail at) and values.
- Exercise

- Values Screen Measure
- Exercise
- Funeral / Birthday party

Homework – Principles and action
- Select a value to work on.
- Homework contract

Session 6
- Mindfulness activity (5 mins)
- Review homework/previous session
- Values and committed action
- Seeing goals (20 mins)
- Recap and review of each session
- What happens next?

Homework – Weekly diary
- Homework contract

Appendix 2.20 RCI and clinical cut-off methods

$$\text{RCI} = \frac{X_2 - X_1}{S_1\sqrt{1} - r_{xx}}$$

Where X_1 = baseline scores; X_2 = post-baseline score; S_1 = the standard deviation at baseline; and $\boldsymbol{r_{xx}}$ = the internal reliability.

Cut-off Scores Formulae:

$$a = \boldsymbol{M_1 + 2s_1}$$

$$b = \boldsymbol{M_0 - 2s_1}$$

$$c = \frac{\boldsymbol{S_0 M_1 + S_1 M_0}}{\boldsymbol{S_0 + S_1}}$$

Where M_1, S_1, M_0, S_0 specifies the means and standard deviations of the participants with sTBI and a normative sample respectively.

Appendix 2.21 Research Proposal

Major Research Project Proposal

REACT – Recovery Enhancement from TBI using ACT; A Pilot Study.

Name: Claire Moynan
Matriculation number: 2058542
University Supervisor: Prof Tom McMillan; Dr Ross White; Dr Hamish McLeod
Field Supervisor: Dr. Brian O'Neil
Date of Original Submission: 28th April 2014
Date of Current Submission: 26th October 2014
Version: 7

Abstract

Introduction: Severe traumatic brain injury (sTBI) is associated with depression, anxiety and low self-awareness. A key factor in recovery is adjustment to the effects of injury. Psychological intervention may facilitate adjustment, although the evidence base for effective strategies remains limited. Acceptance and Commitment Therapy (ACT) seeks to increase psychological flexibility by focusing on the benefits of developing acceptance in the present moment whilst striving towards valued goals. Current research on the use of this therapy with people who have sTBI is limited, but reviews propose it may be useful in rehabilitation (Kangas & MacDonald, 2011).

Design: A preliminary group comparison study as part of a treatment pilot study.

Objective: To investigate the acceptability and feasibility of ACT combined with Treatment as Usual (TAU) for people with sTBI, providing data for effect size parameter estimation and assessing possible change in therapeutic measures in addition to assessing treatment adherence. The study will also aim to characterise TAU.

Method: Participants will be recruited from three Brain Injury Rehabilitation Trust (BIRT) inpatient units in the UK. Study measures assessing psychological flexibility, mood, self-awareness, and treatment engagement motivation will be assessed at two time points with both groups.

Introduction

Traumatic Brain Injury (TBI) is a major public health problem associated with long-term psychological consequences such as depression, anxiety and impaired self-awareness (Caroll & Coetzer, 2011). Although such consequences are well known (Waldron, Casserly & O'Sullivan, 2013), there has been little research evaluating specific psychological interventions (see Comper, Bisschop, Carnide & Tricco, 2005; McMillan, 2013; Soo & Tate, 2009; Snell, Surgenor, Hay-Smith & Siegert, 2009). Further research into the use of psychological therapy in neurorehabilitation could play an important role in helping to promote and develop ways to treat emotional disturbance and increase self-awareness amongst this group.

The current treatment of choice for a range of mood disorders is Cognitive Behavioural Therapy (CBT). Currently limited research exists examining use of this therapy with people who have TBI, however a small number of studies have investigated the effectiveness of ACT with those who have acquired brain injury (ABI). ABI occurs as a result of TBI or nontraumatic brain injury such as stroke, brain tumours, infections and hypoxia. Owing to the limited literature available studies investigating ABI will be examined, however care should be taken in interpretation as some of the participants may differ demographically when compared to pure TBI populations. In a recent review of the literature, positive effect sizes (average d=1.15 for depression; d=1.04 for anxiety) were found following use of CBT with people with ABI (ABI; Waldron et al., 2013). These effect sizes, however, varied widely between (Depression: 0-2.39; Anxiety 0-3.47) studies. Waldron and colleagues (2013) conclude that whilst CBT's structured approach and adaptability to multiple conditions may be useful for those with ABI, it is not a panacea. Hsieh, Ponsford, Wong and McKay (2012) explored the variables associated with therapeutic change and noted that better memory and executive-functioning and motivation were related to positive post-CBT outcomes. They surmised that this was due to the requirement of the individual to keep track of conversations and exercise reasoning during therapy. Indeed, the emphasis on cognitive restructuring may limit CBTs ability to exercise change in people with TBI if they have self-awareness deficits (Whiting et al., 2012). Hsieh et al (2012) acknowledged that although CBT led to modest gains, "it remains a possibility that aspects of the programme [were] still beyond the ability of some participants" (p.412). Therefore, effective psychological treatment options that circumvent the limitations of the approaches currently in use are needed.

One emerging alternative to CBT is Acceptance and Commitment Therapy (ACT). The aim of ACT is not to improve mood per se (although this is often an outcome) but instead emphasis is placed on improving patient's ability to accept difficulties in the service of pursuing valued life goals (Harris, 2006). This is known as psychological flexibility. This could lead to more generalisable effects not currently achieved with standard CBT approaches. ACT helps patients understand that the wish to control

emotions can paradoxically maintain their problems. This is achieved through the implementation of six core principles: *Defusion*, the ability to detach from our own thoughts, *Acceptance*, making room for unpleasant experiences, *Contact with the Present Moment*, through the development of mindfulness, *the Observing Self,* recognition that we are not our thoughts, *Values*, recognising what's important to us and *Committed action*, setting goals to achieve our values. Current published work on the use of ACT with TBI patients is limited to theoretical reviews and position papers. Kangas and McDonald (2011) propose that ACT could aid distressed clients with ABI to try and live a valued life, accepting the presence of their physical and neurological deficits. Through "self-as-context" and "acceptance" principles these researchers propose that clients with ABI could develop increased self-awareness, a key to positive neurorehabilitation outcome (McMillan, 2013). Similarly, a systematic review on ACT for anxiety management, argued that the use of ACT for ABI is feasible (Soo, Tate & Lane-Brown, 2011), based on findings that acceptance helps re-construction of self concept following ABI. However, these propositions have yet to be tested with any rigour in a clinical trial context.

In summary, it is proposed that the evidence base for treating sTBI will be enhanced if new complex interventions are developed, refined, and tested empirically in clinical trials. The existing published reviews (Soo et al., 2011) and treatment protocols (Whiting et al., 2013) provide a theoretical and practical starting point for this work. In line with the MRC Complex Interventions Framework (Craig et al., 2008), we plan to conduct a preliminary pilot/feasibility study of ACT for sTBI. The results will inform the conduct of a future larger trial.

Aims

This study is one part of a pilot study being completed to inform the development of a future trial into the use of ACT in inpatient neurorehabilitation settings (Appendix A). This pilot study is the first to be conducted with people who have sTBI in the UK and will inform the parameters of subsequent trials. It will be focused on investigating the acceptability and feasibility of ACT, assessing treatment adherence in addition to

providing data for effect size parameter estimation and possible change in therapeutic process measures. Although BIRT typically provides a standard level of care the study will aim to characterise TAU as was specifically given to participants in this study. This fits with pilot study design guidelines that suggest formal hypothesis testing should not take place until effect size and sample size estimates have been conducted (Arain, Campbell, Cooper & Lancaster, 2010).

Data will be collected from a range of study measures including psychological flexibility, mood, awareness and motivation to engage in therapy. Their sensitivity to change will then be examined.

ACT Training and Treatment Programmes

ACT training

Training will be provided to researchers (CM, NoM) and psychologists in the Glasgow Brain Injury Rehabilitation Trust (BIRT) unit, Graham Anderson House. Dr Ross White will provide training to therapists addressing the ACT model and how this can be adapted for individuals with sTBI. The training will be based on the published protocol presented by Whiting et al. (2013) which focuses on three phases:

- Phase 1. Socialisation to the model, assessment and formulation
- Phase 2. Progressing with the ACT intervention
- Phase 3. Looking beyond the ACT intervention

Trial therapists will be supervised by Dr White. This will include monitoring of adherence to the protocol and the therapeutic principles of ACT ensuring that the approach provided is consistent with the model.

Treatment Protocol

The treatment programme is based on published work developed for outpatients with TBI (Whiting et al., 2013). This comprises six weekly two-hour sessions and a one-month follow-up. As the proposed treatment will be provided within an inpatient

setting, the follow-up session will be omitted, as it is believed that the inpatient setting will provide support to practice skills. The six core processes of ACT are incorporated into each session. Each session includes: review of homework and previous session, introduction of new topic and setting new homework. Treatment will be provided to groups of three patients by one therapist.

Treatment as Usual (TAU)

This will be provided to both groups. At BIRT, TAU for mental health problems includes a client-centred goal planning system which is linked to community reintegration and based on a holistic rehabilitation model (Scottish Intercollegiate Guidelines Network, 2013). Typical provision includes counselling by mental health nurses, medical management by a GP, CBT by a Clinical Psychologist and pharmacotherapy overseen by a Consultant Psychiatrist. In order to characterise what TAU looks like a checklist of what treatment the client received during the eight week assessment period will be completed (Checklist for TAU).

ACT will not be offered routinely to clients in the TAU only group following completion of the research as, at present, there is little evidence to suggest that ACT is superior to TAU for people with severe TBI. It is hoped that this pilot study will inform a future clinical trial which would seek to provide such evidence.

Treatment Adherence

The degree to which the therapists adhere to the procedures prescribed in the protocol affects the validity of a study and the inferences that can be drawn (Perepletchikova, Treat & Kazdin, 2007). Adherence in this study will be guided by principles drawn from the Implementation of Treatment Integrity Procedures Scale (ITIPS; as described in Perepletchikova et al., 2007) used to assess trial implementation quality (see Table 1).

Table 1.

Treatment Fidelity Monitoring Framework Based on ITIPS Guidelines

ITIPS guideline	Implemented in this study
Definition of Treatment Adherence provided	Description provided in protocol
Provision of Treatment manual	Therapist trained to use provided manual
Therapist training	Training provided and description of training provided in protocol
Supervision of therapist	Supervision provided and description of supervision provided in protocol
Assessment of Treatment Adherence	Completed in Supervision and through subjective measures (focus group) as part of the joint pilot study.

Plan of Investigation

Participants

The aim is to recruit two groups of 15 people with sTBI from BIRT. Participants for the treatment group (N=15) will be recruited from BIRT Glasgow and the comparison group (N=15) from units in York and Leeds. Using separate centres to recruit treatment and comparison groups will minimise unintended leakage of treatment effects across groups. All three units have comparable service-user profiles, based on data collected by BIRT and have the same core philosophy, structure for rehabilitation and outcome measures (B. O'Neil, personal communication, July 3, 2014).

Justification of Sample Size

Views on participant numbers for pilot studies are conflicting. Lancaster, Dodds and Williamson (2004) recommends an overall sample size of 30, whereas other studies suggest numbers between 24 and 50 (Julious, 2005; Sim & Lewis, 2012). In view of these recommendations, the time available for completion of this study, and the number of admissions to BIRT each year (on average 30 per centre; N. Patterson, personal communication August 15th, 2014) it is anticipated that 30 clients in total will be recruited for this pilot study.

Additionally, Craig and colleagues (2008) emphasise that treatment evaluations can often be compromised by "smaller-than-expected effect sizes"(p.10), an issue that can be remedied by thorough preparatory work. One of the study aims is to provide data that will inform effect size parameter estimation which will aid the future calculation of appropriate sample sizes ensuring future trials are suitably powered.

Inclusion and exclusion criteria for clients

This will be assessed by clinicians (Support workers, Key workers, Nursing and Psychology staff) at the units using a checklist (Inclusion and Exclusion Criteria Checklist).

Severity of brain injury will be classified by satisfying one or more of the following criteria:

- a score of less than 8 on the Glasgow Coma Scale for the index injury (Teasdale & Jennett, 1974)
- Post traumatic amnesia for at least 24 hours
- Loss of consciousness for more 30 minutes or more following the injury

Clients will:

- Be aged 18 or over
- Have capacity to give consent to participate in the study (assessed by clinicians at BIRT)
- Have sufficient cognitive capacity to complete study questionnaires and capacity to participate in discussions as part of the ACT intervention (both determined by clinicians at BIRT)
- Have an acceptable level of English language skills which will allow completion of questionnaires
- Exhibiting psychological distress or behavioural dysfunction that is deemed to warrant treatment assessed by the Glasgow Outcome at Discharge Scale (GODS) (McMillan, Weir, Ireland & Stewart, 2013)

Clients will not:

- Have an agreed discharge date within the following eight weeks
- Exhibit current severe challenging behaviour (impulsivity, irritability, disinhibition and or aggression) that may put the researcher and participant at risk or prevent participation in the study.

Inclusion/Exclusion criteria for Psychology staff involved in administration of therapy

Staff will:

- Be based at Graham Anderson House.
- Have completed the 1.5 day training on ACT.
- Have the time and resources to administer ACT intervention to at least one group of 3-4 clients once a week for a six week period within the time frame suggested for this pilot study.

Inclusion/Exclusion criteria for Care staff not delivering the intervention

Care staff invited to complete the awareness questionnaire will:

- Work directly with the clients receiving the intervention.
- Have commenced at BIRT employment prior to the first intervention session.

Recruitment Procedure

To recruit participants the following procedure will be followed:

1. The research will be discussed by both researchers (CM, NoM) with clinicians and clinical leads at each unit.
2. Each unit will provide a named clinician to act as a point of contact in relation to recruitment of client and staff participants.
3. All clinicians briefed on the recruitment process can provide information sheets to clients and staff who fit the inclusion criteria between November 2014 and end of April 2015.

4. Each participant will be given between 24 hours and one week to consider their participation in the project.
5. Both researchers (CM, NoM) will meet with care staff to discuss consent and will provide a consent form for them to complete if they wish to participate.
6. The researchers will then discuss risk with the staff member prior to meeting clients in order to ensure the safety of both researcher and client.
7. Both researchers (CM, NoM) will meet with the clients to discuss and obtain consent and complete baseline measures.
8. Both researchers (CM, NoM) will meet with care staff again to discuss demographic information and complete staff outcome measures, if the client and staff member has agreed to participate.
9. In line with BIRT policy and as the clients in residence at BIRT do not receive general GP care a care plan for all client participants will be drawn up by clinicians at BIRT. This will include the aims of the study and will be accessible to all working with the client.

Measures

Demographic and injury data will be collected at time 1, this will include:

- Gender
- Age
- Best level of occupational attainment pre-injury
- Socio-economic status (Scottish Index of Multiple Deprivation (SMID) and English Indices of Deprivation (ID))
- Time since TBI
- Age at TBI
- Date of admission
- Indices of severity of head injury (minimum GCS and or duration of LoC and or duration of PTA) will be obtained from the casenotes
- Glasgow Outcome at Discharge Scale

A cognitive assessment will be completed using multiple tests as part of the intake procedure at BIRT. This includes:

- Wechsler Test of Pre-morbid Functioning

- Wechsler Adult Intelligence Scale-IV subtests: Similarities, Block Design and Coding

- List Learning and Complex Figure Test from BIRT Memory and Information Processing Battery.

This information will be extracted from client files to provide a cognitive profile of participants.

Process Measures:

1. The Acceptance and Action Questionnaire-Acquired Brain Injury (AAQ-ABI; Sylvester, 2011) is a 15-item questionnaire measuring psychological flexibility and developed to target the difficulties typically faced after a brain injury. It was developed and used by Sylvester (2011) for a study in paediatric ABI.

Outcome Measures:

Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983) will be used to assess depression and anxiety. The 14-item scale has good internal consistency (Zigmond & Snaith, 1983) and is a reliable measure of post-ABI distress (Whelan-Goodinson, Ponsford & Schonberger, 2009).

The Awareness Questionnaire (AQ; Sherer, 2004) will be used to assess self-awareness. This 17-item questionnaire was designed specifically for people with TBI. The patient and staff versions will be administered. The scale is reported to have good internal consistency (Sherer et al., 1998a) and validity (Sherer et al., 1998b) and takes 10 minutes to complete.

Motivation for traumatic brain injury rehabilitation questionnaire (MOT-Q; Chervinsky et al, 1998). Items included in this questionnaire were selected to assess whether factors which facilitate or act as barriers to motivation to engage in rehabilitation TBI, these factors include denial of illness, anger, compliance with treatment, and medical information seeking behaviour. Chervinsky et al, 1998 reported this scale as having good reliability (0.91).

Although psychological interventions are often deemed acceptable to patients it is important that this is consistently assessed, particularly with novel therapies. It is hoped that such information will help refine the protocol and inform a larger future trial. In order to assess the acceptability of the intervention:

- Drop-out rates will be monitored as an indirect indicator of the acceptability of the therapy.
- Participants will complete a short questionnaire assessing their views on the treatment (Satisfaction Questionnaire)
- As part of the second study (NM; appendix A) focus groups will assess participant opinion

Design

A pilot/feasibility study exploring the parameters of a 2 x 2 within- and between-groups repeated-measures design. The treatment manual is based on a published protocol currently being tested with outpatients with TBI (Whiting et al., 2013). Randomisation does not fit within the pilot study parameters but the acceptability of randomisation will be assessed in the second part of this pilot study (appendix A).

Research Procedures

This pilot project has been split into two studies (Appendix A) and each researcher (CM, NoM) will be involved in data collection for the wider project.

The same procedure (Figure 1) will be followed for each participant. Each participant will be tested twice. For the treatment group this will occur before (time 1) and after (time 2) the ACT intervention is provided. For the comparison group testing will begin once consent is received (time 1) and eight weeks later (time 2). ACT training will be provided to both the researchers and psychologists at BIRT in Glasgow. ACT treatment will be provided to a quartet by one of the trained psychologists.

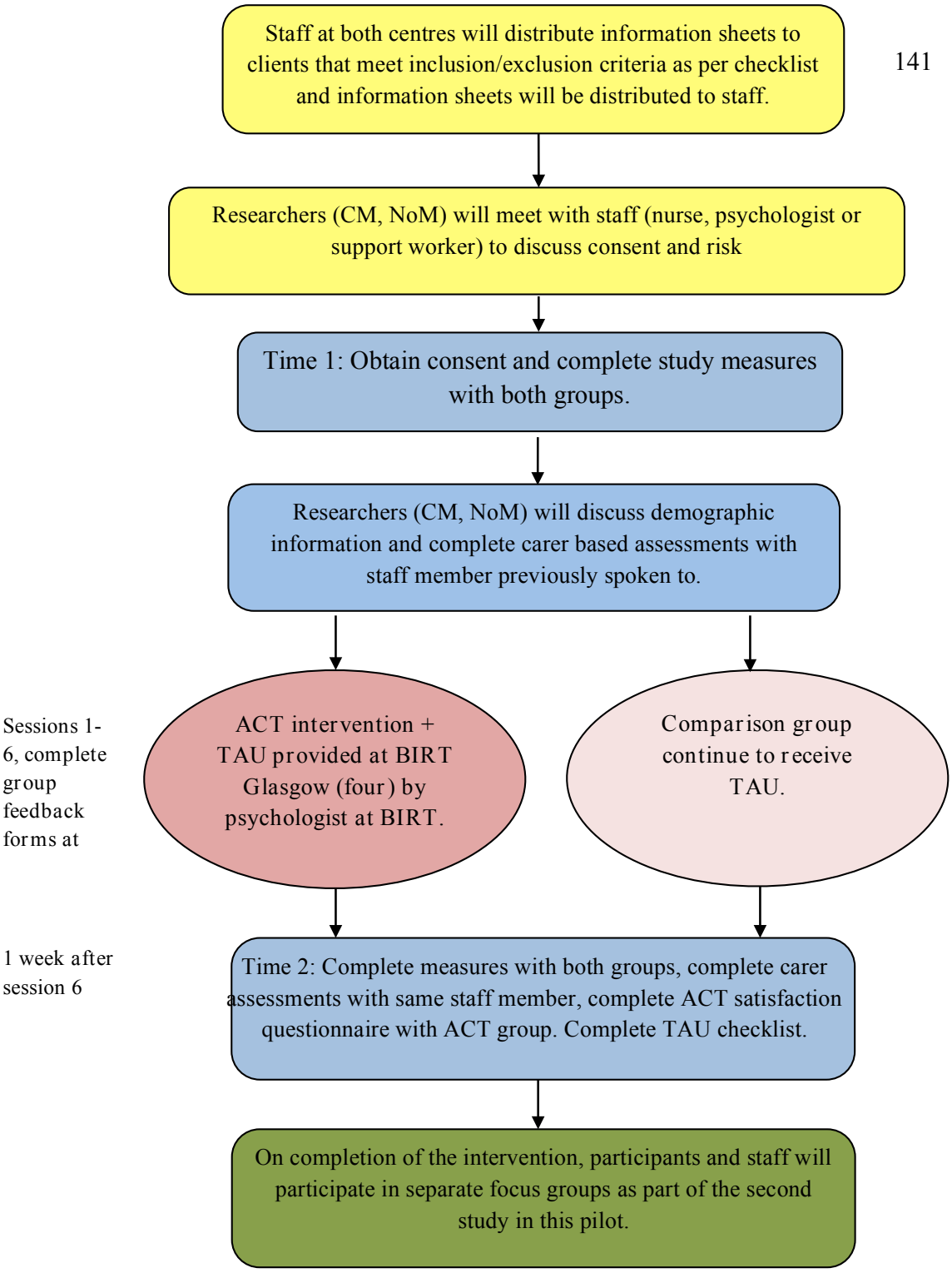

Figure 1. Research procedure

Data analysis

Results will be analysed using SPSS statistics version 20. Descriptive statistics will be conducted on demographic data presented as measures of central tendency (mean or

median at both time points) and dispersion (standard-deviation (SD) and interquartile ranges (IQRs). To ascertain group similarity at baseline, *t*-tests will be used to compare pre-intervention scores on demographic and injury characteristics and outcome measures. If data is non-normally distributed Mann-Whitney *U* tests will be used.

Treatment signals will be explored using a 2x2 mixed ANOVA on each of the study measures employed. This will compare pre and post intervention. If data is found to be non-normally distributed transformations will be performed on the data.

As this is a pilot study any drop-out or missing data will serve to inform the sample-size estimates of the next trial design therefore informing rather than hindering the project. As a consequence drop outs will be monitored rather than replaced.

Omega-squared will be used to estimate for effect size parameter estimation based on the psychological flexibility process measure. This estimate attempts to correct for bias by considering the sample size and factor levels (Hertzog, 2008).

Ethical Approval

All participants will be provided with an information sheet and consent form to obtain informed consent, highlighting that participants can leave the study at any time. Validated questionnaires will be used. As there is limited evidence available concerning treatment effectiveness, TAU is an appropriate comparison.

A university laptop which is encrypted to NHS standards will be used for data collection and the storage of anonymised data. This laptop will have restricted access to the principal researchers. Questionnaire data will be kept on the University of Glasgow Server for 10 years before being destroyed, as per University guidance. All raw data will be stored by the Uni versity of Glasgow for 10 years. Questionnaire data will be backed up by saving on a password protected folder on the University of Glasgow Server.

Ethics permission will be sought from the NHS Research Ethics Service and sponsorship will be sought from University of Glasgow.

Proposed Timetable

August/September	2nd submission of Proposal to University
September	Make changes in line with Glasgow University feedback Obtain sponsorship from University of Glasgow
September/October	Proceed to Ethics
22nd/26th Sep 2014	Administration of ACT training by RW.
Nov/Dec 2014	Staff select participants at both centres, provide I information to participants, collect consent form Researchers administer time 1 outcome measures Participants in treatment group will commence ACT.
Dec 2014	8 weeks later re-administer outcome measures at time 2.
Jan/ Feb 2015	If require further participants, the procedures to implement outcome measures will be repeated within this period.
March 2015	Final recruitment opportunity for participants to commence ACT for treatment group.
April/May 2015	Data analysis
June/July 2015 -	Dissertation write up.

Plans for Dissemination

This study will be written up for a dissertation in part fulfillment of the Doctorate in Clinical psychology. Following this the researchers intend to publish the results of this study in combination with the second part of the pilot study (NOM). The results from both pilot studies will also be written in language appropriate for the layman for distribution amongst participants of the study.

Practical Applications

There is a need for evidence-based psychological therapies for people with sTBI; particularly as the available research primarily focuses on work with people who have mild-moderate TBI. According to McMillan's (2013) review, the key to rehabilitation is an increase in insight which focuses on compensatory approaches. The aim of ACT is to improve psychological flexibility by building awareness and adopting a stance of acceptance whilst striving towards valued goals. Therefore, it is hypothesised that ACT could offer a way to increase insight and support adjustment post injury, therefore improving rehabilitative outcomes. Prior to completing any RCT pilot research assessing the feasibility and acceptability of the therapy should be conducted (Lancaster et al., 2004). It is hoped that this study, combined with part two of this research, will provide justification for the development of a future clinical trial in this area.

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