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

AND CLINICAL RESEARCH PORTFOLIO

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Chapter 1: Systematic Literature Review

A Systematic Review of Mediators of Therapeutic Change in Randomised Controlled Trials of Acceptance and Commitment Therapy

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Prepared in accordance with guidelines for submission to Behavior Therapy (Appendix 1.2)

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Abstract

Background:In line with recent encouragement to identify mechanisms of change in psychological therapies; an increasing number of studies within the Acceptance and Commitment Therapy (ACT) literature have assessed mediators of treatment, or incorporated mediation analysis into the study design. However there has not yet been a review of studies that have conducted mediation analysis of ACT. Therefore at this point it may be helpful to synthesize the findings of these studies in order to direct future research in this area.

Method:Five databases were searched electronically for Randomised Controlled Trials (RCTs) of ACT incorporating mediation analysis, and15 papers met inclusion criteria. The methodological rigour of the studies was examined using the Clinical Trials Assessment Measure (CTAM).

Results:The 15 papers consisted of nine RCTs and six papers presenting data extracted from previously published RCTs. These studies assessed mediation variables for a wide range of presenting problems including tinnitus, fibromyalgia, depression, anxiety, psychosis, aggression and substance abuse. Eleven studies analysed potential mediators based on the core processes of ACT specified by Hayes et al (2004). Four studies investigated mediators not based on the ACT model, and two of these compared mediators with an alternative established treatment. Five studies achieved quality rating scores on the Clinical Trial Assessment Measure above the recommended cut off. All studies reported significant mediation effects for at least one mediator on one treatment outcome.

Conclusions:It is promising that more recent RCTs have included mediation analysis, however there is evidence that many of these studies did not adhere to recommendations for best practice in relation to mediation analysis and study design, such as collecting process measures during treatment. Findings were mixed regarding the role of potential mediators; however psychological flexibility was the most consistently identified significant mediator.

Key words: Acceptance and Commitment Therapy, Mediation, Randomised Controlled trial, Systematic Review.

Introduction

Acceptance and Commitment Therapy (ACT) is a third wave behavioral therapy that combines traditional methods such as skills building with acceptance and mindfulness so as to change a client's relationship with difficult emotions and thoughts, and produce psychological flexibility which allows the client to engage in meaningful value-based behavior (Hayes et al, 1999). A number of reviews have indicated positive results in relation to the effectiveness of ACT with a range of disorders; Powers et al (2009) conducted a meta-analysis of 18 RCT's involving ACT, and concluded that there was a clear overall advantage of ACT compared to control conditions. Ost (2014), more recently, conducted a meta-analysis of 60 RCT's delivering ACT to people with a range of disorders. He concluded the evidence base was most robust in relation to treatment of chronic pain and tinnitus, and potential effectiveness was indicated for depression, anxiety disorders and psychosis. However there was evidence that effect sizes presented in Ost's study were inflated due to publication bias.

The benefits of expanding the focus of research for psychological therapies to incorporate analysis of mechanisms of change are increasingly being documented, most notably in relation to CBT (Ruiz, 2010; Moyer et al 2012). Kazdin (2007) suggested that understanding the critical components by which a therapy is effective allows clinicians to maximize change by refining interventions in light of these findings. The Medical Research Council (MRC) guidance in relation to developing complex interventions advise that an evaluation of therapy process should be nested within a trial design in order to clarify causal mechanisms (Craig et al, 2008, guidance prepared on behalf of the MRC). They state doing so provides information regarding treatment success or failure, and can potentially identify contextual factors associated with variation in outcomes.

A critical first step in examining therapy process is identifying "mediators" of change, defined by Kazdin (2007) as "a construct that shows important statistical relations between an intervention and outcome". Kazdin (2007) also distinguishes between a"mediator" and "mechanism; the term mechanism refers to a more detailed

and specific process through which an intervention translates into events which lead to positive therapeutic change.

As a first step toward identifying potential mediators, the Medical Research Council (Craig et al, 2008) advise that researchers, when considering trial designs, should develop a theoretical understanding of the likely process of change. They should do so by drawing on existing evidence/theory, and consult with experts in the field when competing theories exist. In the ACT literature, Hayes's (2004) theory is widely recognized as the model underpinning ACT; The six key processes which Hayes propose underlie ACT are; contacting the present moment, acceptance, values, committed action, self as context and cognitive defusion. Hayes proposed thattechniques involved in promoting acceptance, cognitive defusion and the observing self, provide the psychological context to allow clients to move in a valued direction. For example by clients adopting the "observer role", he proposed this helps develop the capacity to experience private events as "just" thoughts and feelings. Such techniques contribute to constructing an alternative context for that individual which allows them to carry out value based behaviour. Commitment and behaviour change processes central to ACT incorporate many aspects of traditional behaviour therapy such as exposure, skills acquisition and goal setting. It is proposed that these techniques allow the individual to continue to build patterns of effective behaviour (Hayes, 2004).

Although research addressing mediating factors in ACT is limited, Ruiz (2010) provided a brief review. Ruiz identified 30 studies which assessed the mediating role of experiential avoidance and acceptance. He reports the literature is most robust in relation to chronic pain, and a number of studies report that pain acceptance significantly predicts positive outcomes in this population (Kratz et al, 2007; McCracken & Vowles, 2007; Wicksell et al, 2008). Vowles et al (2008) reported that acceptance mediated the effects of catastrophising thoughts in depression and anxiety. Ruiz also identified studies which indicated a causal link between experiential avoidance in peoples' adjustment following traumatic events (Greco et al, 2005; Gold et al, 2009). The aims of Ruiz's review was very broad i.e. to examine all empirical data (articles, published and under review and dissertations)

in relation to ACT. Therefore examination and discussion specifically of mediation studies was limited, for example there was no information with regard the number, type or quality of studies which had conducted mediation analysis and it was therefore difficult to draw conclusions regarding ACT mediators based solely on this review. To date fifteen RCTs have incorporated mediation analysis into the aims of the study. At this point it may be helpful to synthesize these results in order to direct future research in this area.

Recommendation for high quality mediation analysis

Given the increasing emphasis on examining processes of therapeutic change, papers critiquing statistical techniques for mediation analysis have emerged, and recommendations for best practice are available as a result. It is generally considered that the first documented mediation analysis, which was a simple regression based method outlined by Baron & Kenny's (1986), is now outdated and more sophisticated analysis has been developed with greater power and ability to detect a mediating effect (Gelfand et al, 2009; Hayes 2009). Hayes (2009) argued that although the Sobel test (1982) is a more sensitive test (a product of coefficients approach); it requires the assumption of normality which is limiting. He described two approaches which do not require the assumption of normality; the bootstrapping technique and the M-test. Simulation tests for both techniques have reported high power and good ability to type one error control, however he proposed that given the M test (distribution of products approach) is quite time consuming and requires additional assumptions, that bootstrapping is the optimal technique. The consensus in the literature supports this view and the bootstrapping technique specifically outlined by Preacher and Hayes (2004) has been identified as most robust test for mediation analysis (Gelfand, 2009, Gaudiano, 2010). Despite these emerging recommendations, the causal steps approach is continuously in use. Gelfand et al (2009) suggest that it may take a number of years for recommendations to take effect, for example many studies use bootstrapping techniques in addition to the causal steps approach rather than instead of (Hayes, 2009).

Recommendations have also been identified in relation to study design for mediation analysis, for example Kraemer et al (2002) propose for a rigorous test of treatment mediation, that mediators must be tested during the intervention and preferably at multiple times points. Doing so is necessary for establishing temporal precedence i.e. that change in the proposed mediator preceded change in the outcome measure. Further recommendations have emerged in relation to using an active control;Smout et al (2012) argue that conducting mediation analysis on an active control, allows comparison between interventions thus potentially providing valuable information regarding the unique process of change associated with a therapeutic intervention.

The heterogeneity of types of mediational analysis, such as those outlined above, adds to the challenge of systematically analysing the results of these studies, and meta-analyses are often not feasible as a result. Moyer et al (2012) who conducted a systematic review of mediators in CBT for cancer patients outline some further challenges, in particular the variation in the extent to which formal theoretical constructs are tested, the type and goals of these studies and the types of outcomes and mediators examined.

Research Objectives

The objective of the current review is to identify the mediators of change that have thus far been examined in RCT's of Acceptance and Commitment therapy. Describing the potential mediating variables that have been empirically examined, assessing the quality of mediation analysis conducted to date and arriving at conclusions regarding the main mediators currently identified, are important steps toward understanding what is known thus far about mediators of Acceptance and Commitment therapy and identifying the focus for future research.

Research Aims

1) To assess the quality of ACT RCT's incorporating meditational analysis as a primary or secondary aim; this includes examining the appropriateness of

meditational analysis adopted in accordance with recommendations in the literature.

2) To examine the mediators of ACT investigated to date, and identify whether adequate rationale was provided for assessing these mediators; specifically assessing whether mediators are linked with the six core processes of ACT as outlined by Hayes et al (2004).

Methods

Search procedures

The following databases were searched electronically up to April 5th 2015: Cochrane Database of Systematic Reviews, EMBASE, Web of Science, PsychINFO, PsychARTICLES and Ovid Medline. A hand search of key journals was conducted to identify further studies.

The following search terms were utilized,

"Accept n3 commit* n3 therap*"[1]

"Acceptance and Commitment Therapy"

"Accept* n3 commit* n3 therap*" OR "Acceptance and Commitment Therapy

"Mediation" OR "Mediat*"

"Randomised controlled trial"

"Random* n3 control* n3 trial*"

"Clinical trial"

"Randomised controlled trial or Random* n3 control* n3 trial*" or "Clinical trial"

Search terms were combined as follows;

("Accept* n3 commit* n3 therap*" OR "Acceptance and Commitment Therapy") AND ("Mediation" OR "Mediat*") AND ("Randomised controlled trial" or "Random* n3 control* n3 trial*" or "Clinical trial")

[1] * Denotes the truncation command meaning that the search will identify all words beginning with that term.
N3 denotes that the following word appears within three words of the preceding word.

Selection Criteria

Inclusion Criteria:

- RCTs which included mediation analysis on ACT interventions for a variety of psychological disorders and presenting problems.
- Trials which reported quantitative outcomes.
- Studies which conducted secondary analysis on data from previously conducted RCTs

Exclusion Criteria:

- Studies not published in the English language
- Reviews, dissertations, conference abstracts and book chapters.
- Preliminary/Pilot studiesi.e. small scale studies specifically designed and specified by the author, to assess feasibility of study protocol as opposed to statistically analysing treatment effects.
- Studies where ACT was not the primary focus of an intervention; i.e. intervention studies which only incorporated certain processes of ACT.

Sample description

Figure one illustrates the results of the search procedure. Implementation of the search strategy yielded 68 results. Search results from each database were transferred to Refworks referencing software. Forty-five studies remained after duplicates were removed. The abstracts of the 45 remaining studies were examined and the selection criteria were applied which resulted in excluding a further 25 studies. The full texts of the remaining 20 studies were reviewed, following which 15 studies met all study criteria. The reference lists of these 15 papers were hand searched, however no further studies were included following this search. The final review included 10 RCT's and 5 studies which conducted secondary analysis on data from previously conducted RCTs.

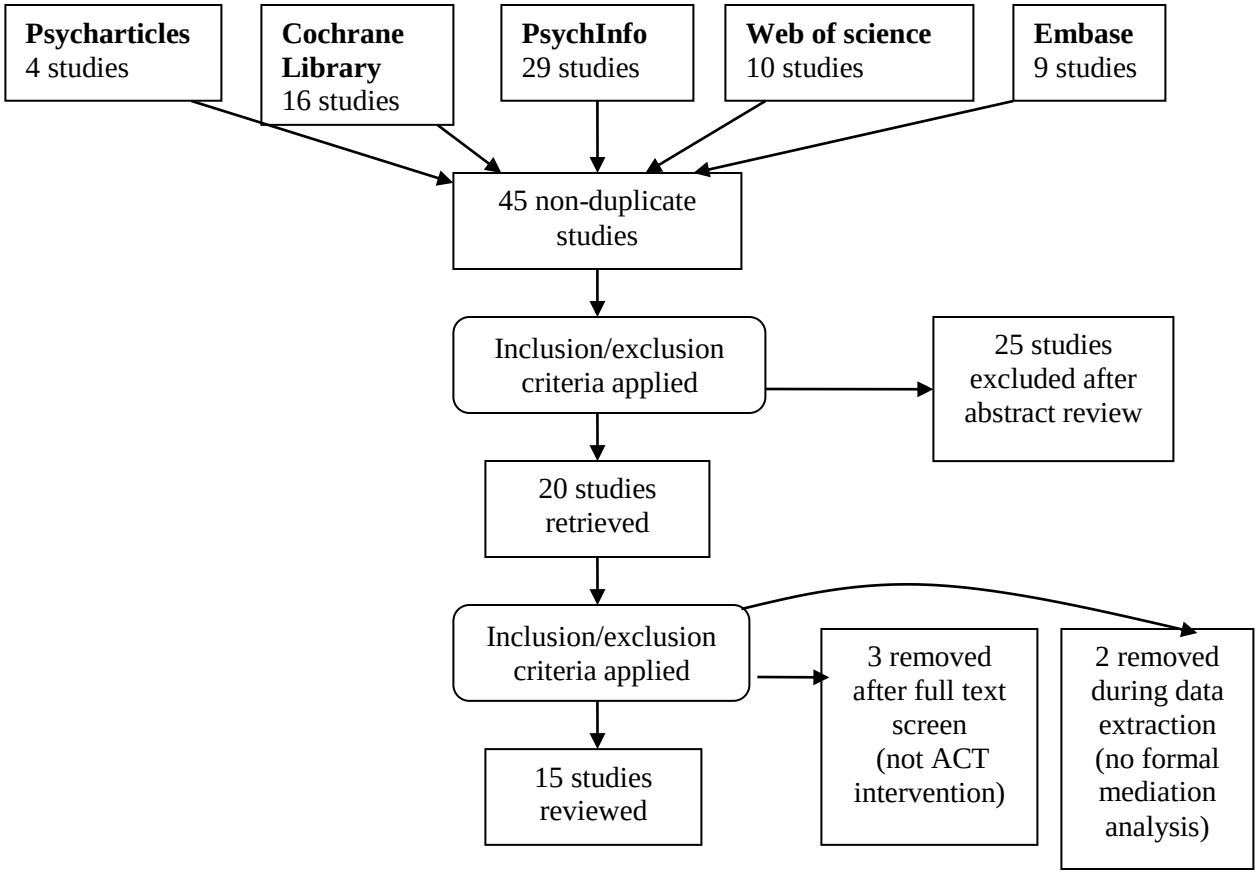

Figure 1: PRISMA flowchart illustrating search process

Quality rating

The methodological rigour of each study was assessed using the Clinical Trial Assessment Measure (CTAM) (Tarrier & Wykes, 2004). This fifteen item measure consists of six subscales extracted from the CONSORT guidelines (CoNsolidated Standards of Reporting Trials) devised to provide a gold standard of clinical trial design. Use of the CTAM in this review provides information regarding how studies meet this standard, and thereforeprovides a context to critically appraise the results reported. The following dimensions of trial quality are examined: sample size and recruitment method, allocation to treatment, assessment of outcome, control groups, description of treatment, and analysis. Points are rewarded for meeting quality standards on each of these subscales. A maximum score of 100 points can be achieved. Wykes et al (2008) suggest that a score of over 65 indicates a good quality

study; however Lobban et al (2013) advised that studies should be compared based on subscales scores as a more meaningful comparison. The CTAM measure has demonstrated adequate internal consistency and excellent concurrent validity (Wykes et al, 2008).

Seven papers chosen at random were reviewed by a second researcher in order to assess inter-rater reliability. The agreement rate was (95%) and discrepancies were resolved following discussion. The quality of the studies varied with overall scores ranging from 41 to 75. The mean score was 59.16 (SD = 10.11).

Data Synthesis

Given the heterogeneous nature of the studies reviewed, in terms of disorders treated, outcome measures utilised and meditational analysis adopted; a meta-analytic approach was considered inappropriate and a narrative synthesis approach was adopted to compare studies. Guidelines provided by Popay et al (2006) for conducting narrative synthesis in systematic reviews were referred to for the purpose of this review.

Results

A summary of the characteristics of 15 studies are providedin Table 1. The range of presenting problems treated by ACT in this review included: tinnitus (two studies), chronic pain (three studies), mild/moderate distress (four studies), anxiety (two studies), aggression (one study), psychosis (one study), substance abuse (one study) and difficulties with smoking cessation (one study). The design of each study differed in terms of timing of assessment measures and delivery format of ACT interventions which included; group treatment, individual sessions and self-help internet based ACT.

Table 1: Characteristics of RCT's Investigating Mediators of ACT.

Study; rationale for mediation analysis	***Design***	***Subjects and presenting problem***	***ACT Intervention***	***Mediators investigated***	***Measures***	***Findings***
Luoma et al (2011); Research indicates that substances used to avoid and suppress shame, hypothesis: ACT address avoidance.	RCT; pre and post outcomes measures; no follow up (FU) data.	N = 133. All participants (P's) diagnosed with **Substance Abuse Disorder.**	Three 2-hour sessions scheduled in one week. Manualised intervention developed and tested in an initial trial.	Internalized Shame	Outcome: TSR, TLFB, GHQ, QOL, MSPSS. Process: ISS.	Internalised shame significantly mediated likelihood of participants to utilise treatment (at follow up only). Outcomes in Quality of life and other measures were not mediated by shame.
Niles (2014); To compare treatment mediators in ACT and CBT.	RCT; data collected, pre, 5 times during, 6 and 12 month FU.	N = 50 Diagnosis: **Social Anxiety Disorder.**	Manualised ACT intervention (Eifort & Forsyth, 2005); 12 weekly one hour session, targeting all six ACT processes (Hayes et al, 2004).	Experiential avoidance and negative cognitions.	Outcomes: LSAS-SR, QOL, ADS. Process: AAQ II and SPSS	AAQ mediated anxiety symptom and reductions in anhedonia in ACT but not CBT. AAQ did not mediate Quality of life in ACT. As hypothesised negative cognitions did not mediate any outcome in ACT treatment group.
Gifford et al (2004): proposed Psychological flexibility mediates smoking cessation outcomes.	RCT; data collected pre, weekly, post, 6 month FU and 1 yr FU	N = 124. P's were people struggling with **Smoking Cessation.**	ACT participants received 7 individual and 7 group sessions of ACT (1 individual and 1 group each week)	Experiential avoidance and psychological flexibility	Outcome; FTND. Process: AIS.	Experiential avoidance and psychological flexibility as measured by the AIS mediated the effect of ACT treatment of smoking cessation

AAQ II = Acceptance and Action Questionnaire -II
ADS = Anhedonic Depression Scale
AIS = Avoidance and Inflexibility scale
FTND = Fagerstrom Test for Nicotine Dependence
GHQ = General Health Questionarre
ISS = Internalized Shame Scale
LSAS-SR = Liebowitz Social Anxiety Scale-Self report
MSPSS = Multidimensional scale of perceived social support.
QOL = Quality of life
SPSS = Self-Statement during public speaking questionnaire
TLFB = Alcohol and drug timeline follow back interviews
TSR = Treatment services review

Study; rational for mediation analysis.	*Design*	*Subjects and presenting problem*	*ACT Intervention*	*Mediators investigated*	*Measures*	*Findings*
Hesser et al (2014); Previous correlational studies indicating the important role of acceptance in treating tinnitus	RCT; Ps completed outcomes pre, mid and post-treatment.	N = 99, moderately/severely distressed by **Tinnitus.**	Guided self-help via the internet. Self-help treatment protocols adapted from Zetterqvist et al (2011) specifically designed for tinnitus.	Tinnitus acceptance	Outcome: THI Process: TAQ	Partial support for tinnitus acceptance mediating changes in tinnitus severity in internet based ACT (iACT) but not iCBT, i.e. part criteria for mediation met; indirect effect demonstrated.
Wicksell (2012); Exploration of mediating role of PF in ACT for chronic pain sufferers	RCT; Outcomes completed 3-4 month FU.	N=33, all p's Were **chronic pain**sufferers.	12 weekly 90 min sessions. Adhering to protocol based on 6 core processes (Hayes et al, 2006)	Psychological inflexibility.	Outcome: PDI, FIQ, SF-36, SES, BDI, STAI. Process: PIPs	Changes in Psychological inflexibility during the course mediated pre to follow up improvement in pain disability.
Luciano (2014); Previous studies indicating the role of PF in pain management	RCT: outcomes completed pre, post, 3 and 6 month FU.	N = 156 All p's had **Fibromyalgia** (FM). Recommended Pharmacological Treatment group:52, waitlist: 53 ACT: 51.	Group based ACT intervention (GACT) based on program adapted for FM patients (Wilson et al (2002).	Pain acceptance.	Outcome: FIQ PCS, HADS PVAS, EQ-5D. Process: CPAQ	Four in five tested pathways did not show a mediation effect. Changes in pain acceptance only mediated the relationship between ACT and health related quality of life.

BDI = Beck Depression Inventory
CPAQ = Chronic Pain Acceptance Questionnaire
EQ – 5D = Visual analogues scale of EuroQol
FIQ = Fibromyalgia Impact Questionnaire
HADS = Hospital Anxiety and Depression Scale
PCS = Pain Catastrophising Questionnaire
PDI = Pain Disability Index
PIPs = Psychological inflexibility in pain scale
PVAS = Pain Visual Analog Scale
SES = Self Efficacy Scale
SF-36 = Short Form – 36 Health Survey
STAI = Spielberger Trait State Anxiety Inventory
TAQ = Tinnitus Acceptance questionnaire
THI = Tinnitus Handicap inventory

Study; rational for mediation analysis	*Design*	*Subjects and presenting problem*	*ACT Intervention*	*Mediators investigated*	*Measures*	*Findings*
Arch et al (2012) Assess whether similar mechanisms of change operate in CBT and ACT.	RCT: six follow up points during treatment.	N = 67. Diagnosis: **Anxiety Disorder.** CBT group n = 35, ACT = 32	12 weekly one hour individual sessions following anxiety specific manual (Eifert and Forsyth, 2005) Incorporated six processes of ACT (Hayes, 2004)	Anxiety sensitivity (AS) and cognitive defusion (CD)	Outcome: ADIS-IV, PSWQ, FQ. Process: ASI, BAFT.	AS and CD mediated post-treatment worry outcomes in both ACT and CBT. CD mediated outcomes in QOL and depression in both CBT and ACT.
Wicksell et al (2010). Further exploration of mediating role of PF in ACT for chronic pain sufferers	RCT: measures collected pre, post, 4 and 7month FU.	N = 20 All p's were suffering from**chronic pain** following whiplash. ACT group n=11, TAU, n=9	10 weekly one hour sessions. ACT intervention adapted to incorporate difficulties associated with pain.	Psychological Flexibility (all other variables assessed for mediation also)	Outcome: PDI, SWLS, pain analogue scale, HADS, SES, TSK. Process: PIPs	Psychological flexibility mediated pain related disability and life satisfaction outcomes. No other variable mediated treatment outcomes in ACT.
Westin et al (2011); Emergence of evidence for ACT treating distressing health conditions.	RCT; Outcomes completed pre, post, 6 and 18 month FU	N = 64. All P's suffered with **tinnitus.** ACT group n= 21, Tinnitus retraining therapy, n=20 Waitlist, n= 22.	10 weekly 1-hour individual sessions. ACT manual devised incorporated 6 processes of ACT (Hayes et al, 2004)	Tinnitus Acceptance	Outcome: THI, ISI, QOLI, HADS, CGI-I. Process: TAQ.	Tinnitus acceptance at mid-point significantly mediated the impact of treatment on tinnitus impact post treatment.

ADIS – IV = Anxiety Disorders Interview Schedule for DSM-IV
ASI = Anxiety Sensitivity Index
BAFT = Believability of Anxious Feelings and Thoughts
CGI-I = Clinical Global Impression-Improvement
FQ = Fear Questionnaire
HADS = Hospital Anxiety and Depression Scale
ISI = Insomnia Severity Index
PDI = Pain Disability Index
PSWQ = Penn State Worry Questionnaire
QOLI = Quality of Life Inventory
SES = Self-Efficacy Scale
SWLS = Satisfaction with Life Scale
TAQ = Tinnitus Acceptance Questionnaire
THI = Tinnitus Handicap inventory
TSK = The Scale of Kinesiophobia
PIPs = Psychological Inflexibility in Pain scale

Study; rational for mediation analysis	*Design*	*Subjects and presenting problem*	*ACT Intervention*	*Mediators investigated*	*Measures*	*Findings*
Fledderus et al (2010); To test the mediating effect of psychological flexibility on the promotion of mental health.	RCT; Pre, post, 3 and 5 month FU	N = 140. P's demonstrated **mild/moderate psychological distress.**	8 weekly two-hour manualised ACT intervention	Psychological Flexibility (PF)	Outcome: MHC-SF. Process: AAQ-II	PF mediated positive mental health outcomes during the intervention; however the change in psychological flexibility after the intervention was not a significant mediator.
Gaudiano et al (2010); to understand potential mechanisms of action in psychological treatments for psychosis	RCT, measures collected pre and post intervention	N = 40. P's suffered affective or non-affective **psychosis**.	ACT sessions were delivered in a stand-alone format did not require completion of predetermined number of sessions	Hallucination Believability	Measures developed for study. Outcome: 10pt scale (distress). Process: 10pt scale (believability of hallucinations). 7pt Likert scale (frequency of hallucinations).	Analysis of indirect effect indicated that hallucination believability was a significant mediator on distress associated with hallucinations.
Muto et al (2011); to test mediation effect of psychological flexibility on psychological distress.	RCT; measures collected pre, post and 2 month FU.	N = 50. P's demonstrated **mild/moderate psychological distress.**	ACT was delivered via an 8 week internet based self-help manual	Psychological Flexibility (PF)	Outcome: GHQ-12, Process: AAQ-II.	PF mediated changes on the General Health Questionnaire at follow up but not immediately post intervention.

AAQ – II = Acceptance and Action Questionnaire -II
GHQ – 12 = General Health Questionnaire
MHC – SF = Mental Health Continuum-Short Form

Study; rationale for mediation analysis	*Design*	*Subjects and presenting problem*	*ACT Intervention*	*Mediators investigated*	*Measures*	*Findings*
Fledderus et al (2013); Psychological flexibility identified as mediating outcomes in ACT, this study aimed to further explore.	RCT. Outcome completed: pre, during and 3 month FU.	N = 376. P's suffered with **mild/moderate depression/ anxiety** ACT group: N=250 Waitlist, N=126	Online self-help ACT intervention consisting of 9 modules incorporating the six processes of ACT.	Psychological Flexibility	Outcome: HADS, CES-D. Process: AAQ-II	Psychological flexibility mediated outcomes for both depression and anxiety
Bohlmeijer et al (2011); Studies suggesting the need to better understand mediators in ACT for depression.	RCT; outcomes completed; pre, 2 and 5 month FU.	N = 93. All P's suffered with **mild/moderate depression.** ACT group n=49, waitlist n=44.	Eight weekly two-hour group sessions. Followed "Living in full" manual, incorporating six process of ACT (Hayes et al 2004)	Acceptance	Outcome: CES-D, HADS, CIS. Process: AAQ-II.	Improvement in acceptance during treatment mediated depressive symptoms at follow up points.
Zarling et al (2012); propose willingness to experience difficult emotions allows opportunity for appropriate expression, thus reducing physical outbursts.	RCT: Pre, 2 within session, post, 3 & 6 month FU.	N = 101 P's demonstrated **Aggressive behaviour** ACT = 50, Control = 51	12 weekly 2-hour sessions with focus on aggression. Specific manual developed	Experiential avoidance and emotional regulation	Outcome: MMEA, CTS-2. Process: AAQ-II, DERS.	Both experiential avoidance and emotional dysregulation partially mediated outcomes of ACT

AAQ – II = Acceptance and Action Questionnaire -II
CES-D = Center of Epidemiological studies –depression scale
CIS = Checklist Individual Strength
CTS = Conflict Tactics Scales-2-Physical Assault S
DERS = Difficulties in Emotion Regulation Scale
HADS = Hospital Anxiety and Depression Scale
MMEA = Multidimensional Measure of Emotional Abuse.

Table 2: CTAM subscale scores

	Sample (10)	*Allocation (16)*	*Assessment (32)*	*Control Group (16)*	*Analysis (15)*	*Treatment (11)*	*Total (100)*
Hesser et al (2014	7	16	16	10	15	6	**70**
Wicksell et al (2012)	2	16	13	0	9	11	**51**
Luciano et al (2014)	7	16	16	6	15	11	**71**
Fledderus et al (2013)	10	13	16	0	15	11	**65**
Luoma et al (2011)	7	13	6	10	11	11	**58**
Niles et al (2014)	2	13	6	10	5	11	**47**
Zarling et al (2012)	10	0	6	10	15	11	**52**
Fledderus et al (2010)	7	16	6	0	15	6	**50**
Arch et al (2010)	10	13	16	10	15	11	**75**
Wicksell et al (2010)	2	16	16	0	15	3	**52**
Westin et al (2011)	7	13	13	10	15	11	**69**
Bohlmeijer et al (2011)	7	16	6	0	15	6	**50**
Gaudiano et al (2006)	7	13	0	10	15	11	**56**
Muto et al (2011)	10	13	16	6	15	3	**63**
Gifford et al (2004)	10	0	6	10	10	11	**41**

Quality of study reporting and methodology

Table 2 provides CTAM scores for each of the 15 RCTs reviewed. Five studies achieved a score higher than the recommended cut off for quality (65). Two of the studies (Arch et al, 2012 & Niles et al, 2014) had an active control. Six of the fifteen studies used a waitlist control and therefore non-specific treatment effects could not be controlled for which contributed to poor ratings for these papers. Generally poor scores were obtained for the assessment subscale with five of the thirteen studies achieving only a score of six out of a potential score of 32; this was mostly related to lack of blinding, or poor reporting of blinding procedures of assessors during the trial. The processes of randomisation were generally described, but blinding procedures were reported in only five of the fifteen studies. With regards to ACT interventions; the delivery of treatment was guided by a manual for nine of the fourteen studies. All 15 studies conducted Intent-to-treat analysis and all 15 examined whether groups were equivalent at baseline.

Theory or Stated Rationale for Mediator Analyses

The rationale for conducting meditational analyses varied across RCTs. Thirteen of the studies analysed mediators directly linked with the core process of ACT as outlined by Hayes et al (2004) i.e. psychological flexibility, acceptance and cognitive defusion (Hesser et al 2014; Wicksell et al 2012; Luciano et al, 2013; Fledderus et al, 2013; Niles et al, 2014; Zarling et al, 2012; Fledderus et al, 2010; Arch et al, 2012; Wicksell et al, 2010, Westin et al, 2011, Muto et al, 2011, Gifford et al, 2004 & Bohljeimer et al, 2011). These studies described how their proposed mediation model fit with the six processes of ACT and referred to previous studies where further exploration of these processes as potential mediators were indicated.

Wicksell et al (2010) in addition to analyzing the mediating role of psychological flexibility also investigated the potential mediating role of anxiety, depression, self-efficacy and kinesiophobia on chronic pain outcomes (pain disability and life satisfaction). They proposed that exploring several plausible mediator variables, including some not based directly on theoretical considerations was done in order to highlight the functional importance of the hypothesized mediator variable. They refer to an article by Kazdin & Nock(2003) who conducted similar analysis in

their mediation study. Luoma et al (2011) also analysed the potential mediating effect of post-treatment measures in addition to the proposed mediator, but did not provide a rational for doing so.

Three studies analysed the mediating roles of variables which were not directly linked theoretically with the ACT model. Luoma et al (2011) hypothesized that internalized shame mediated the effectiveness of ACT intervention for participants suffering with substance misuse disorders. Luoma and colleagues proposed that given high levels of shame are documented in substance misuse literature; the pathway by which ACT is effective is through promoting acceptance of shame, as opposed to avoiding experiencing shame through substance abuse. They therefore hypothesised that greater acceptance and acknowledgement of shame would mediate changes in levels of substance abuse. It is worth noting this hypothesis is still consistent with the ACT model i.e. that acceptance of shame is a pre-requisite in this process. Zarling et al (2012) analysed use of ACT for participant's engaging in aggressive behavior and hypothesised that emotional dysregulation (in addition to experiential avoidance) would mediate aggression outcomes. They proposed that the willingness to experience difficult emotions would allow participants to experience frustration and therefore the opportunity to express these emotions more appropriately, thus reducing the occurrence of physical outbursts. Furthermore Zarling et al referred to preliminary findings in the existing literature indicating that experiential avoidance may mediate positive outcomes of ACT for aggression. Gaudiano et al (2010) analysed the potential mediating role of believability of hallucinations on distress associated with hallucinations. Gaudiano et al proposed that believability in hallucination is a measure of cognitive defusion i.e. hallucination believability is a measure of the extent to which a person views their hallucination mindfully as an ongoing experience. Therefore they proposed that rather than attempting to change the form of the hallucination, that promoting mindful acceptance of the hallucinations will reduce their emotional and behavioral impact.

Two trials compared mediating variables of ACT with CBT (Arch et al, 2012; Niles et al 2014). Niles et al (2014) stated that it is necessary to compare mediators of a therapy with another active treatment in order to fully understand if that mediator is specific to that therapy; therefore in addition to assessing the mediating role of

experiential avoidance, they investigated the potential mediating role of "negative cognitions" in ACT. Similarly for the CBT condition experiential avoidance was analysed as a potential mediator. Arch et al (2012) provided a similar rationale for analysing the potential mediating role of "Anxiety Sensitivity" (a key element targeted as part of a CBT intervention) in addition to analysing the mediating role of "Cognitive Defusion" in an ACT intervention for anxiety disorders.

Measurement of mediators

For studies investigating mediator variables directly linked with core processes of ACT outlined by Hayes et al (2004); 5 studies investigated "Psychological Flexibility" as a potential mediating factor; (Fledderus et al. 2010; Fledderus et al, 2014; Wicksell et al, 2010, Wicksell et al, 2012& Muto et al, 2011). Three studies investigated "Experiential Avoidance" as a potential mediator (Niles et al, 2014, Gifford et al, 2004& Zarling et al, 2012), one trial investigated "Cognitive Defusion" (Arch et al, 2012) and three studies investigated "Acceptance" (Hesser et al, 2014; Luciano et al, 2014; Westin et al. 2011 and Bohlmeijer et al, 2011). Studies which reported to assess the mediating effect of either "Experiential avoidance", "Acceptance" (not disorder specific) and "psychological flexibility" provided similar definitions for each of these variables, and appeared to use the same terms interchangeably to describe the same process. For example Fledderus et al (2010) described psychological flexibility as the core process of ACT, stating that it "included 2 mutually dependent processes: acceptance of experiences and value-based behaviour". Zarling et al (2015) described targeting experiential avoidance as the fundamental goal of ACT, and also referred to the role of acceptance and value-based behavior in achieving this goal. Supporting the claim that these terms were used interchangeably, is the fact that five of these studies utilised the same measure to assess these variables; the Acceptance and Action Questionnaire-II (AAQ-Bond et al 2011). Bond et al (2011) who developed this 10 item questionnaire proposes it is a measure of the core process of Act referred to as experiential avoidance, psychological flexibility or acceptance. This measure has demonstrated good psychometric properties (Jacobs et al, 2008).

For the remaining RCTs examining processes of ACT as potential mediators they utilised disorder specific measures. Wicksell et al (2012)& Wicksell et al

(2010)utilised the Psychological Inflexibility in Pain scale (PIPs is a measure designed specifically to target variables in acceptance based treatments, and has been identified as a useful process measure in treatments of people with chronic pain, Wicksell et al, (2009)). Gifford et al (2004) utilised the Avoidance and inflexibility scale (AIS) to examine whether experiential avoidance mediated smoking cessation outcomes for participants struggling with nicotine addiction, the AIS is a 13 item questionnaire developed specifically to examine smokers endorsement of avoidance strategies, and has demonstrated good psychometric properties (Gifford et al, 2002).Three of the studies included in this review analysed the mediating role of acceptance of physical symptoms. Hesser et al (2014) analyzed the mediating role of "tinnitus acceptance" in an ACT intervention for tinnitus measured by the Tinnitus Acceptance Questionnaire (TAQ) derived from the AAQ and developed by Westin et al (2008). The TAQ consists of twelve items and divided into two factors; activity engagement and tinnitus willingness. Westin et al (2011) also analyzed the mediating role of tinnitus acceptance using the TAQ. The TAQ demonstrated good psychometric properties and has been recommended for use in mediation analysis of tinnitus treatments (Weise et al 2013). Luciano et al (2014) analysed the role of "pain acceptance" in mediating outcomes of ACT for Fibromyalgia sufferers using the Chronic Pain acceptance Questionnaire (CPAQ) developed by McCracken et al (1994) and studies assessing psychometric properties recommend its use with this population (McCracken et al, 2004).

Mediation analysis

The type of and quality of mediation analysis varied significantly between studies. Two studies; Wicksell et al (2010) and Gifford et al, (2004) (the two oldest studies included in this review) adopted the causal steps approach developed by Baron & Kenny (1986); however this approach has been increasingly criticized in recent reviews of mediation techniques (Zhao et al, 2010; Hayes, 2009). Nine studies utilised mediation analysis with bootstrapping techniques as outlined by Preacher & Hayes (2004) which is generally considered the most powerful test of mediation (Westin et al, 2011; Wicksell et al, 2012; Luciano et al, 2014; Fledderus et al, 2010; Fledderus et al 2013; Bohljeimer et al, 2011; Guadiano et al, 2006; Luoma et al, 2011 & Muto et al, 2011). One study (Hesser et al, 2014) adopted a lesser known mediation model

outlined by Bauer et al, (2006). Zarling et al (2015) was the only study to adopt the Sobel (1982) test for mediation. Finally both Niles et al (2014) and Arch et al (2012) followed the MacArthur guidelines for mediation analysis outlined by Kramer et al (2006).

Ten of the 15 studies did not administer outcome measures during treatment; therefore mediation analysis on these studies was conducted without establishing temporal precedence i.e. that changes in mediators predated changes in outcome measures.

Results of Mediation Analysis

All of the studies included in this review reported a significant mediating effect of at least one mediator. Results of the studies are presented in relation to the disorders/presenting problem addressed by ACT, and in relation to quality as assessed by the CTAM quality rating scale.

Chronic pain

The three studies investigating mediators of ACT for Chronic pain sufferers demonstrated that either psychological flexibility or acceptance significantly mediated pain related outcomes; Luciano et al (2014) reported that pain acceptance mediated change between ACT and Quality of Life but not in subjective pain, anxiety and depression. This received a high score CTAM rating (71) well above the recommended cut-off; however meditational analysis conducted on results from the active control group would have added to the quality of mediation analysis and temporal precedence was not established. Wicksell et al (2012) reported that changes in psychological flexibility during the course of therapy mediated pre to follow up improvement in pain disability. This study adopted the more powerful bootstrapping technique (Preacher & Hayes, 2004) and also received a CTAM score above the recommended cut off (69) however limitations included lack of an active control group and female only participants. Wicksell et al (2010) reported that psychological flexibility mediated pain related disability and life satisfaction outcomes during ACT. Limitations of this study included utilisation of the less robust causal steps mediation analysis, temporal

precedence was not established and the study received a relatively low rating on the CTAM (52), furthermore the authors advise caution given the small sample size.

Tinnitus

Two RCTs reported "tinnitus acceptance" as significantly mediating ACT interventions addressing distressing symptoms of tinnitus; Hesser et al (2014) reported that tinnitus acceptance partially mediated changes in tinnitus severity in an internet based ACT intervention, an effect not observed in CBT. This RCT received a high score (70) on CTAM ratings; strengths identified were comparison with an established treatment and rigorous study procedures. However they adopted the lesser used mediation model specified by Bauer et al (2006), temporal precedence could not be demonstrated due to lack of within treatment data. Westin et al (2011) also investigated potential mediators of ACT for tinnitus sufferers. Results of mediational analysis outlined by Preacher and Hayes (2004) indicated that "tinnitus acceptance" at mid-point significantly mediated the impact of ACT treatment on tinnitus post treatment. This study used an active control group and received high ratings on the CTAM (69).

Mild/Moderate Depression and Anxiety

Four RCTs reported on the significant mediating roles of psychological flexibility and acceptance during ACT interventions addressing mild to moderate depression and anxiety. The only study which received a high rating on the CTAM scale was conducted by Fledderus et al (2013) who conducted mediation analysis on data extracted from an online ACT intervention; they reported that psychological flexibility significantly mediated depression and anxiety outcomes; The CTAM rating (65) indicated the RCT had methodological strengths, additionally temporal precedence was demonstrated and optimal mediation analysis (bootstrapping) was conducted. Muto et al (2011) also conducted an RCT on the effects of an ACT intervention on positive mental health. The intervention was delivered in an online format to Japanese university students. This study received a CTAM score below the suggested quality cut off (58), no measures were administered mid-treatment and treatment fidelity was not monitored. Fledderus et al (2010) conducted an RCT on the effects of a group

delivered ACT intervention; they reported that "psychological flexibility" mediated positive mental health outcomes during the intervention.No between session data was collected for this study and low scores were observed on the CTAM (50). Bohlmeijer et al (2011) also investigated mediating factors for depression and anxiety as a part of their RCT; they reported that improvement in "acceptance" during treatment mediated depressive symptoms at follow up points. Limitations included lack of between session measures and the CTAM rating was in the lower range (50).

Anxiety Disorders

Two RCT's specifically addressed anxiety disorders.Arch et al (2013) extracted data from a previously conducted RCT and investigated mediators of ACT for a range of anxiety disorders. They also compared mediators with an established treatment (CBT). This RCT provided 12 individual ACT sessions to participants, obtained a high quality rating score (CTAM = 75) and collected process measures at numerous points during therapy. They reported that both cognitive defusion and anxiety sensitivity mediated worry outcomes in the ACT condition. Cognitive defusion, but not anxiety sensitivity, mediated quality of life and depression outcomes (It was also reported that cognitive defusion mediated changes in depression and anhedonia in the CBT treatment group). Niles et al (2014) investigated mediators of ACT specifically for Social anxiety disorder; although this study received a low score on the CTAM (47; points were lost of assessment processes and analysis), methodological strengths included comparison with an established treatment (CBT), additionally process measures were administered five times throughout the treatments. Mediation was tested using MacArthur guidelines (outlined by Kraemer et al, 2002), Niles concluded that experiential avoidance mediated anxiety and anhedonia in the ACT condition but not in CBT. As predicted, "negative cognitions" did not mediate outcomes in the ACT condition.

Substance Use

Luoma et al (2011) analysed the mediating role of "internalised shame" in an ACT intervention for eating disorders. They reported that changes in internalised shame mediated treatment utilization at follow-up, but no mediating effect was observed for

substance abuse, quality of life and levels of distress. This study scored in the lower range on the CTAM (58) with limitations including absence of mid-session measures.

Aggression

Zarling et al (2012) analysed mediating variables in an ACT intervention for aggressive behaviour. They reported that both experiential avoidance and emotional dysregulation partially mediated a reduction in aggressive behaviours. CTAM ratings for this study indicated a number of methodological limitations including poor quality randomization procedure. However strengths included administration of within session process measures, and adopting mediation analysis outlined by Kruss & MacKinnon (2001) which included establishing temporal precedence.

Psychosis

Gaudiono et al (2006) reported a significant mediation effect of believability in hallucinations on frequency of hallucination. This study scored below the suggested cut off on the CTAM rating (56) and a number of methodological weaknesses were observed, no measures were administered mid-treatment, and the measures used had been devised specifically for the study, therefore no psychometric properties were available.

Smoking cessation

Gifford et al (2004) who investigated the mediating role of experiential avoidance on smoking cessation outcomes stated they found a significant mediation effect, however a very short description of mediation analysis and how they arrived at this conclusion was provided. In addition they adopted mediation analysis by Baron & Kenny (1986) which is no longer advised as best test of mediation. Strengths included a well-defined ACT intervention which incorporated both group and individual sessions. Over all this study received a low CTAM rating of 41, this score was mainly due to poor description of randomisation and blinding procedures.

Discussion

This review, as a first step toward understanding the mechanisms of change in ACT, endeavored to collate and critically evaluatemediation analysis of ACT conducted in all RCTs to date. The fact that 14 of the 15 studies identified in this review were conducted since 2010, highlights the fact that mediation within the field of ACT has only recently been recognized as beneficial to analysis of the intervention.

Many of the studies identified aimed to investigate the potential mediating role of core processes of ACT, and the first issue noted was that a number of studies appeared to use different terminologies to describe the same construct i.e. psychological flexibility, experiential avoidance and acceptance. This may be explained in relation to the differing terminology utilised throughout the years to define the core process of ACT. When ACT was initially developed (Hayes et al, 1996) the overarching term used to describe the underlying model was "experiential avoidance" i.e. the process of avoiding experience of difficult private events despite the fact this struggle lead to behavioural problems. At this point it appeared that the term "acceptance" was utilised to positively describe this process i.e. allowing experiencing of difficult emotions which reduced the struggle and hence behavioural problems. Bond et al. (2006) suggest that as ACT developed, and processes such as "cognitive defusion" and "contacting the present moment" were given greater emphasis, the terms acceptance and experiential avoidance developed a narrower meaning, and more recently the term "psychological flexibility" is accepted as the defining the overarching model (Hayes et al, 2006). The results of this review indicated that these three terms continue to be used interchangeably in the literature to describe the same process. Due to the looseness of terminology it is therefore more challenging to draw conclusions regarding the identifiable mediators of ACT, future studies should therefore carefully consider terminology, and perhaps consider that "psychological flexibility" is at present the term most commonly recognised.

It was also interesting to observe the differential use of process measures to measure these constructs. Many of these studies utilised the AAQ-II to measure psychological flexibility/acceptance/experiential avoidance for arrange of disorders, however many utilised disorder specific measures. Wicksell et al (2008) highlights the benefits of using a disorder specific process measures, they suggest given it measures

the main targets of ACT specifically for that disorder, that this can have positive clinical implications i.e. the results can inform refinements of the ACT intervention for that disorder. All disorder specific process measures included in this review were supported by studies indicating good psychometric properties.

For all three studies which reported on mediators that were not linked with Hayes's six process of ACT (internalised shame, emotional regulation and believability in hallucinations) they suggested theories by which the process of change which may be at work during ACT, however this is not within keeping the Complex intervention guidance proposed by the MRC, who prescribed that analysis should be based on well-established theories. All three studies do however described preliminary studies which indicated the benefits of further exploring these constructs as potential mediators.

The design and types of mediation analysis differed widely between studies. Although many studies adopted the recommended bootstrapping technique (Preacher & Hayes) many of these did not demonstrate temporal precedence i.e. that changes in the mediators preceded changes in the outcome measures. Kraemer et al, (2002) stated that for a rigorous test of treatment mediation the mediators must be tested during the intervention and preferably at multiple times points. However for studies reporting on data extracted from previously conducted RCT's they were restricted to the design of the study.

Only two studies compared with an alternative active treatment. The benefits of conducting mediation analysis on an active control as advised by Smout et al (2012) were evident in this review, for example Arch et al (2012) reported that cognitive defusion mediated main outcomes for anxiety disorders in both the ACT and CBT conditions, this raises interesting questions regarding the process of change for both therapies.

The diverse set of studies, analysing differing mediating relationships with a variety of disorders, producing mixed findings resulting in few clear general conclusions. However, bearing in mind the limitation of the studies, tentative conclusions can be drawn regarding the mediating role of the core process of ACT (referred to as either acceptance, experiential avoidance and psychological flexibility) during ACT treatment. Given each RCT analysing this process reported mediating

effects on at least one outcome variable, there is sufficient evidence to suggest its' mediating role during ACT treatments. There were too few studies to draw conclusions for specific disorders, and the quality of studies varied.

Recommendations for future research include further studies assessing the process of change with particular attention paid to study design, incorporating at least one or more of the following; multiple assessment points during treatment, analysing more than one plausible mediator to allow statistical comparison and ideally comparing with an active control group or alternative established therapy. Future studies should also consider the optimal analysis for analysing the results which at present is considered to be Preacher and Hayes's (2008) meditational analysis with bootstrapping techniques. Future studies should also explore the potential use of disorder specific process measures if they are available, which it is suggested provide more information for clinical use with certain populations.

To conclude it is a positive step that mediation analysis has been incorporated into more recent RCTs, however additional research is required with robust methodology in order to draw meaningful conclusions regarding the mechanisms of change in operation during ACT interventions.

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Chapter 2: Major Research Project Paper

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

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Prepared in accordance with guidelines for submission to Neuropsychological Rehabilitation (see Appendix 2.5)

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Submitted in part fulfillment of the requirements for the qualification of Doctorate in Clinical Psychology

Lay Summary

Following a severe brain injury people often cannot function as they once did; this may mean not returning to work, being unable to drive, and having difficulty with social relationships. As a result, people can become anxious and depressed; they often have difficulty accepting their injury and can exhibit poor awareness of how it impacts on their lives.

In this study we investigated whether "Acceptance and Commitment Therapy" (ACT) could be beneficial for the specific type of emotional difficulties experienced by this population. This therapy does not focus on "getting rid" of unpleasant thoughts and emotions, but instead helps people relate differently to their distress in a way that it has less impact on their lives. One way this is achieved is by developing greater acceptance of difficult emotions. There is little research assessing the use of ACT with people who have a brain injury. A large research study is required to confirm whether ACT is an appropriate intervention for people with brain injury. Before carrying out a potentially costly piece of research, some key questions need to be addressed, specifically 1) whether a larger study might be practicable and 2) if so, how best to design this study.

To achieve these aims we provided an ACT intervention to people with a brain injury and asked them to provide feedback in relation to: 1) their experience of therapy, and 2) their experience of being part of the study. Participants were recruited from three Brain Injury Rehabilitation Trust centres in Glasgow and England. To allow comparison, the group in Glasgow received the ACT intervention for a six-week period, while the groups in England continued to receive care as usual without the intervention during this time. Results from focus groups indicated that participants had difficulty understanding the concept of ACT; this was mainly due to cognitive deficits such as impaired memory and difficulty processing complex information. Recommendations to address these deficits were: increased repetition and support outwith the session to retain the information. Due to these findings the conclusion of this study was that further piloting of an intervention incorporating such recommendations was required prior to conducting future research

Abstract

Objective: There is a growing body of research which demonstrates positive effects of Acceptance and Commitment Therapy (ACT) on a diverse range of psychological disorders (e.g. chronic pain, depression, psychosis). Several reviews suggest that ACT may benefit people struggling to adjust to life following a Traumatic Brain Injury; however there are no published treatment trials using ACT with this group.

The present study examined the feasibility of an intervention trial of ACT for people with severe Traumatic Brain Injury (TBI) treated in an inpatient rehabilitation centre. The findings informed recommendations made for the design and conduct of a larger study.

*Method:*Mixed quantitative and qualitative methods were used including Focus Groups and questionnaire measures. Data were collected from patients and unit staff at multiple time points across three research sites. Focus Group data were analysed using thematic analysis in accord with best practice guidelines. Questionnaires and forms completed by the staff in order to establish application of inclusion/exclusion criteria and participant flow were analysed descriptively to get an indication of the acceptability of features of the study protocol.

Results; Focus group findings indicated that due to cognitive deficits exhibited by participants, they perceived the ACT intervention as being too complex, and a number of amendments were suggested to support participants with cognitive deficits in future trials such as increasing repetition of key processes during intervention. Further suggestions were made in relation to future conduct of the study protocol such as revising the inclusion/exclusion criteria, family involvement in data collection, and provision of easy read materials to clients. Results indicated that participants had no issue with the randomisation design, there were no adverse events associated with the study protocol or intervention.

Conclusions: Further piloting of the amended intervention protocol in line with recommendations made in this study is recommended prior to drawing any conclusion with regard the suitability and acceptable of ACT with people with a severe TBI in an inpatient facility. Further research should consider the amendments to the study protocol as recommended in this study.

Introduction

Traumatic Brain Injury and Psychological Distress

High levels of psychological distress are common in people who have suffered a severe Traumatic Brain Injury (TBI). Typical problems include anxiety (Soo et al, 2011), depression (Guillamondegui, 2011) and a disturbed sense of self (Myles, 2004). For many there is a prolonged, often distressing post-injury adjustment period. Studies have highlighted the importance of proactively addressing psychological difficulties so that the individual can successfully engage in all areas of rehabilitation (Fleming et al 2011).

Khan-Bourne and Browne (2003) reviewed studies assessing the use of psychological therapies for depression with TBI sufferers and concluded that despite previous research highlighting the importance of addressing psychological health in rehabilitation services, the evidence base is limited. There have been some studies indicating positive outcomes when treating anger (Medd & Tate, 2000), but the evidence for treatment of anxiety and depression for this group is limited (Whiting et al., 2013).

Acceptance and Commitment Therapy (ACT)

Acceptance and Commitment Therapy (ACT; Hayes, Strosahl & Wilson, 1999) is a psychological intervention that aims to enhance willingness to accept difficult experiences while persisting with values-consistent behaviour. The key component of ACT, which sets its approach apart from CBT is the focus on changing the person's relationship with their psychological difficulties rather than pathologising difficult emotions and endeavouring to be rid of them (Hayes, 2004).

ACT is guided by a model of psychological functioning that comprises six core processes that are thought to underpin psychological flexibility and adaptive functioning. The aim of ACT is to aid the client to be in contact with the present moment more fully and to live according to personally relevant values. Acceptance processes help individuals embrace emotional pain and make space for difficult

experiences, thereby creating an alternative emotional and psychological context which allows them to engage in value consistent behaviour (Hayes, 2004).

Several reviews support the potential effectiveness of this intervention in improving functioning and well-being in a variety of populations with psychological difficulties and medical problems such as chronic pain (Ruiz, 2010) and depression (Powers et al., 2009). However the suitability and effectiveness of ACT for people with brain injury is yet to be determined.

ACT and Traumatic Brain Injury

A number of reviews suggest that ACT is potentially useful as an alternative to CBT in people with TBI (Soo et al, 2011). In contrast to CBT, logical analysis plays a limited role in ACT, which relies on metaphors, stories, behavioural tasks and experiential processes. ACT also adopts acceptance-based techniques (including mindfulness practices) rather than attempting to facilitate changes in thought content through logical disputation and evidence evaluation. Kangas and MacDonald (2011) highlighted that the emphasis on acceptance in ACT may be particularly beneficial for people with irreversible brain damage who are struggling to adjust to their new 'reality'. Whiting et al (2013) argue that it is the adoption of traditional behavioural techniques as part of ACT that could be of particular benefit to severe people with a TBI. This focus reduces the demands on verbal reasoning, which is often impaired after severe TBI. In addition, behavioural interventions can incorporate skill acquisition and self-management skills thus potentially addressing further difficulties experienced by TBI sufferers.

Rationale for feasibility study

The Medical Research Council (MRC) guidelines for developing complex interventions emphasise the importance of conducting feasibility and pilot work prior to conducting a large scale study. They state there is often too much focus on the main evaluation without sufficient preparatory work or proper consideration of practical issues which may impact the conduct of the trial. They caution this can result in weaker interventions that are harder to evaluate and therefore less likely to be

implemented. Feasibility studies should assess the acceptability of an intervention, determine compliance and recruitment and retention rates, conduct pre-trial economic evaluation, and resolve any uncertainties identified during the development phase. The benefits of conducting feasibility studies are also well documented in the literature (Sampson, 2004; Lancaster et al, 2002; Arain et al, 2010) with the general conclusion that preparatory work enhances the design and conduct of larger scale studies.

Given there are no published studies on the use of ACT with people with TBI in the UK, conducting a feasibility study to assess the suitability and acceptability of carrying out such an intervention is necessary would be good practice consistent with the MRC complex intervention guidelines. It is of note that the terms "feasibility" study and "pilot" study are often used synonymously in the literature (Thabane et al, 2010) however, meaningful distinctions can be made. A pilot study is a small scale version of the larger study conducted in advance, specifically focusing on the process of the study and indicating if changes are required for the larger study, as opposed to a feasibility study which asks the question "can this study be done", which is the primary aim of this study. In addition to guidance provided in the MRC guidelines the aims of the current study reflect published recommendations by Lancaster et al. (2002).

This work is part of a larger study which, in addition to addressing the objectives outlined below, also involved investigating the acceptability of ACT to people with TBI, exploring treatment signals in potential treatment measures, determining rates of patient recruitment and retention, characterising treatment as usual against which an ACT intervention could be compared and investigating the availability of data. The elements that were conducted by another researcher are described in Appendix 2.2.

The design of the following study was adapted from a protocol developed in Australia for patients with a mild TBI seen in an outpatient setting (Whiting et al., 2013). The modifications have taken into account the differences in the setting of the current research (i.e. people in the UK with a more severe TBI which requires inpatient treatment).

Research aims

1) Testing the applicability of the inclusion/exclusion criteria
2) Identification of barriers to implementing the treatment protocol
3) Evaluation of therapist training procedures
4) Ascertaining participant views about random allocation to treatment and control groups.
5) Obtaining opinions regarding the most appropriate primary outcome measure from the perspective of patients and staff members at the research sites
6) Testing and refinement of data collection forms
7) Obtaining service users opinions regarding participation in the ACT group and conduct of the study.
8) Development and piloting of ethical and quality management procedures including refinement of Standard Operating Procedures for detecting and reporting Serious Adverse Events (SAEs)

Methods

Approval

Ethical approval was obtained from NHS West of Scotland Research Ethics Committee (Appendix 2.3). Ethical and Management approval for the protocol was granted by the Brain Injury Rehabilitation Trust (Appendix 2.4).

Design

Mixed quantitative and qualitative methods were used including focus groups and questionnaire measures. Data were collected one week prior to intervention and within one week post intervention. Participants included clients at the rehabilitation units, psychology staff administering the intervention, staff at the treatment site and staff at the comparison sites.

Justification of sample size

There are conflicting views in the literature regarding the number of participants required in a pilot study to estimate parameters for a larger study. Many pilot studies cite Lancaster (2004) who recommends an overall sample size of 30, i.e. 15

participants in treatment and control arms. In other reviews sample sizes between 24 (Julious, 2005) and 50 (Sim & Lewis, 2012) have been recommended. In this pilot study it was anticipated (taking into account previous rates of participation in research conducted at BIRT) that about 30 clients in total could be recruited in the time available. The researchers aimed to recruit all psychology staff based at the unit in Glasgow (two Clinical Psychologist and two Assistant Psychologists) in order to gain the view of staff members at different grades.

Participants

Three separate participant groups were invited to participate in this feasibility study. All participants were either staff or service users based independent sector inpatient brain injury rehabilitation units (Brain Injury Rehabilitation Trust; BIRT).

Service users

1) Treatment group participants were recruited from Graham Anderson House in Glasgow. They were invited to attend focus groups in order to provide feedback of their involvement in both the study protocol and the ACT intervention.
2) Comparison group participants were recruited from York House in York and Daniel Yorath House in Leeds. They were invited to participate in this study in order to provide feedback in relation to their experience of the assessment protocol and views with regard having been allocated to the comparison group.

Psychology staff

Psychology staff at the treatment site were recruited to deliver the intervention and provide feedback following provision of the treatment. They were invited to participate in this study in order to provide feedback in focus groups addressing their experience of delivering the intervention including discussion of barriers and facilitators of treatment.

Care staff

Care staff at both sites were recruited to complete clinician questionnaires. Only care staff at the treatment site were invited to take part in order to contribute to a focus

regarding their views of the intervention as part of overall rehabilitation programme at BIRT and their opinion regarding implementation of the study protocol.

Inclusion and exclusion criteria for clients

Suitability for inclusion was assessed by a Clinical Psychologist based in each of three units; all kept a record of the inclusion/exclusion criteria for each client to provide information regarding recruitment for future studies (see Appendix 2.24 for recording form). These criteria were as follows:

Inclusion criteria

Patients aged 18 years or older; score of less than 8 on the Glasgow Coma Scale (GCS; Teasdale & Jennett, 1974) for the index injury, or Post Traumatic Amnesia (PTA) for at least 24 hours, or Loss of Consciousness (LoC) for more than 30 minutes following the injury. Participants also displayed: 1) capacity to consent 2) sufficient residual cognitive ability to complete study questionnaires and participate in discussions as part of the ACT intervention 3) have sufficient English language skills to allow completion of questionnaires and 4) psychological distress or behavioural dysfunction that was deemed to warrant treatment.

Exclusion criteria

Individuals with an agreed discharge date within eight weeks of the commencement of treatment or those who exhibited challenging behaviour (impulsivity, verbal or physical aggressiveness) which could impair meaningful participation in treatment.

Inclusion/Exclusion criteria for Psychology staff

Psychology staff with at least an undergraduate level psychology qualification, who had completed the 1.5 day ACT training and who agreed to commit the time and resources to complete the research tasks were eligible for participation.

Inclusion/Exclusion criteria for Unit staff.

Unit staff not delivering the ACT intervention at Graham Anderson House who worked directly with the clients receiving the intervention were invited to participate.

The aim was to recruit staff who worked closely with the participants in the study; staff groups included Nursing, Support Workers, Assistant Psychologists and Occupational Therapists.

Treatment Allocation

The trial design being piloted involved cluster randomisation with stratification within each separate unit. The Glasgow unit acted as the test site for the ACT intervention and the other units acted as controls. This design was chosen assuming that for any future effectiveness studies; that inadvertent implementation of ACT strategies within the same unit would need to be controlled.

Study setting

The Brain Injury Rehabilitation Trust (BIRT) provides various rehabilitation services across the UK. This study was conducted in BIRT inpatient units or "independent hospitals" which specialise in the rehabilitation of people who are experiencing behavioural or mental health disorders following a brain injury. BIRT adopt a neurobehavioral approach to rehabilitation, i.e. combining scientific methods of changing behaviour with an understanding that brain injury leads to neuropsychological changes. Interventions are delivered by on-site multi-disciplinary teams. Each client has a highly structured personalised rehabilitation programme, involving individual sessions and group attendance. Clients admitted to the unit have restricted access to the community. Access is determined by risk to the individual and others. Some patients require one-to-one support in the community and others are given a pass, but are required to return at specified times. The three participating units all had comparable service user profiles and philosophy of care as described above.

Measures

Demographic and Clinical Information

The following information was extracted from participant files: gender, age, best level of occupational attainment pre-injury, socio-economic status (Scottish Index of Multiple Deprivation, SMID, and English Indices of Deprivation, ID), date of admission to the unit and date of TBI. Where there was more than one TBI the date of

the most recent TBI was recorded. Information extracted from the client files was also used to calculate the Glasgow Outcome at Discharge scale (GODS) (McMillan et al, 2013), (see Appendix 2.11). Information extracted from the clients neuropsychological records included the Test of Pre-morbid Functioning (TOPF), Subtest scores for Block Design, Similarities and coding from the Wechsler Adult Intelligence Scale-IV and List Learning and Complex Figure Test from BIRT Memory and Information Processing Battery.

Measures

1) The Acceptance and Action Questionnaire-Acquired Brain Injury (AAQ-ABI; Sylvester, 2011) is a 15-item questionnaire measuring psychological flexibility specifically devised to assess difficulties observed in TBI sufferers. It was developed and used by Sylvester (2011) for a study in paediatric Acquired Brain Injury (ABI). (appendix 2.6). Whiting et al. (2015) provided preliminary validation data on the AAQ-ABI and recommend its use with people who have suffered an ABI, concluding it was a valid measure of psychological flexibility about thoughts and feelings relating specifically to brain injury.
2) Hospital Anxiety and Depression Scale (HADS), Zigmond and Snaith (1983). The HADS is a 14-item scale with good internal consistency for both the anxiety (Cronbachs alpha = 0.8) and depression subscale (Cronbachs alpha = 0.81). Previous studies have adopted this measure for use with TBI sufferers (see appendix 2.7)
3) The Awareness Questionnaire - AQ (Sherer, 2004). This is a 17-item questionnaire designed to assess self-awareness in TBI sufferers. There are three versions of the AQ, one for staff, one for a family member and one for service users. Two of these (staff and service user questionnaires) was adopted in this pilot study. Sherer et al (1998a) reported good internal consistency for the AQ (Cronbachs alpha = 0.88), and good validity(see appendix 2.8).
4) 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 assessed by Cronbach's alpha (0.91). (appendix 2.9)

5) The Structured Assessment of Feasibility measure (SAFE) (Bird et al., 2014) was used to assess the feasibility of implementing a complex mental health intervention, and completed by both CP's. It comprises 16-items that obtain information about barriers and facilitators in relation to implementation of intervention such as time constraints, cost and complexity of intervention. Bird et al. (2014) reported excellent inter-rater (0.84) and test-retest reliability (0.89) (appendix 2.10).

ACT Intervention

Participants in the treatment group attended a two hourly session of ACT once a week for six weeks. Each client was provided with a manual which provided information regarding the session content including descriptions of metaphors and mindfulness exercises. Each session involved: a review of homework, mindfulness exercises and the use of metaphors to convey the key processes of ACT. Session one focused on discussing the workability of current strategies to reduce psychological distress. Session two discussed the challenge of pursuing value-based activities whilst attempting to avoid difficult emotions. Session three addressed strategies to promote cognitive defusion and the benefits of using defusion in order to carry out meaningful behaviour were discussed. Session four introduced the concept of the "observing self", and used metaphors to encourage clients to separate the concept of self from thoughts and feelings. In session five values were introduced as "the lighthouse guiding us" and clients were encouraged to identify personal values. Finally, session six introduced committed action and a review of strategies discussed in previous weeks.

The intervention was administered to groups of three or four and delivered by two Clinical Psychologists (CP's). Facilitators received two supervision sessions from an experienced ACT practitioner during delivery of the intervention. The treatment sessions followed a manual developed by Whiting et al. (2013) specifically for people with a TBI. The control group received Treatment As Usual (TAU) during the same

time period. TAU typically involved client centred goal planning, counselling support provided by mental health trained Nurses, medical management by a GP and in some cases CBT administered by Clinical Psychologist.

Procedures

Table 1 below illustrates the study procedures.

Recruitment

ACT facilitators and unit staff – Intervention site

CP's at the intervention site were approached directly by the researchers and invited to participate (see appendices 2.12 for information sheet and 2.13 for consent form). Unit staff were also directly approached by the researchers and asked to take part (appendices 2.14 and 2.15)

Unit staff – Comparison site

Staff at the comparison sites were approached directly by the researchers and were given information sheets. Following a period of 24 hours they completed the consent process with the researchers (appendix 2.16 and 2.17)

BIRT service users – Intervention and comparison sites

Once the consent procedure had been completed with unit staff, recruitment of participants within each unit commenced. Participants who met criteria were approached by a member of staff. The staff member provided the participant with the information sheet (appendix 2.18) and responded to any queries. All participants had a minimum of 24 hours to consider participating prior to completing the consent process with the primary researchers. Separate information sheets were devised for participants in the treatment condition and participants in the comparison group (appendices 2.18 and 2.20 respectively). Separate consent forms were also devised (appendices 2.19 and 2.21).

Study Procedures

Clinical Psychologists (ACT facilitators)

Both CP's delivered the ACT intervention for six weeks. One facilitator delivered the intervention to two groups (one group of three and one group of four) and the second facilitator delivered the intervention to one group of four. On completion of the study, both facilitators completed the SAFE questionnaire and attended a focus group to provide feedback with regard their experience of the study protocol. This focus group took place one week after final data collection. (See appendix 2.26 for a list of all focus group topics).

Unit staff

Unit staff participants completed the Awareness Questionnaire pre- and post-intervention at both the control and treatment sites. The same staff member completed the awareness questionnaire at both time points. Staff participants at the treatment site attended a one hour focus group providing feedback regarding client participation in the study.

Study procedures for participants (BIRT service users)

All questionnaire data were collected from participants in the treatment group over a five month period (January 2015 – May 2015). Participants involved in the study were invited to attend focus groups examining their experience of being involved in the study. For those at the treatment site, participants remained within their treatment groups for the focus groups.

Focus group procedure

Focus groups were exploratory, unstructured and used open-ended questions to encourage participants to reflect on their experience of the study. A list of topics was developed for each group to focus discussions on areas of interest investigated in this pilot study (see appendix 2.5). Guidelines proposed by Kitzinger (1995) were considered prior to focus group facilitation; participants were encouraged to speak to each other, ask questions and comment on each other's contributions.

Further research tasks

The researchers systematically collected data on participant flow across the study period, recorded any difficulties with storage and transportation of study materials. Furthermore Guidelines for reporting Serious Adverse Events (SAE's) were piloted (appendix 2.25). In order to establish base rates for this group, a record was kept of any SAE experience by participants of intervention or comparison group. A checklist of potential SAE's was used at both times of testing for treatment and control group in order to establish whether any SAE's had occurred.

Table 1. Study procedures for treatment and control groups

	TREATMENT	COMPARISON	CARE STAFF	PSYCHOLOGY
		.		Approached by researchers w provided information regard t study, after 24 hours asked to sign consent form.
	Approached individually by psychology staff who provided an information sheet and answer any questions		Approached by psychology staff who distributed information sheets and answered any questions. After 24 hrs met with researchers to sign consent.	
			A staff member who had agreed to take part in the study met with researchers to discuss risk factors	
Time 1	Interested parties met with researchers to ask any further questions, sign consent forms and complete baselines measures.		Staff participants met with researchers to collect demographic date from client files and complete staff questionnaire	
Sessions 1-6	**ACT intervention + TAU provided at BIRT Glasgow**	**Comparison group continue to receive treatment as usual**		**Delivered ACT intervention treatment group**
Time 1	Time II outcome measures administered		Same staff member who completed time I completed time II staff questionnaire	
				SAFE questionnaire comple
	On completion of the intervention patients and staff attended separate focus groups to provide feedback regarding the study protocol			

Data analysis

Descriptive analysis was used for questionnaires and completed record forms. For qualitative data, thematic analysis was chosen due to its high flexibility in addressing 1) the range of research questions and 2) diversity of participants partaking in this study. It was anticipated that for participants with a TBI, cognitive deficits would likely impact their ability to engage in discussions within focus groups. Therefore it was considered that thematic analysis provided a more accessible means of analysing the content as opposed to more technological approaches such as Grounded Theory (GT) and Interpretative Phenomenological Analysis (IPA).

The analysis was data driven; taking a similar stance to IPA, in that the researcher was concerned with the individual's experience of the study protocol/intervention as opposed to examining the protocol/intervention itself. An inductive and semantic approach to thematic analysis was conducted and analysis of the data adhered to the six phase process outlined by Braun & Clarke (2006). The six phases involved; 1) familiarisation with the data 2) involved generating initial codes 3) searching for themes 4) involved reviewing themes 5) defining and naming themes and 6) producing the report. The researcher focused on looking for shared themes between transcripts and searching for patterns in the content. Analysis involved repeated reading of the data and development of coding sheets which contained all possible themes and subthemes. Themes were initially identified within individual transcripts for separate participant groups, prior to examining whether themes were present across all groups. Interpretation of these themes involved theorising the significance of patterns and their implications regarding the conduct of the study protocol.

Results

Participant flow

Figure 1 illustrates the flow of client participants through the pilot study. A total of 89 inpatients were based in the three units. This includes participants in the unit on day one of recruitment, even if they were discharged before the study ended (further

details regarding those excluded due to early discharge discussed later in the study in relation to recruitment rate). This number does not include those admitted after the onset of the study (and who were not eligible for inclusion).

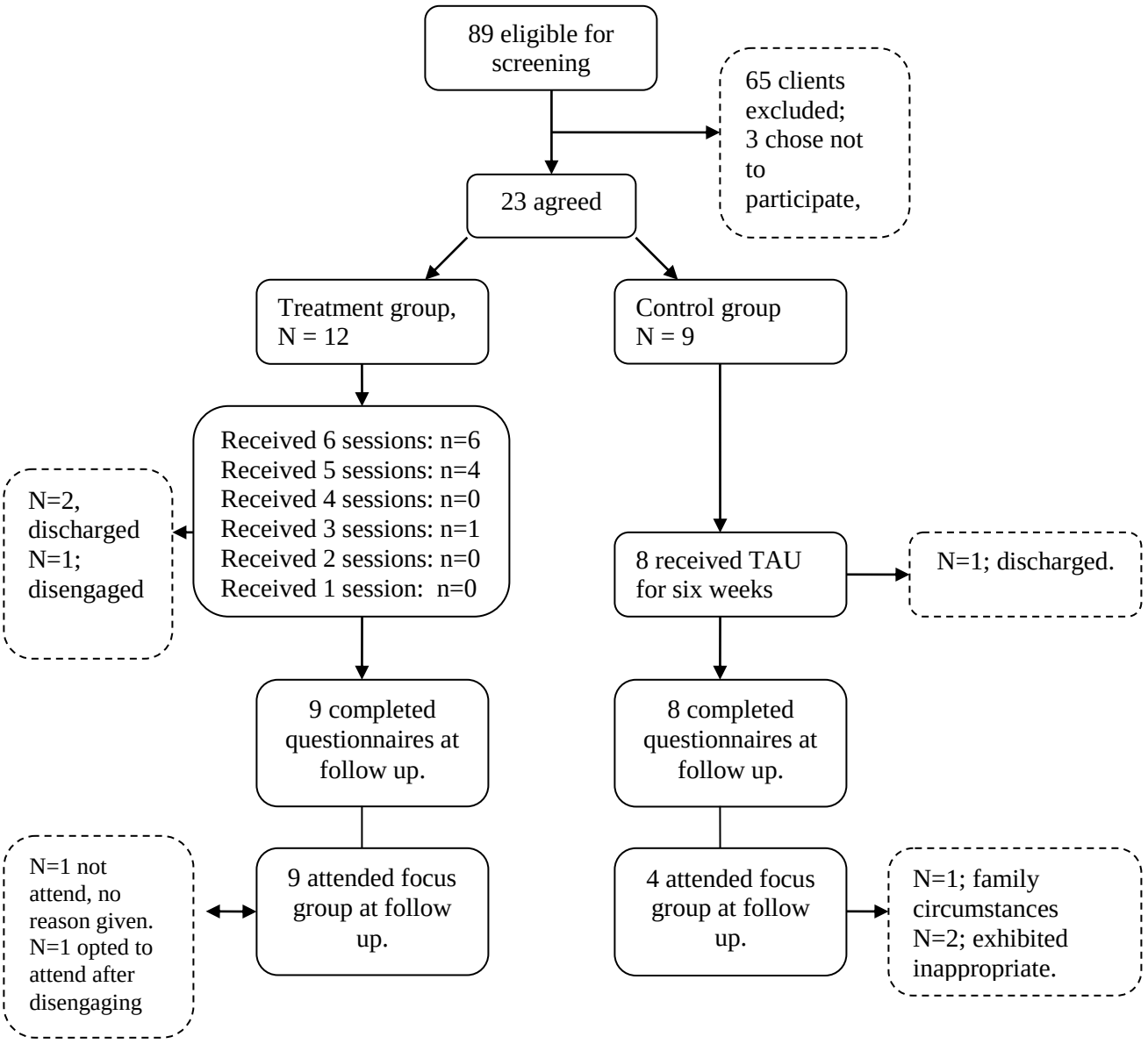

Figure 1: Participant flow.

Participant characteristics

The intervention group comprised eleven males and one female. The comparison group consisted of nine males. The mean age of the treatment group was 48 years old and the mean age of the control group was 30 years old. (demographic details analysed more fully in the sister project of the overall pilot/feasibility study).

Participant Characteristics for overall sample (N=21) at Time 1

		Intervention group (overall)	Control group (overall)	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 subscale score		7 (12)	7 (2)	.549
Block-design subscale score		7 (11)	11 (2)	.749
Coding subscale score		4 (11)	10 (3)	.225

* Indicates the presence of a significant difference between groups

Application of the inclusion/exclusion criteria

Of 89 clients based in the three units, 26 met recruitment criteria. All 89 clients were over 18 and were considered to be experiencing psychological distress that warranted treatment. Of the 64 clients who did not meet the recruitment criteria; 24 did not have a TBI, nine were assessed as not having capacity to consent to participate, 37 clients were assessed as not having the cognitive ability to complete the research tasks and 21 clients had discharge dates within eight weeks. Finally seven clients were considered as having challenging behaviour that would interfere with participation. Figure 2 below illustrates the criteria which excluded clients from the study, note the percentages below indicate the percentage of excluded patients who did not meet each criteria.

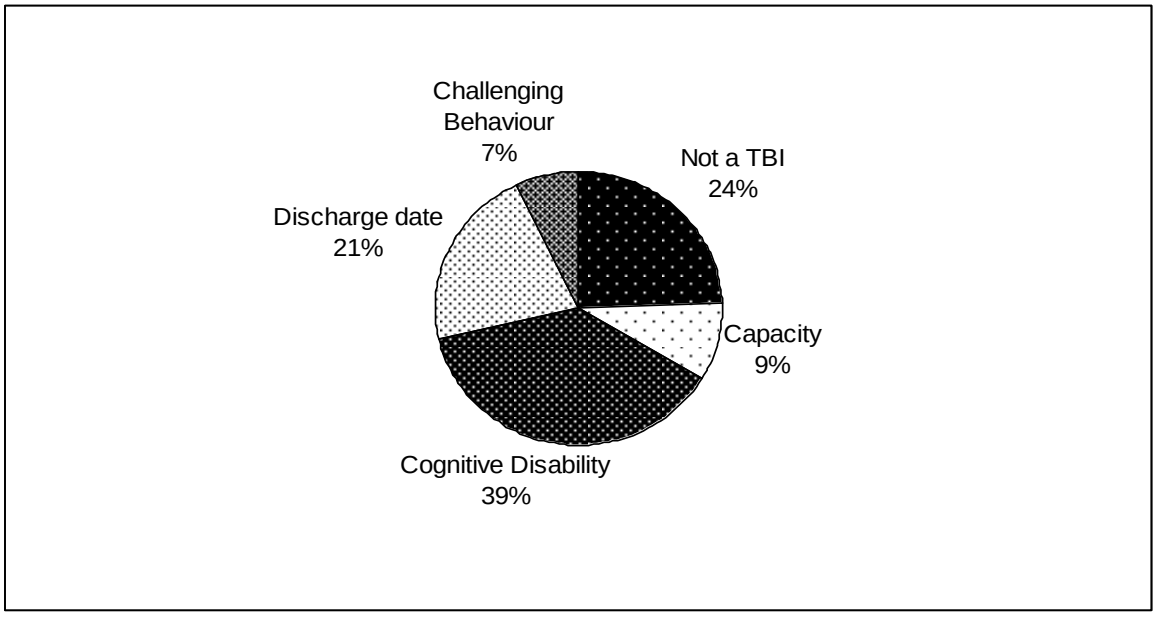

Figure 2: Summary of reasons for exclusion from the study.

In Glasgow 14 of a potential 30 met all criteria, In Leeds five participants of a potential 24 based at the unit met all criteria, and in York six participants of a potential 35 met all criteria. A chi-square test demonstrated that participant inclusion was dependent on the site in which they were based, (χ^2= 7.827, df = 2, $p<0.05$). At Glasgow of the 16 clients who did not meet the recruitment criteria; eight were excluded due not having a TBI, seven were assessed as not having capacity to

consent, ten were assessed as not having the cognitive ability to partake in the research tasks, six had discharge dates within eight weeks and seven were considered as having challenging behaviour that would interfere with participation. At Leeds 19 of 24 clients did not meet the recruitment criteria; ten were excluded due to not having a TBI, one client was assessed as not having capacity to consent, four were assessed as not having the cognitive ability to partake, 13 had discharge dates within eight weeks and no clients were excluded as a result of challenging behaviour.At York 29 clients of 35 clients did not meet the recruitment criteria; six were excluded due to not having a TBI, one client was assessed as not having capacity to consent, 23 were assessed as not having the cognitive ability to partake, two had discharge dates within eight weeks and no clients were excluded as a result of challenging behaviour.

Focus group facilitation

Qualitative data was obtained from six focus groups.Three focus groups were attended by participants who had completed the intervention. Both CP's attended the focus group for ACT facilitators. Two Assistant Psychologists (AP's) attended the focus group for unit staff; both AP's contributed to the everyday running of the unit and facilitation of psychological interventions under the guidance of Clinical Psychologists. At the Leeds comparison site participants attended a focus group immediately following questionnaire completion.

Taking into consideration the cognitive deficits often experienced by people with a brain injury such as poor memory and concentration, it was necessary for the researcher to be more involved in directing and encouraging discussion than is generally advised for conduct of focus groups (e.g. Kitzinger, 1995). However many participants reported that they enjoyed the experience and valued the opportunity to discuss their experiences. Discussion in focus groups with staff members and ACT facilitators was more spontaneous, participants offered opinions and reacted to each other's experience; therefore less input was required from the researcher

Validity

A second researcher (a Trainee Clinical Psychologist) who has experience utilising thematic analysis as part of completing master's level research, coded transcripts and identified themes from the focus group with ACT facilitators and a randomly selected focus group with clients. Following discussion minor changes were made to themes and outstanding discrepancies were resolved through discussion.

Focus group findings

Themes and sub-themes were selected for discussion based on their relevance to the feasibility, acceptability and suitability of the ACT intervention and study protocol. Table three illustrates the themes and subthemes identified in relation to the areas of interest in this study. All themes were carefully selected for inclusion in relation to the primary aims of the study.

Table 3. Themes identified in focus groups

Categories	*Themes (BIRT service users)*	*Themes (Assistant Psychologists)*	*Themes (Clinical Psychologists)*
Views of therapy (Treatment site only)	Cognitive Deficit Amendments required. Outcome.	Relevance. Amendments required.	Amendments required. Relevance.
Inpatient environment	Rehabilitation programming. Challenges.	Rehabilitation programming.	
Coping mechanisms for current distress	Focusing on the future.		Adaptive vs. mal-adaptive.
Recruitment issues		Knowledge of the study. Accessibility of information.	Inclusion. Group considerations.
Data collection forms	Ease of use. Opportunity to reflect Impact of inpatient status on response.		

Randomisation (comparison site only)	Value of research. Remaining informed. Dissemination of findings.		
ACT training and supervision		Complexity	Usefulness
Primary Outcome Measure			Self-awareness

<u>Focus Group Findings – BIRT clients</u>

Views of therapy

One of the clearest themes identified with treatment recipients was the impact of cognitive deficits on ability to engage with ACT. Participants highlighted difficulties in relation to 1) memory 2) understanding abstract concepts and 3) processing of complex information. Therefore discussion of experiencing therapy among clients were dominated by two themes; "Cognitive deficits" and "Amendments required".

"Cognitive Deficits"

Cognitive deficits were reported to a greater or less extent by all participants receiving ACT, and also clearly evident during the conduct of focus groups.
All participants reported difficulties with memory.

"My memory's shocking, but while you're talking about it, a memory may trigger in my head"
[Client 1, page 11, line 15].

Two stated they could not remember the content of sessions even with prompts. In response to a query regarding values based behaviour, one client stated;

""*I can't remember sorry pal...I believe it was good at the time...but it's just as you were talking but when I try to speak about it or anything, I can't it's just gone*""
[Client 4, page 5, line 4-6].

Difficulties with abstract thinking were also reported, particularly in relation to understanding metaphors. For four participants, it was clear that their interpretation of metaphors had been quite literal, for example discussion of the chess board metaphor did not extend beyond rules of the game. Two participants reported being aware that there was additional meaning attached to the metaphors, but described difficulty with this level of abstract thinking. In response to a description of the metaphor of "passengers on the bus, one participant stated;

"*Iremember what you said there, I just find it hard to tune in that way*".
[Client 5, page 6, line 6]

Four participants reported difficulties processing the information presented in the groups within the six week time-frame;

"It was just too much, too much for my brain to take"
[Client 2, page 18, line 22].

"Amendments to increase accessibility"

Participants alluded to a number of specific supports which may have helped engage with ACT. For example it was suggested that the information may have been more accessible if sessions were shorter, and distributed over twelve weeks as opposed to six weeks.

"I feel it started and then, now it's over, I hadn't even learned anything, I needed more time in there to learn"
[Client 7, page 37, line 11]

Outcome

The extent to which participants believed ACT would be helpful in addressing mental experiences varied. As discussed above, most experienced the group content as being too complex, and had difficulty implementing strategies outwith the session. One participant stated despite being broadly aware of the strategies, he had difficulty implementing these

"It sounds so easy when you say it…but I can't get the brain to stop the thoughts, you know, down to one"
[Client 6, page 35, lines 2-3]

Despite difficulties accessing the material outlined above, four clients stated they had benefited from attending the group. Participants were unable to elaborate on what was helpful, but overall reported enjoying the experience and valuing the space which the group provided to discuss difficulties with others in a similar position.

"It was good being there with the rest of them, we're all in the same kinda boat, just being able to talk and that…it was good, I'm kinda down now that it's finished, I was thinking I was getting better and better the more I went"
[Client 6, page 31, lines 8-9].

Inpatient Environment

Regardless of topic, participants consistently returned to discussing their experience of life within the unit. Themes identified during these discussions were; "rehabilitation programming" and "challenges". Although these issues were not intended for discussion, they are presented due to their prevalence in the data, and clear importance to participants. It is therefore important to consider what can be derived from such themes in terms of future research.

"***Rehabilitation programming"***

Participant discussion relating to rehabilitation programming tended to focus on physical rehabilitation. Seven participants suggested that their main focus was to physically recover in order return to their previous life. One participant who was close to discharge stated;

"*When I came here, I wasn't thinking about the mental side of things, I was trying to improve physically... I wasn't thinking about my life at that point"*
[Client 8, page17 line 20]

Another participant noted that once physical recovery was underway, his emotional difficulties became more prominent.

"It's all the stuff I've pushed to the back of my mind is now come back to the front, so one minute you think great I'm doing well, then all this stuff comes back to the front of your mind, setting you back again"
[Client 4, page 18, lines 4-7]

"***Challenges"***
Challenges of living in an inpatient unit were raised by all participants at both the treatment and control site. The following issues were discussed: positive and negative interactions with staff, restricted freedom within the unit and the desire to leave.

"You see the thing is, I can't get out, well I can get out, but I've to come back otherwise they'll (staff) call the police you know"
[Client 2, page10, line 22]

One client stated that they felt the extent of the challenges they faced were not appreciated by others, and two others in that focus group indicated they agreed.

"I think there needs to be more attention given that we're here, and we really don't want to be here"
[Client 1, page 21, line 7]

Coping Mechanisms

"Focusing on the future"
"I feel I'm ok as long as I'm moving forward, then you're not going to be sitting in front of a brick wall"
[Client 7, page 17, line 7]

Six participants made reference to the fact that focusing on the future was their primary means of coping within the unit. One participant discussed the challenge of focusing on the future in light of all the difficulties they faced due to injuries;

"It's a really fine balance though because you feel like, you think too much about what's up ahead then you'll go backwards"
[Client 6, page 19, lines 15-16]

Data collection forms
The main themes identified in relation to completion of data collection forms were; "Ease of use" "Opportunity to reflect" and "Impact of inpatient status on responses"

"Ease of use"
All participants who completed the forms stated they did so with relative ease. Three participants commented on the benefits of the researcher being present for completion of the questionnaires, in order to readquestions in the case of physical disabilities or to answer questions if required.

"For one question I didn't know what that meant, but then I remembered you (researcher) told me what it meant the last time you were here"

[Client 3, page 5, lines 5-8]

"Opportunity to reflect"

Two participants commented that completing questionnaires had provided an opportunity to reflect on the issues raised, and two other participants agreed with this point.

"It made you think, how you felt, emotionally and stuff like that... made you look inside yourself I would say, and see how you were feeling...it was a good thing for me"

[Client 3, page 26, line 27-30]

"Impact of inpatient status on responses"

Four participants noted that responses to questions in the "awareness questionnaire" differed depending on the context in which they considered their response. Some considered they were functioning "better" in some areas such as managing money, but this was due to compensatory strategies implemented within the unit rather than improved ability.

"I think there should be one question for outside, and one for in here, they're two separate questions"

[Comparison client 1, page 4, line 13]

Randomisation strategy (Comparison site only)

Themes identified during discussions with clients at the comparison site with regards to allocation to comparison group were; "Value of research", "Remaining informed" and "Dissemination of findings".

"*It's fair…enough, if you need to do some studies on people first then you can see if it helps everybody else, it's just fair, if it gets accepted then everybody should get that as well"*

(Comparison client 2, page 1, lines 22-26]

One participant discussed the benefits of enhancing the evidence base of rehabilitation strategies in relation to increase his confidence in engaging with these approaches, and emphasised the trust they placed in rehabilitation programmes;

"So I was like"prove it then" (that an intervention is effective), don't just say it, you don't just say something unless you can back it by proof…it's a risk to come here on the assumption that I can get better quicker"
[Comparison client 1, page 2, line 5-8]

All three participants expressed their desire to remain informed about developments in the study.

"What you could do is let us know what the actual results are… that would actually be nice, it feels like you're more included"
[Comparison client 3, page 16, lines 2-4]

<u>Focus Group Findings – Clinical Psychologists</u>

Views of therapy

Two themes were identified during the CP's discussion of ACT; "Amendments required" and "Relevance of ACT".

"Amendments required"

Both CP's emphasise the difficulties clients had accessing and retaining the material due to cognitive deficits, and amendments for future trials to support participants with these deficits was a clearly identifiable theme in the data. Recommendations included; 1) reducing the quantity of information and increasing the frequency of presentation 2) introduction of key processes such as mindfulness and valued consistent living at an earlier stage 3) introduction of a running theme, meaningful to

clients, to increase accessibility to the material and 5) reduced emphasis on processes of ACT which require abstract thinking, specifically cognitive defusion.

"*If the "observing self" was a line in the guided mediation every time you went through them, that would eventually get through because....you are practicing it"*
[CP 1, page 3. line 20 -23]

Practical supports were also discussed by both CP's involving inclusion of homework in the weekly timetable and implementation of ACT outwith therapy sessions.

"*We would need to have it on the timetable as homework, we would need to put the practice in daily, you know we would really need to hammer home the themes of ACT, and what is about and why we are doing it because, practicing mindfulness...it's a lifestyle change isn't it"*
[CP 2, page 10, line 3-6]

"Relevance of ACT"

The discussion relating to potential for ACT among the therapy facilitators was coloured by discussion of barriers and amendments which were necessary as a first step, and doubt remained with regard to whether, even with these changes, some of the more complex processes would be appropriate for the level of disability exhibited by this group. However it was noted that if clients were able to access the message of ACT, it could be helpful in addressing the specific problems experienced by this group.

"I think it is an appropriate therapeutic intervention, because a lot of people have negative stories about, you know, their life being over ... or they're broken in some way, and that's almost the story that so far clinicians along their way have told them, to increase their insight and orientation. So, being aware that explicitly their

brain may have been injured but their values are still the same...could support them to live in accordance with their values"
[CP 1, page 9, lines 16 -21]

Coping mechanisms available to clients

For both CP's the desire to increase strategies for developing resilience within this group was highlighted. One CP discussed how earlier adoption of maladaptive coping strategies following a brain injury may have influenced the development of mental health difficulties in people with a TBI;

"I think when people are in the early parts of recovery that you can give them these skills that they could use...the psychological morbidity of the chronic people is really quite pronounced in these cases, that's why they've ended up in here, whereas with another group who are receiving these skills that are more appropriate to resilience, it might … stop those problems developing"
[CP 1, page 5, line 32-36]

Recruitment

Two key themes were identified in relation to discussion of the recruitment process; "inclusion" specifically whether they should be expanded to include all inpatients with an acquired brain injury and secondly "group allocation".

"Inclusion"

One CP shared the opinion that the clinical presentation of all Acquired Brain Injuries (ABI) were very similar, and therefore both groups would benefit equally from an intervention designed to target the difficulties associated with any ABI.

"I don't see a reason to treat the TBI as separate ...certainly it would be nice to include a group of people who had an ABI other than TBI"
[CP 1, page 7, line 16-17]

In addition, this CP suggested that adjusting the criteria to include those with any type of ABI could potentially increase participant numbers in future trials, and emphasised that the need for psychological interventions was equally relevant for those without a TBI in inpatient units such as BIRT. Both CP's considered that although clinical presentation may be similar the underlying pathology is quite different, for example between someone who had received trauma to the head as opposed to suffering a stroke. However one CP pointed out in order to conduct "clean research" it was important to separate the two. It was suggested that all could be included in future studies with a larger sample size, with the view that analysis would be conducted separately.

"It is quite separate ABI vs. TBI... you would probably look at them both individually before coming to the conclusion that it works for everybody, but we could put them all in the one group and analyse the results separately"
[CP 2, page 6, lines 31-33]

"Group allocation"

Issues relating to group allocation were a key point of discussion regarding the recruitment process. Both CP's stated the two most important variables they considered when allocating to the ACT treatment groups were: cognitive ability and existing relationships between clients. They described the challenges of meeting these criteria.

"I guess thinking about having similar people with similar cognitive difficulties ... also need to consider the level of aggression...we know people fairly well and how their personalities would interact with each other...We identified four that would have been a good dynamic together, then ..I think they were discharged sooner than we thought,and we had to fill these spaces with two different am service users, I don't think they gelled quite as well"
[CP 2, page 4, lines 16-21]

One CP observed that the challenges, narrative and outlook for service users who were long standing residents differed to that of service users recently admitted and questioned the potential negative impact of this, and suggested that where possible these two groups (new inpatients or longs-term patients) should be in separate groups.

"I guess what I noticed appeared to be difficult was that service users were talking about their experience happening years ago and still being in the rehabilitation hospital.... for people who had recent suffered their injury, that was quite difficult to hear"
[CP 2, page 6, lines 18-21]

ACT training and supervision
Data extracted from the SAFE questionnaire indicated that both CP's believed the specific training received was necessary for facilitating the intervention. Focus group discussions were consistent with this view. Both CP's stated they drew on their experience of training to address questions or difficulties experienced by participants;

"I think only one member of my group got that (metaphor), the description was really wordy and it's just really difficult, I mean you could read it to neuro-typical person and they mightn't get it, but I had the explanation from training and I used that...which seemed to sit better"
[CP 1, page 7, lines 12-16]

Primary outcome measure
Views about the most appropriate primary outcome measure were mixed and discussion was limited given that positive outcomes for clients were not observed by the therapists. However there was a suggestion that supporting clients to increase awareness of deficits may be a first step toward building resilience and coping with the difficulties they face in light of their injury.

"One service user was very, I guess positive... and you could say lacked insight where he was going to progress to...and I don't think it was helpful"
[CP 2, page 5, line 6]

Focus Group Findings – Assistant Psychologist's

Views of therapy

"Relevance"

For the focus group with AP's, there was evidence they perceived the ACT group as a discrete piece of research, which was somewhat out of stepwith the overall rehabilitation programme. One AP stated:

"I guess when they were in the ACT group, the other psychological therapies for them were put on hold a bit, so I guess I wondered how that might be affecting them"
[AP 1, page 14, lines 23-24].

For both AP's; apart from being aware that the group was scheduled on the client's timetable, and having completed some of the staff questionnaires, they described having no further knowledge of the intervention..

"Amendments required"

Both AP's stated that in their experience of running groups in the unit, success was enhanced by incorporating breaks at regular intervals and having a co-facilitator to support clients with any practical difficulties such as organising materials and supporting with toilet breaks.

With regard to group content they both noted the importance of being able to deliver the content flexibly;

"I know when we run groups, we adapt it depending on ability level within the group... there's always a sort of a core structure but then you would think,, oh I wouldn't use that part with this group, or actually if they were more able so I could challenge them a bit more"
[AP 2, page 14, lines 9-12]

Inpatient environment
Both AP's believed considerations should be made with regard how the group fitted within their weekly timetable.

"I know that some of the participant sessions were scheduled in the afternoon and it was running on past timetabled sessions, so at this time they would normally have their break, after completing full day, so timetabling... could be an issue"
[AP 2, page 5, lines 3-6]

Both AP's expressed the view that greater awareness among staff in relation to 1) the fact service users were receiving this therapy and 2) the general principles of therapy could enhance generalisabilty of ACT outwith sessions.

"*That could be something that was brought up in key worker sessions, if they were aware of it, like a point of contact as a key worker"*
[AP 1, page 9, lines 25-26]

Recruitment
The following themes were identified in relation to discussion of the recruitment process with AP's; "knowledge of the study" and "accessibility of information".

"Knowledge of the study"
One AP had received the ACT training and one did not. For the AP who had received training, she described being more confident in addressing client queries

relating to study and believed they could make a more informed decision as a result. The AP who had not received training stated:

"Ya that would have been more useful if I had (attended training), because obviously I only had the information that was given if they had any more questions or wanted more on exploration, I couldn't expand on that really"
[AP 1, page 10, lines 13-16]

"Accessibility of information"
The AP's also believed the information sheet was too complex for the service users. They suggested that "easy read" version of the information sheet should be made available for potential participants, with carefully selected key points, in addition to the more detailed information for those who wish to refer to this.

ACT training
The AP who had received the training considered that some concepts were too difficult and was of the opinion that qualified CP's, with an existing knowledge, appeared to engage in deeper discussion of processes which likely enhanced their understanding.

"It's interesting to sit and listen to and get an understanding about what it's all about...but in terms of if you had to run the group from that... I don't think that I would feel overly confident...having not done the clinical doctorate, I was kind of lost in parts"
[AP 1, page 11, lines 21-24]

Data collection forms
During the focus group with AP's, both described the challenges of collating information for the clinical form. They stated that information relating to client functioning prior to injury was difficult, or not possible to source and suggested that it may be more appropriate for a family member to complete this information.

Reporting of serious adverse events

No serious adverse events were reported for any participant, as defined by the guidelines for reported adverse events piloted, for the duration of the study period. Furthermore no additional incidences of harm (not included in the guidelines) occurred that staffconsidered important to report, nor did they advise any amendments for the proposed reporting guidelines.

SAFE questionnaire results

A copy of the SAFE questionnaire was completed by both ACT facilitators. There was 100% agreement on all 16 items. Findings are reported descriptively in line with reporting guidelines, and under the following categories; intervention, resource consequences and evaluation.The response options available were "yes", "partial", "no" and "unable to rate"

Intervention

CP's rated the manual as facilitating intervention. They rated the ACT intervention as being "partially" designed for the population of interest i.e. that it was designed for more general TBI population and required adaptations to be directly applicable to an inpatient setting. Both reported the intervention as being "partially" flexible; however commented that this was only after discussion with the primary researcher that deviation from the manual was appropriate if comprehension was very poor. They agreed that it was possible to stop the ACT intervention without any harmful or unwanted effects. Both CP's identified the intervention as complex i.e. incorporating more than three separate components.

Resource consequence

Barriers to implementing the intervention identified by CP's were necessity of training and the fact the intervention required "partial" on-going support in the form of fortnightly supervisions. They stated that intervention was "partially" time-consuming to provide i.e. it required more than 30 minutes per week per client and

required additional material resources such in this case, manuals, CD's and access to a CD player. However they stated that only one member of staff was required to provide the intervention and that although the intervention was identified as "partially" costly (in relation to therapist time), that this was offset by the group format.

Evaluation

Both CP's reported there were no known serious or adverse events associated with the intervention. They reported that effectiveness of this intervention was indicated, however noted that effectiveness for this group was limited due to the nature of a TBI. Finally the CP's responded that the intended goals of the intervention matched the prioritised goals of the NHS i.e. improving mental health and wellbeing and supporting recovery.

Discussion

The main objective of this study was to inform future research by examining the feasibility, acceptability and suitability of the ACT intervention and study protocol. This was achieved by exploring participant views of ACT, applicability of the inclusion/exclusion criteria, recruitment processes and patient flow, barriers to implementation of therapy, randomisation procedures and attitudes toward randomisation, attitudes toward primary outcome measures, questionnaire administration, and reporting of serious adverse events. In this section the results are discussed in relation to the relevant literature, following which recommendations for future research are made. These recommendations are presented in Table 4.

Recruitment& Patient Flow

The numbers of participants meeting eligibility criteria varied at each site. Ineligible participants in Leeds were primarily excluded due to discharge date, while most were assessed as being cognitive able. The opposite was seen in York where most participants were excluded on the basis of cognitive ability and only three participants due to impending discharge. One explanation may be that participants

based at Leeds were more cognitively able and thus required shorter admission. In addition it is possible that in this study that subjective assessment of cognitive ability to partake in the study may have been interpreted differently by referrers at each site. This problem could be reduced in future trials by using more formal objective measures for determining whether patients have the cognitive capacity to participate. Finally broadening the inclusion criteria to all patients with an ABI might not affect recruitment as just 6.7% of the overall sample was excluded on that basis alone.

Table 4. Recommendations of amendments to study protocol

Protocol Aspect	Recommendation
Recruitment	• Provide more objective methods for determining cognitive ability for inclusion in the study. • Consider participant readiness for therapy prior to inclusion. • Researchers, or those who received ACT training should provide detailed information regarding the ACT intervention to staff involved in recruitment • Provide an "easy to read" version of the information sheet to participants in addition to the more detailed form
Manual	• Reduce reading material in client manual • Introduce key concepts early in treatment such as mindfulness and values based behaviour • Increase repetition of key processes throughout intervention • Introduce a running theme throughout the manual to aid with retention. • Reduce emphasis on the more complex/abstract processes such as cognitive defusion. • Consider a more flexible manual which has a core structure but allows manoeuvrability to allow for deficits exhibited by specific groups.
Amendments to promote engagement	• Dedicate time to understanding participants view of the therapeutic intervention as part of their rehabilitation programme within the unit • Incorporate discussion of stressors specific to the unit within the ACT intervention. • Draw on existing coping mechanisms, such as focusing on the future, to discuss how they relate to process of ACT such as values based behaviour.
Support outwith	• Include homework activities on the daily schedule

sessions	• ACT facilitators should liaise with key worker/members of staff to encourage implementation of strategies outwith sessions and support with homework if required.
Group considerations	• Consider the following when allocating participant to ACT groups 1) cognitive ability and 2) history of aggressive behaviour or poor relationships with participant. • For delivery of groups incorporate many breaks at regular intervals to increase motivation • Consider Introducing shorter sessions e.g. one hour spanning over a longer time period e.g. 12 weeks as opposed to six. • Liaise with unit staff to consider timing of the intervention i.e. ensuring that therapy sessions are not restricting client's activities in other areas or adding additional stress to an already busy timetable which may impact motivation.
Data collection forms	• Provide clear instructions to clients that for the awareness questionnaire answers must reflect their perceived ability in these areas without the compensatory strategies used in the unit • Ensure a researcher is present to answer any questions
Primary outcome measure	• For future effectiveness studies consider use of participant self-awareness questionnaire to measure outcome.
Supervision and training	• Ideally Clinical Psychologists should deliver the intervention and receive training from an experienced clinician (1.5 days was deemed adequate) • CP's should receive regular supervision (CP in this study suggested fortnightly).
Comparison site	• Provide updates of the study to participants in the comparison group • Ensure dissemination of results once study is complete

Cognitive deficits

The prominent theme in focus groups relating to the impact of cognitive deficits mentioned by treatment recipients and CP's suggested that overall, greater consideration needs to be given to how to best deliver the intervention with this population. To a lesser extent, minor amendments to the study protocol, such as provision of easy to read version of information sheets, may be beneficial. Analysis

of results from the focus group with Assistant Psychologist's indicated that drawing on strategies already in place to support participants with cognitive deficits could support participants in future trials, for example considering the inclusion of numerous breaks at regular intervals. Consideration of cognitive deficits, specifically in relation to self-awareness, also influenced discussion of primary outcome measures for future effectiveness studies. Impaired self-awareness was identified as a significant barrier to successful engagement with therapy, and in the focus groups with CP's there was the suggestion that as a first step participants needed to be aware of the challenges they face. The research has indicated that for psychological interventions who reported improved self-awareness in TBI clients, concurrent low mood was often observed (Schonberger et al, 2006). Results from focus groups in this study indicate why this may be the case; one CP discussed the sometimes unrealistic goals of patients, and suggested that supporting a person to move forward may involve challenging these unrealistic goals, which would likely be a difficult experience for people thus impacting mood. Furthermore the benefits of addressing self-awareness as part of therapy to support with functioning and overall rehabilitation is well documented (Hoofien et al, 2004; Noe et al 2005). Wood and McMillan (2001) suggest that for some, lack of self-awareness may be serving as a defence mechanism as opposed to reflecting brain injury deficits. This indicates the potential role of ACT in addressing poor self-awareness as an avoidance strategy/defence mechanism by promoting acceptance of the difficult emotions associated with the impact of a brain injury. For future trials it may be worth considering how these processes of ACT can support with increasing self-awareness.

Inpatient considerations

The fact that patients consistently opted to discuss stressors within the unit rather than the study, was striking. It may be advisable for future studies to planfully include opportunities to directly address issues such as restricted freedom within the unit, and consider how ACT can promote more adaptive responding to these challenges. It appeared that participants' viewed their lives within the unit as artificial; most spoke about their focus on the future and plans following discharge

rather than goals to achieve within the unit. This suggests they may have viewed committed action as being irrelevant given their status as inpatients, and were therefore falling into the "when-then" trap as described by ACT i.e. "when I get out of the unit, then I will be able to engage in meaningful behaviour". This may be acting as a barrier for some, and may need to be anticipated and explicitly addressed in future trials.

The fact the manual utilised in this study was originally designed for outpatients may also account for participant's difficulty engaging with the process. For example, it is possible that outpatients are at a point that they are more ready to address emotional difficulties. There is evidence to support this view in focus group findings, one participant spoke about emotional challenges he faced as he approached discharge and that when first admitted physical rehabilitation had been his primary concern. However it is also likely that those who nearing discharged or are outpatients are more cognitively able which will impact engagement with a psychological approach. Furthermore Wood and MacMillan (2001) suggest that motivation to engage for this population can fluctuate and that it is worth considering DiClementes (1982) stages of change when assessing readiness for therapy. They also highlight the potential influence of family pressures and court orders on engagement. As above, they stressed the role of poor self-awareness as a barrier in this process. The suggestion for further studies is that readiness for psychological therapy may need to be addressed prior to engagement in this study.

Given that the results from focus groups indicate that the Assistant Psychologists viewed the ACT intervention as an additional task as opposed to a potential valuable addition to the rehabilitation programme, perhaps greater consideration needs to be paid to involving the staff in the discussion of ACT as part of the rehabilitation plan. It was suggested this could be achieved through discussion with key workers/staff members, and what their role would be in maximising the effectiveness of the intervention out with therapy sessions. Having these discussions with staff at an early point in recruitment may improve motivation to recruit. A clear role for staff in

supporting participants with homework exercises, and implementing strategies outwith the ACT sessions was also indicated. Referring to research investigating barriers to staff implementation of intervention may be helpful in directing discussions with staff. Corrigan and McCracken (1997) synthesised survey results from over 400 staff members within psychiatric rehabilitation teams and some of the key barriers identified were: insufficient support and supervision, viewing the treatment as irrelevant, unfamiliarity with theory underpinning the intervention, reliance on the medical model and mistrust implementing an innovative programme.

Feasibility

Despite the barriers outlined above, there were a number of aspects of the protocol which ran smoothly, and could be replicated in future studies. For example the questionnaires utilised in this study were acceptable to participants. There were no issues with regard to randomisation; participants at the comparison site were happy to participate. All psychology staff members were willing to be involved in recruitment and motivated to support further therapeutic work with this group. No ethical issues were raised, and the piloted guidelines for reporting serious adverse events were deemed acceptable. Guidelines issued by the NHS in 2012 in relation to serious adverse events during study trials, advise careful consideration in relation unanticipated adverse events and whether they should be reported; feedback from AP's and CP's indicated that participants experienced no ill effects as a result of treatment. Furthermore there were no issues with regard management of material.

Responses by Clinical Psychologists to the SAFE questionnaire were consistent with results from the focus groups. They indicated that the manual was only partially targeted at the population of interest, thus supporting the above recommendations for amendments to suit a severe TBI population. Responses to the question regarding flexibility of the intervention was rated only "partially flexible". Handwritten comments indicated that one CP had made changes to the manual of his own initiative in the best interest of participants, mostly to support with cognitive deficits. Considering this feedback, and findings from the focus group with Assistant

Psychologists who stressed the importance of flexible delivery of interventions with a TBI, this is a point to consider for future intervention development. However it important to consider the literature relating to the importance of treatment fidelity in clinical trials as described by Perepletchikova et al (2007); i.e. ensuring that changes can be attributed to the intervention and also that the intervention can be replicated. A number of studies have highlighted the challenges of adapting interventions to suit client needs without compromising fidelity (McHugh et al, 2009; Kendall & Beidas, 2007). Kendall and Beidas (2007) proposed that there can be "flexibility within fidelity" and suggest that treatment manuals should "have life" i.e. an overarching structure that permits flexibility in fulfilling the main goals of the treatment. They suggest fidelity should be assessed by assessing transcripts of sessions by an experience clinician. Doing so would meet quality criteria as advised by the CONSORT(CoNsolidated Standards of Reporting Trials) guidelines while also allowing for flexible delivery.

The results also indicated that the CP's viewed the intervention as complex; this supports the AP's description of difficulties understanding training, and may be worth considering that ideally an intervention should be delivered by more experienced clinicians such as CP's. Furthermore results of the SAFE questionnaire indicated that that consideration need to be made in relation to the cost of material, and whether the resources are available to allocate time to training, preparation of sessions and of study material.

Limitations

Limitations of the present study include the fact the manualised intervention utilised was developed for use with outpatients in Australia. It is possible that cultural differences affected engagement with the group in Glasgow. A further limitation is that facilitation of the focus groups with participants who had a TBI was more directive than is usually advised (Kitzinger, 1995), and the researcher was more involved in encouraging discussion with TBI patients than with staff. Although every effort was made to remain objective, this may have biased some of the

participant reporting. Participants in the study included only one female, however this likely reflects the larger proportion of males accessing rehabilitation at BIRT centres. Finally only two members of staff, both of whom were AP's, attended the focus group for staff. It may have been beneficial to gain perspectives from staff within different disciplines on the unit. Strengths of the study include adherence to guidelines for conduct of a high quality pilot/feasibility study.

Conclusion

In summary there was evidence that with minor adjustments and consideration the study protocol was feasible and acceptable for this population. The results indicate that major adjustments are required to the ACT manual for use with this population. This conclusion is drawn as a result of considering the parameters of good quality pilot/feasibility study in relation to recruitment, data collection forms, randomisation and reporting of serious adverse events. Therefore in keeping with MRC guidelines further piloting of this intervention would be required prior to making any final recommendations for large scale research.

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Chapter 3: Advanced Practice I Reflective Account

Selection and Implementation of Psychological Interventions

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Submitted in part fulfillment of the requirements for the qualification of Doctorate in Clinical Psychology

Abstract

Introduction

I chose this topic as I felt it was an interesting area to examine in the context of my development through training. Given this aspect of Clinical Psychology was what I had envisioned prior to starting my studies, the journey of adapting and growing to account for the many influences on my learning in this area has been of particular interest to me. I chose this topic also as fundamentally we are expected to be highly skilled in this area and therefore we constantly need to challenge ourselves in this domain.

Reflection

I used Gibb's (1988) model of Reflection to structure my answer. Throughout my reflection, I use this model to focus on change, not only in relation to specific areas on a particularly placement, but also to reflect on change throughout my training. The process of examining my emotional reaction to events and how this fits into this model of reflection has been particularly helpful. Referring to this model has also have been useful in reinforcing the message that reflection is about informing practice and continuously assessing the impact of these changes.

Reflective Review

It was useful to identify themes which arose as I wrote my account; for example the importance of supervision and continuing to use this appropriately, that reflection is a continuing process and acknowledgement of our own particular weaknesses is not sufficient to change practice, that we may always be vulnerable in certain areas and need to mindful and manage these. I also believe it may be useful to keep some form of written account; doing so is a helpful means ofconsidering the implications of reflections.

Chapter 4: Advanced Practice II Reflective Account

How the role of Clinical Psychologist is understood with an MDT.

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Submitted in part fulfillment of the requirements for the qualification of Doctorate in Clinical Psychology

Abstract

Introduction: This account focuses on my personal experience of the changing role of the Clinical Psychologist. Recent drives within the NHS, including the implementation of the Heat target, have resulted in increased pressure for services to deliver, and with that greater consideration regarding how best to utilise the skill set of clinical psychologists. Given these developments, and my observations throughout each placement of their impact on various services, I believe it would be useful to reflect on this issue. Specifically I consider how the role is perceived in our working environment and in wider society and how this affects our practice and working relationships.

Reflection: I refer mainly to Atkins & Murphy (1993) model of reflective practice to structure my account. Atkins & Murphy encompass a number of important reflective practice models. This model allows me to describe my feelings in relation to my observations during placement including; my experience of fulfilling this role as a trainee. Analyses of my emotional experience in relation to my knowledge lead to my developing new perspectives which I describe in my account. I also have incorporated Gibb's (1988) model of reflection which allowed me to demonstrate how I made changes in line with reflections, and continue to monitor and reflect on changes in my practice.

RESEARCH PORTFOLIO APPENDICES **Page**

Appendix 1: Systematic Review

Appendix 2: Major Research Project Paper

Appendix 1.1 Clinical Trial Assessment Measure

Reviewer Name:

Paper Reviewed:

Date:

Clinical Trials Assessment Measure (Tarrier & Wykes, 2004)

		Score
Sample		
1	Is the sample a convenience sample (score 2) or a geographic cohort (score 5) or highly selective sample (score 0) (*Convenience sample: e.g. clinic attendees, referred patients. Geographic cohort : all patients eligible in a particular area)*	
2	Is the sample size greater than 27 participants per group (score 5) or based on adequate and described power calculations (score 5) If no to both questions score 0.	
	Subtotal	/10
Allocation		
3	Is there true random allocation or minimisation allocation to treatment groups (if yes score 10)	
4	Is the process of randomisation described (score 3)	
5	Is the process of randomisation carried out independently from the trial research team (score 3)	
	Subtotal	/16
Assessment (for the main outcome)		
6	Are the assessments carried out by independent assessors and not therapists (score 10)	
7	Are standardised assessments used to measure symptoms in a standardised way (score 6), idiosyncratic assessments of symptoms (score 3)	

8	Are assessments carried out blind (masked) to treatment group allocation (score 10)	
9	Are the methods of rater blinding adequately described (score 3)	
10	Is rater blinding verified (score 3)	
	Subtotal	/32
Control Groups		
11	TAU is a control group (score 6) and/or a control group that controls for non-specific effects or other established or credible treatment (score 10)	
	Subtotal	/16
Analysis		
12	The analysis is appropriate to the design and type of outcome measure (score 5)	
13	The analysis includes all those participants as randomised (sometimes referred to as an intention to treat analysis) (score 6) and an adequate investigation and handling of drop outs from assessment if the attrition rate exceeds 15% (score 4)	
	Subtotal	/15
Active Treatment		
14	Was the treatment adequately described (score 3) and was a treatment protocol or manual used (score 3)	
15	Was adherence to the treatment protocol or treatment quality assessed (score 5)	
	Subtotal	/11
	Total Score	/100

Appendix 1.2 Guidelines for submission to Behavior Therapy.

Behavior Therapy; Guide for Authors

Policy and ethics
All manuscripts should be prepared in conformity with the format described in the Publication Manual of the American Psychological Association, Sixth Edition, (2009), and it is the responsibility of the author that manuscripts adhere to the format and other requirements of Behavior Therapy. Medical Journals, manuscripts should follow the guidelines of the Publication Manual of the American Psychological Society as opposed to the Uniform Requirements for Manuscripts Submitted to Medical Journals.

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NOTE: This statement should be inserted as a separate paragraph in the section on "Manuscript Requirements". It can be inserted as the third paragraph in this section - before the paragraph that begins "Authors are strongly encouraged to submit online....

Reporting Standards: **For randomized clinical trials**, Behavior Therapy requires use of the CONSORT (Consolidated Standards of Reporting Trials) Guidelines. CONSORT Guidelines offer a standard way to improve the quality of such reports, and to ensure readers have the information they need to evaluate the quality of clinical trials. The CONSORT Checklist and Flowchart can be viewed athttp://www.consort-statement.org

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Divide your article into clearly defined sections. Each subsection is given a brief heading. Each heading should appear on its own separate line. Subsections should be used as much as possible when cross-referencing text: refer to the subsection by heading as opposed to simply 'the text'.

Introduction
State the objectives of the work and provide an adequate background, avoiding a detailed literature survey or a summary of the results.

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Provide sufficient detail to allow the work to be reproduced. Methods already published should be indicated by a reference: only relevant modifications should be described.

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The main conclusions of the study may be presented in a short Conclusions section, which may stand alone or form a subsection of a Discussion or Results and Discussion section.

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Acknowledgements

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Reference to a book:
Strunk, W., Jr., & White, E. B. (2000). The elements of style. (4th ed.). New York: Longman, (Chapter 4).
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Appendix 2.1

Major Research Project Proposal

Title

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

Name:	**Niamh O'Meara**
Matriculation Number:	**2059064o**
University Supervisors:	**Professor Tom McMillan, Dr Hamish McLeod, Dr Ross White**
Field Supervisor:	**Dr Brian O'Neill**
Collaborator:	**Dr Nikki Patterson**
Date of Submission:	**26/10/2014**
Version number:	**7**
Word Count	**4,155**

Abstract

Background

There is an extensive body of research which demonstrates the effectiveness of Acceptance and Commitment Therapy (ACT) for a diverse range of psychological disorders (e.g. chronic pain, depression, psychosis). Several reviews suggest that ACT may benefit people struggling to adjust to life following a Traumatic Brain Injury; however there are no published treatment trials using ACT with this group. **The present study** will examine the feasibility of an intervention trial of ACT for people with severe Traumatic Brain Injury (TBI) treated in an inpatient rehabilitation centre. The data will inform recommendations for the design and conduct of a larger study.

Method

Mixed quantitative and qualitative methods will be used including Focus Groups and questionnaire measures. Data will be collected from patients and unit staff at multiple time points across three research sites.

Data analysis

Data collected from Focus Groups will be analysed using thematic analysis using published best practice guidelines (Braun & Clarke, 2006). Questionnaires and forms completed by the staff in order to establish application of inclusion/exclusion criteria and participant flow will be analysed descriptively to determine the acceptability of features of the study protocol.

Introduction

Traumatic Brain Injury and Psychological Distress

High levels of psychological distress are common in people who have suffered severe traumatic brain injury (TBI). Typical problems include anxiety (Soo et al, 2011), depression (Guillamondegui, 2011) and a disturbed sense of self (Myles, 2004). For many there is a prolonged, often distressing adjustment period following the brain injury. Studies have highlighted the importance of proactively addressing psychological difficulties so that the individual can successfully engage in all areas of rehabilitation (Fleming et al 2011).

Khan-Bourne and Browne (2003) reviewed studies assessing the use of psychology therapies for depression with TBI sufferers and concluded that despite previous research highlighting the importance of addressing psychological health in rehabilitation services, the evidence base is limited. There have been some studies indicating positive outcomes when treating anger (Medd & Tate, 2000), but the evidence for treatment of anxiety and depression for this group is limited (Whiting et al, 2013).

Acceptance and Commitment Therapy (ACT)

Acceptance and Commitment Therapy (ACT; Hayes, Strosahl & Wilson, 1999) is a psychotherapeutic intervention that aims to enhance individuals' willingness to have difficult experiences but persist with behaviours that reflect what is important to them. ACT has emerged as one of the "third wave" of behaviour therapies in response to perceived limitations of standard CBT approaches, the key component of ACT which sets this therapeutic approach apart from CBT is the focus on changing the persons relationship with their psychological difficulties rather than pathologising difficult emotions and endeavouring to rid of them (Hayes, 2004).

ACT is guided by a model of psychological functioning that comprises six core processes that are argued to underpin psychological flexibility and adaptive

functioning. It is proposed that these processes support each other to aid the client to contact the present moment more fully as a conscious human being and to live according to personally relevant values. Acceptance processes help individuals embrace pain and make space for difficult experiences, thereby creating an alternative emotional and psychological context which allows them to partake in valued behaviour (Hayes, 2004).

The potential effectiveness of this intervention in improving functioning and well-being in a variety of populations with psychological difficulties and medical problems (e.g. chronic pain; Ruiz, 2010) is now being documented (Powers et al., 2009). However the suitability and effectiveness of ACT among a brain injury population is unknown and has yet to be investigated.

ACT and Traumatic Brain injury

A number of reviews have suggested the potential usefulness of ACT as a viable alternative to CBT for use with TBI sufferers (Soo et al 2011). In contrast to CBT, logical analysis plays a limited role; ACT relies on metaphors, stories, behaviour tasks and experiential processes to achieve its aims. The ACT approach also adopts acceptance-based techniques (including mindfulness practices) rather than attempting to facilitate changes in thought content through logical disputation and evidence evaluation techniques. Kangas and MacDonald (2011) highlighted that the emphasis on acceptance in ACT may potentially be particularly beneficial for this group, many of whom have irreversible brain damage and are struggling to adjust to their new reality. However Whiting et al (2013) argue that it is the adoption of traditional behavioural techniques as part of ACT that could be of particular benefit to TBI sufferers; the focus on behavioural techniques reduces the demands on verbal reasoning, which is often impaired in this group. In addition behavioural interventions can incorporate skill acquisition and self management skills thus potentially accounting for and addressing further deficits displayed by TBI sufferers.

Rationale for pilot study

There are no published studies on the use of ACT with TBI sufferers in the UK. As a cost-effective first step, a pilot study is required to assess the suitability, feasibility and acceptability of carrying out such an intervention. The benefits of conducting an external pilot study are well documented in the literature (Sampson, 2004; Lancaster et al, 2002; Arain et al, 2010) most notably in relation to estimating the parameters of a subsequent RCT. Following their review of external pilot studies conducted to inform the design of RCT's, Lancaster et al. (2002) published guidelines highlighting a clear list of objectives required to ensure methodological rigour in a high quality pilot study. The present study is structured using these objectives.

This work is part of a larger study which, in addition to addressing the objectives outlined below, will also involve estimation of effect sizes to guide sample size targets for a larger study, development of procedures for assessing fidelity to treatment, and assessment of the suitability of ACT from the perspective of service users (the elements to be conducted by CM are described further in Appendix A).

The design of the following study has been adapted from a protocol developed in Australia for patients with a mild TBI seen in an outpatient setting (Whiting et al., 2013). The modifications take account of the differences in the setting of the current research (i.e. people in the UK with a more severe TBI which requires inpatient treatment).

Research aims

1) To assess the integrity of the study protocol including:
    - Testing the application of the inclusion/exclusion criteria
    - Evaluation of therapist training procedures
    - Identification of barriers to implementing the treatment protocol
    - Development of ethical and quality management procedures including refinement of Standard Operating Procedures for detecting and reporting Serious Adverse Events (SAEs)
    - Management of study materials

2) Testing and refinement of data collection forms
3) Ascertaining participant views with regards to random allocation to treatment and control groups.
4) Obtaining opinions regarding the most appropriate primary outcome measure from the perspective of patients and staff members at the research sites
5) Determination of recruitment and consent rates

Plan of investigation

Participants

1) Patients in independent sector inpatient brain injury rehabilitation units (Brain Injury Rehabilitation Trust; BIRT) in Glasgow (Graham Anderson house), York (York House) and Leeds (Daniel Yorth House). Glasgow will be the treatment site and York or Leeds will be control site(s). All three centres have comparable service user profiles and philosophy of care.
2) Psychology staff who will be trained in the ACT protocol and will administer the intervention.
3) Care staff based at Graham Anderson House involved in the day to day care of inpatients but not involved in the delivery of the intervention.An added rationale for seeking the views of care staff is that it is likely that these individuals will be involved in identifying and referring patients to the present study and any larger scale study conducted

Justification of sample size.

There are conflicting views in the literature regarding the number of participants required in a pilot study to estimate parameters for a larger study. Many pilot studies cite Lancaster (2004) who recommends of an overall sample size of 30, i.e. 15 participants in treatment and control arms. In other studies, sample sizes between 24 (Julious, 2005) and 50 (Sim & Lewis, 2012) have been recommended. For this pilot study it is anticipated (taking into account previous rates of participation in research conducted at BIRT) that about 30 clients in total will be recruited in the time available.

It is proposed there will be a maximum of three psychology staff participants. This number is based on the availability of psychology staff at the intervention site BIRT centre and the numbers needed to administer the intervention.
Based on recommendations of sample sizes for focus group in a guide for qualitative research practices edited by Ritchie and Lewis (2003), a minimum of eight and maximum of 12 staff members will be required to conduct a successful focus group.

Treatment Allocation

Participants will not be randomised. The Glasgow unit will be the test site for the ACT intervention and the other unit(s) will be used as controls. As part of this study, service user and staff views about the acceptability of random assignment to treatment and control groups will be sought.

Inclusion and exclusion criteria for clients

- Inclusion and exclusion criteria will be assessed by clinicians (support workers, key workers, and nursing and psychology staff) at the units.

Severity of brain injury will be determined by one or more of the following criteria being met:

- a score of less than 8 on the Glasgow Coma Scale (GCS) for the index injury (Teasdale & Jennett, 1974)
- Post Traumatic Amnesia (PTA) for at least 24 hours
- Loss of consciousness (LoC) for more than 30 minutes following the injury.

Participants will:

- Be aged 18 or over
- Have capacity to consent to participate in the study (determined by BIRT clinicians)
- Have sufficient residual cognitive ability to complete study questionnaires and participate in discussions as part of the ACT intervention (both determined by clinicians at BIRT)

- Have sufficient English language skills to allow completion of questionnaires
- Be exhibiting psychological distress or behavioural dysfunction that is deemed to warrant treatment.

Participants will not:

- Have an agreed discharge date within the following eight weeks
- Show current challenging behaviour (impulsivity, verbal or physical aggressiveness) which could impair meaningful participation in treatment, or put the participant or researchers at risk.

Inclusion/Exclusion criteria for Psychology staff

Psychology staff will have attended a 1.5 day training course provided by Dr Ross White, Senior Lecturer in Clinical Psychology and a Clinical Psychologist who is trained and experienced in ACT.

Furthermore Psychology staff will have the time and resources to:

- Administer ACT intervention to at least one group of four clients once a week for a six week period within the time frame suggested for this pilot study
- Participate in a focus group following intervention providing their views of the study protocol
- Complete the SAFE questionnaire identifying barriers to treatment implementation

Inclusion/Exclusion criteria for Care staff not delivering the intervention

Care staff invited to take part in the focus group will;

- Be based at Graham Anderson House
- Work directly with the clients receiving the intervention.
- Have commenced employment at BIRT prior to the first ACT intervention session.

Recruitment procedures for psychology staff

Dr Brian O'Neil (Consultant in Neuropsychology and Rehabilitation at Graham Anderson House and acting as field supervisor for this research) will invite psychology staff to attend a meeting at BIRT where details of the study will be provided by NO'M and CM including a discussion of what their participation would involve. Copies of the protocol will be available including a list of inclusion criteria for psychology staff. Staff who meet inclusion criteria will be provided with an information sheet by NoM or CM. They will be given at least 24 hours to consider their participation, following which they will have further opportunity to ask questions and will be invited to sign a consent form by NoM or CM.

Recruitment procedures for clients

1) Participants will be recruited from BIRT Graham Anderson House Glasgow (Treatment group) and BIRT unit(s) in England (Control group) over a six month period (November 2014 – May 2015). Following a discussion with clinical staff at BIRT who will be involved in the intervention, a preliminary plan is for four clinical staff involved in training to select a six week period in the time frame outlined above and for each clinician to administer therapy to one/two groups of four once a week for six weeks. If participant uptake levels are below 12, a further six week block will be considered.
2) The research will be discussed by both researchers (CM, NoM) with all clinicians and clinical leads at each unit.
3) Each unit will provide a named clinician (Assistant Psychologist; AP) to act as a point of contact in relation to recruitment.
4) Psychology staff briefed on the recruitment process can provide information sheets to participants who fit the inclusion criteria between November 2014 and end of April 2015. Clients will have a minimum of 24 hours to consider participation before meeting with CM and NoM to complete the consent process.
5) Both researchers (CM, NoM) will meet with clinical staff prior to meeting participant to discuss risk.

6) Both researchers (CM, NoM) will meet with the potential participants to further discuss and obtain consent.
7) In line with BIRT policy regarding service users who are partaking in research, a care plan will be drawn up incorporating their participation in the study. This will include the aims of the study and will be accessible to all staff working with the client.

Recruitment procedures for care staff

Care staff who work directly with clients at the treatment group centre but are not involved in administration of the intervention (Graham Anderson house) will be invited to take part in a Focus Group. Prior to intervention an information sheet summarising the study will be distributed to care staff via Dr O'Neil at BIRT, which will include an invitation to participate in a Focus Group on completion of the intervention. Staff will have a minimum of 24 hours to consider their participation. Those interested in participation will have the opportunity to meet with CM or NoM in order to ask further questions and will be asked to sign a consent form. At this point they will be asked to provide their email address. Those who agreed to take part will be contacted with the time and location of focus group following intervention.

The information sheet will also specify that those who agree to take part may be asked to complete carer based questionnaires on behalf of clients, and may also be involved in collecting demographic information for participants and discussing risk issues with the researchers.

Measures

Demographic and Clinical details

- 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)
- Glasgow Outcome at Discharge scale (GODS) (McMillan et al, 2013). The information required to complete the GODS will be available in the client file. The researchers, with the aid of staff members, will access the client files to gather the information required.

Cognitive Assessment

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

- Wechsler Test of Pre-morbid Functioning
- Subtests of Wechsler Adult Intelligence Scale-IV: 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.

The following measures will be used explore treatment effects and determine motivation to engage in therapy:

6) The Acceptance and Action Questionnaire-Acquired Brain Injury (AAQ-ABI; Sylvester, 2011) is a 15-item questionnaire measuring psychological flexibility specifically devised to assess difficulties observed in TBI sufferers. It was developed and used by Sylvester (2011) for a study in paediatric Acquired Brain Injury (ABI).
7) Hospital Anxiety and Depression Scale (HADS), Zigmond and Snaith (1983). The HADS is a 14-item scale. Zigmond and Snaith (1983) reported good internal consistency for both the anxiety subscale (Cronbachs alpha =

0.8) and the depression subscale (Cronbachs alpha = 0.81). Previous studies have adopted this measure for use with TBI sufferers.

8) The Awareness Questionnaire - AQ (Sherer, 2004). This is a 17-item questionnaire designed to assess self-awareness in TBI sufferers. There are three versions of the AQ, one for staff, one for a family member and one for service users. Two of these (staff and service user questionnaires) will be adopted in this pilot study. Sherer et al (1998a) reported good internal consistency for the AQ (Cronbachs alpha = 0.88), and good validity.
9) 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 assessed by chronbach's alpha (0.91).

The following measure will be used to assess blocks to, and facilitators of, implementation of intervention.

The Structured Assessment of Feasibility measure (SAFE) (Bird et al., 2014): This measure was designed to assess the feasibility of implementing a complex intervention within mental health services within the NHS. It is a 16-item measure which aims to obtain information about barriers and facilitators of implementation of intervention. Bird et al. (2014) reported excellent inter-rater (0.84) and test-retest reliability (0.89) assessed by chronbach's alpha.

Design

Mixed quantitative and qualitative methods will be used including focus groups, questionnaire measures, and semi-structured clinical interviews. Data will be collected at multiple time points, participants will include clients at the rehabilitation

units and unit staff at both research sites, i.e. control and treatment group. See Appendix A for proposed methodology to address each research aim.

Research Procedures

Psychology staff participation

- Psychology staff who have consented to take part in the study, will recruit clients at BIRT. They will complete a record form identifying inclusion criteria which were met, and criteria which excluded potential participants. This form will include a section inviting staff to detail any barriers or difficulties encountered as part of this process.
- On completion of the study, clinicians will be asked to complete the SAFE questionnaire identifying barriers to intervention.
- Psychology staff will also be asked to attend a focus group in order to provide feedback with regard their experience of the study protocol. The focus group will be facilitated by NoM and CM and will last no longer than one hour.

Care staff participation

- In the information sheet provided to staff they will be informed they may be asked to complete a questionnaire based on their knowledge of working with the individual. This questionnaire will be completed at two time points (Pre and post intervention). The same staff member will complete the questionnaire for individual clients at both time points.
- All Care staff participants will attend a focus group addressing their personal views on: 1. The most appropriate primary outcome measure for a treatment trial; 2. Potential improvements to the recruitment process; 3. Their view of service user experience of study participation and 4. Any identified ethical issues.

Treatment group

- The ACT intervention will be delivered to groups of four clients by psychology staff participants. Treatment content will be adapted from the ACT treatment manual prepared by Whiting et al (2013) which has been specifically developed for TBI sufferers. The intervention will be administered by psychology staff based at Graham Anderson House. Treatment will consist of six sessions lasting appropriately two hours (break included).
- Because commencement of ACT for each group will be staggered, CM and NO'M will visit Graham Anderson house regularly over a seven month period (October 2014 – May 2015) to collect baseline and outcome measures at the appropriate time points. Table 1 provides further details of planned data collection procedures.
- Clients involved in the study will be invited to attend focus groups addressing their experience of being involved in the study. These groups will be conducted with groups of six and will be structured around questions addressing: 1. The experience of receiving ACT; 2. The experience of completing the outcome measures; 3. The experience of the recruitment and consent process; and 4. Views about the most appropriate primary outcome measure. It is proposed that the focus groups will last between 45 minutes to one hour that will occur after the post-intervention study measures. Participants who decided to drop out of the ACT intervention will also be given the opportunity to attend the focus groups and express their views with regard the study protocol.

Comparison group

- Participants in the comparison group will receive Treatment As Usual (TAU) which will involve: client centred goal planning within a holistic rehabilitation focus, counselling support provided by mental health trained nurses, medical management by a GP, CBT administered by clinical psychologist and potentially medication overseen by a consultant psychiatrist.

- CM and NO'M will travel to the control group BIRT centres twice over a seven week period to administer the study measures at the relevant time points (see Table 1).
- In addition to completing outcome measures at Time 2 participants will be invited to attend focus group on completion of the intervention seeking their view with regard having been allocated to comparison group rather than treatment group.
- Given this is a pilot study, decisions can be made about the appropriateness of carrying out a similar large scale study but not about the effectiveness of ACT intervention with this group therefore it would not be appropriate to recommend treatment to the comparison group based on the outcome of this study.

Further Research tasks

- Systematically collect data on participant flow across study period. The following will be recorded: number of eligible participants, number approached by staff, number willing to discuss consent, number who consented and number who completed intervention.
- Record any difficulties with storage and transportation of study materials
- Guidelines for reporting Serious Adverse Events (SAE's) will be piloted as part of this study. In order to establish base rates for this group, a record will be kept of any SAE experience by participants of intervention or comparison group. A checklist of potential SAE's will be used at both times of testing for treatment and control group in order to establish whether any SAE's occurred.

Table 1 Study procedures for treatment and control groups

<table>
<tr><th></th><th>TREATMENT</th><th>CONTROL</th><th>CARE STAFF</th><th>PSYCHOLOGY</th></tr>
<tr><td rowspan="3"></td><td></td><td>.</td><td></td><td>Approached by researchers who will provide information regard the study, after 24 hours asked to sign consent form.</td></tr>
<tr><td colspan="2">Approached individually by psychology staff who will provide information sheet and answer any questions</td><td>Approached by psychology staff who will distribute information sheets and answer any questions. After 24 hrs meet with NoM or CM to sign consent.</td><td></td></tr>
<tr><td colspan="2"></td><td>A staff member who has agreed to take part in the study will meet with NoM or CM to discuss risk factors</td><td></td></tr>
<tr><td>Time 1</td><td colspan="2">Interested parties will meet with CM or NoM to ask any further questions, sign consent forms and complete baselines measures.</td><td>Staff member will meet with NoM or CM to collect demographic date from client files and complete staff questionnaire</td><td></td></tr>
<tr><td>Sessions 1-6</td><td>ACT intervention + TAU provided at BIRT Glasgow</td><td>Control group continue to receive treatment as usual</td><td></td><td>Deliver ACT intervention to treatment group</td></tr>
<tr><td>Time Two</td><td colspan="2">Readminister outcome measures</td><td>Same staff member who completed time I will complete time II staff questionnaire</td><td></td></tr>
<tr><td rowspan="2"></td><td colspan="2"></td><td></td><td>Complete SAFE questionnaire</td></tr>
<tr><td colspan="4">On completion of the intervention patients and staff will be invited to participate in separate focus groups to obtain feedback regarding the study protocol</td></tr>
</table>

Data analysis

Descriptive analysis will be used for questionnaires/feedback forms and record forms completed. Data collected from focus groups will be analysed using thematic analysis as described by Braun & Clarke (2006) who outline best practice guidelines for use of thematic analysis in psychological research.

Settings and equipment

- A quiet room to administer outcome measures
- Access to a photocopying machine, computer and printer
- Copies of outcome measures
- Locked filing cabinet to store files for duration of study
- Encrypted laptop to carry out statistical analysis

Ethical issues

Sponsorship will be provided by Glasgow University, and ethical approval will be sought from the West of Scotland Research Ethics Service. Separate information leaflets detailing the study will be provided to participants (Clients, Psychology staff and care staff) in a clear and understandable manner in order to obtain informed consent. Capacity to give this consent will be assessed by staff at BIRT. The voluntary nature of the study will be emphasised to those approached. Participants will be advised prior to participation in the study that they can leave the study at any point.

Confidentiality

- Data protection rules outlined by BIRT and by Glasgow University will be adhered to.
- The data base will be anonymised: Each participant will be assigned a research code which will allow researchers to compare outcome measures between times of testing.

- The key linking participant name and number will be saved for five years in the university study archive prior to being deleted. This information will be saved separate to the data.
- Electronic anonymous data will be stored at Glasgow University for ten years prior to being deleted.
- Outcome measures for each participant will be stored in separate folders, the folder will have a label with the number assigned to that participant
- Outcome measures will be shredded or placed in dedicated confidential refuse sacks following completion of data analysis.
- Focus group recordings will be stored and transcribed using a university encrypted laptop. Personal identifiable information will be removed from transcripts. Electronic transcripts will be held on the university server for ten years before being destroyed. Data will be backed up on a password protected folder on the University of Glasgow server.

Dissemination and Publication Plan

The work will result in Doctoral Theses, scholarly publications, and conference presentations. Participants will be able to opt in to receive feedback on the overall results of the research.

Health and safety

As part of this study we will also pilot a procedure for detecting and reporting Serious Adverse Events (SAE) and also ascertaining a base rate of SAE's for this group.

References

All references are included in the MRP Project Paper (Chapter Two)

Appendix 2.2 Division of Pilot Study

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	NoM; CM

	3. Dropout 4. Complete study protocol	
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 documentany 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

Appendix 2.3 Ethics committee approval letter

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.

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

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

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

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

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

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

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

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

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

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

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

Ethical review of research sites

NHS sites

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

Non-NHS sites

I am pleased to confirm that the favourable opinion applies to the following research site(s), subject to site management permission being obtained prior to the start of the study at the site (see under 'Conditions of the favourable opinion below').

Research site	*Principal Investigator / Local Collaborator*
Brain Injury Rehabilitation Trust	Dr Hamish McLeod

Approved documents

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

Document	*Version*	*Date*
Covering letter on headed paper [Cover letter]		17 November 2014
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance from sponsor]		30 July 2014
GP/consultant information sheets or letters [Letter to care staff team at intervention site]	2	19 November 2014
GP/consultant information sheets or letters [Letter to care staff team at comparison site]	2	19 November 2014
Interview schedules or topic guides for participants [Focus Group questions]	1	26 October 2014
Non-validated questionnaire [Satisfaction Questionnaire]	1	24 October 2014
Other [BIRT Endorsement letter]		27 October 2014
Other [Brian O'Neil CV]		21 July 2014
Other [Checklist for Treatment as Usual]	1	21 November 2014
Other [Dr Ross White CV]		29 October 2014
Other [Insurance form BIRT (employee)]		
Other [Insurance, BIRT (public)]		
Other [Letter detailing ammendments]		19 December 2014
Other [N. O'meara Student CV]		14 November 2014
Other [Record Form for Inclusion and Exclusion Criteria]	1	12 November 2014
Other [Reporting Serious Adverse events]	1	24 October 2014
Participant consent form [Consent for clients]	2	11 November 2014
Participant consent form [Consent form for care staff at the intervention centre]	2	19 November 2014
Participant consent form [Consent form for psychology staff]	2	11 November 2014
Participant consent form [Consent form, Care staff at comparison group centre]	2	19 November 2014
Participant information sheet (PIS) [Information sheet for care staff at intervention centre]	2	19 December 2014
Participant information sheet (PIS) [Information Sheet for care staff at comparison centre]	3	19 December 2014
Participant information sheet (PIS) [Information sheet for psychology staff participants]	3	19 December 2014
Participant information sheet (PIS) [Participant information sheet for clients in comparison group]	2	19 December 2014

Document	*Version*	*Date*
Participant information sheet (PIS) [Participant information sheets for clients in Intervention Group]	2	19 December 2014
REC Application Form [REC_Form_20112014]		20 November 2014
Research protocol or project proposal [Integrated proposal]	2	19 December 2014
Summary CV for Chief Investigator (CI) [Dr Hamish McLeod CV]		12 August 2014
Summary CV for student [Claire Moynan CV]		14 November 2014
Summary CV for supervisor (student research) [Prof. Tom McMillan]		14 October 2014
Validated questionnaire [Acceptance and Action Questionnaire-Acquired Brain Injury]		
Validated questionnaire [Awareness Questionnaire Clinician form]		
Validated questionnaire [Awareness Questionnaire-Patient]		
Validated questionnaire [Glasgow Outcome at Discharge Scale]		
Validated questionnaire [Hospital Anxiety and Depression Scale]		
Validated questionnaire [Motivation for Traumatic Brain Injury TBI Questionnaire]		
Validated questionnaire [Structured Assessment of FEasibility (SAFE) Version 1.1]	1.1	

Statement of compliance

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

After ethical review

Reporting requirements

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

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

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

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form

available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

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

14/WS/1152	**Please quote this number on all correspondence**

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

Yours sincerely

Abibat Ackwumi

***For* Dr Brian Neilly**
Chair

Enclosures: "After ethical review – guidance for researchers"

Copy to: *Miss Emma-Jane Gault*

Appendix 2.4 BIRT approval letter

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.

Yours sincerely

Susan Copstick
Clinical Director

Appendix 2.5 Guidelines for submission to Neuropsychological rehabilitation

SUBMISSION OF MANUSCRIPTS:
Please email your paper to the editorial assistant, saved in a standard document format type such as Word or PDF, at reviews@psypress.co.uk. You may also contact the Editorial Assistant by phone on 02070 177730.
Your covering email must include full contact details (including email), the title of the journal to which you are submitting, and the title of your article. There is no word limit for papers submitted to this journal.
All manuscripts must be accompanied by a statement confirming that it has not been previously published elsewhere and that it has not been submitted simultaneously for publication elsewhere.
Authors will normally receive a decision on their papers within three months of receipt, and if accepted they will normally be published six to nine months later. The date of receipt of the manuscript will be printed. Where minor revision of a paper is requested the original date of receipt will appear, provided that a satisfactory revision is received within one month of the request. Otherwise it will bear the revised version date.
Journal Production Editor: authorqueries@tandf.co.uk

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FORMAT Typescripts. The style and format of the typescripts should conform to the specifications given in the Publication Manual of the American Psychological Association (6th ed.). Typescripts should be double spaced with adequate margins, and numbered throughout. The title page of an article should contain only: (1) the title of the paper, the name(s) and address(es) of the author(s); (2) a short title not exceeding 40 letters and spaces, which will be used for page headlines; (3) name and address of the author to whom correspondence and proofs should be sent;
4) Your telephone, fax and e-mail numbers, as this helps speed of processing considerably.
(5) 3-5 keywords
Abstract. An abstract of 50-200 words should follow the title page on a separate page.
Headings. Indicate headings and subheadings for different sections of the paper clearly. Do not number headings.

Acknowledgements. These should be as brief as possible and typed on a separate page at the beginning of the text.

Permission to quote. Any direct quotation, regardless of length, must be accompanied by a reference citation that includes a page number. Any quote over six manuscript lines should have formal written permission to quote from the copyright owner. It is the author's responsibility to determine whether permission is required from the copyright owner and, if so, to obtain it. (See "Seeking permission to use other sources" for a template letter to use when seeking copyright permission.)

Footnotes. These should be avoided unless absolutely necessary. Essential footnotes should be indicated by superscript figures in the text and collected on a separate page at the end of the manuscript.

References: Reference citations within the text. Use authors' last names, with the year of publication, e.g., "(Brown, 1982; Jones & Smith, 1987; White, Johnson, & Thomas, 1990)". On first citation of references with three to five authors, give all names in full, thereafter use [first author] "et al.". In the references, the first six authors should be listed in full. If more than one article by the same author(s) in the same year is cited, the letters a, b, c, etc., should follow the year. If a paper is in preparation, submitted, or under review, the reference should include the authors, the title, and the year of the draft (the paper should also be cited throughout the paper using the year of the draft). Manuscripts that are "in press" should also include the publisher or journal, and should substitute "in press" for the date.

Reference list. A full list of references quoted in the text should be given at the end of the paper in alphabetical order of authors' surnames (or chronologically for a group of references by the same authors), commencing as a new page, typed double spaced. Titles of journals and books should be given in full, e.g.: Books: Rayner, E., Joyce, A., Rose, J., Twyman, M., & Clulow, C. (2008). Human development: An introduction to the psychodynamics of growth, maturity and ageing (4th ed.). Journal article: Adlington, R. L., Laws, K. R., & Gale, T. M. (2009). The Hatfield Image Test (HIT): A new picture test and norms for experimental and clinical use. Journal of Clinical and Experimental Neuropsychology, 31, 731-753.doi:10.1080/13803390802488103

Tables. These should be kept to the minimum. Each table should be typed double spaced on a separate page, giving the heading, e.g., "Table 2", in Arabic numerals, followed by the legend, followed by the table. Make sure that appropriate units are given. Instructions for placing the table should be given in parentheses in the text, e.g., "(Table 2 about here)".

Figures. Figures should only be used when essential and the same data should not be presented both as a figure and in a table. Where possible, related diagrams should be grouped together to form a single figure. Each figure should be on a separate page, not integrated with the text. The figure captions should be typed in a separate section, headed, e.g., "Figure 2", in Arabic numerals. Instructions for placing the figure should be given in parentheses in the text, e.g., "(Figure 2 about here)". For more detailed guidelines see Preparation of Figure Artwork.

Statistics. Results of statistical tests should be given in the following form:
"... results showed an effect of group, $F(2, 21) = 13.74$, $MSE = 451.98$, $p < .001$, but there was no effect of repeated trials, $F(5, 105) = 1.44$, $MSE = 17.70$, and no interaction, $F(10, 105) = 1.34$, $MSE = 17.70$."
Other tests should be reported in a similar manner to the above example of an F-ratio. For a fuller explanation of statistical presentation, see the APA Publication Manual (6th ed.).

Abbreviations. Abbreviations that are specific to a particular manuscript or to a very specific area of research should be avoided, and authors will be asked to spell out in full any such abbreviations throughout the text. Standard abbreviations such as RT for reaction time, SOA for stimulus onset asynchrony or other standard abbreviations that will be readil understood by readers of the journal are acceptable. Experimental conditions should be named in full, except in tables and figures.

Appendix 2.6

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 2.7

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 2.8

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?

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

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

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

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

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

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

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

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

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

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

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?

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

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

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

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

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

Appendix 2.9

MOT-Q

Motivation for Traumatic Brain Injury Rehabilitation Questionnaire

Defense and Veterans Head Injury Progaram, 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				

		Strongly Disagree	Disagree Somewhat	Undecided	Agree Somewhat	Strongly Agree	For Office Use Only LD	IR	LA	RH
18	I rely on doctors to help me with my problems.	-2	-1	0	1	2				
19	I don't have any problems worth mentioning.	2	1	0	-1	-2				
20	I'd ask my therapists to do extra therapy tasks.	-2	-1	0	1	2				
21	I always follow medical orders because I think they'll help me.	-2	-1	0	1	2				
22	Doctors know what I need and I'll do what they say.	-2	-1	0	1	2				
23	I'd do what a therapist tells me even if it doesn't make sense.	-2	-1	0	1	2				
24	I'm very interested in rehabilitation, but it's not for me.	2	1	0	-1	-2				
25	I don't have time for rehab.	2	1	0	-1	-2				
26	It's fine to see a rehabilitation therapist.	-2	-1	0	1	2				
27	My problems are my own business.	2	1	0	-1	-2				
28	I don't like people prying too deeply.	2	1	0	-1	-2				
29	Therapists would waste my time.	2	1	0	-1	-2				
30	Going through rehabilitation will help me get (or keep) a job.	-2	-1	0	1	2				
31	Doctors shouldn't say I have problems without knowing how I was before my injury.	2	1	0	-1	-2				
For Office Use Only	Subtotal Page 2									
	Subtotal Page 1									
	Total									

Appendix 2.10

Structured Assessment of FEasibility (SAFE) Version 1.1

SAFE assesses the extent to which an intervention is feasible for implementation in mental health services in the National Health Service (NHS) in England.

The reference for this measure is:

Bird V, Le Boutillier C, Leamy M, Williams J, Bradstreet S, Slade M (2014) *Evaluating the feasibility of complex interventions in mental health services: standardised measure and reporting guidelines*, British Journal of Psychiatry, 204, 316-321.

SAFE Version 1.1 (this document) and the SAFE Version 1.1 rating manual can be downloaded at www.researchintorecovery.com/safe

The measure comprises two sub-scales: Blocks (8 items) and Enablers (8 items). Circle **one** answer for each item.

BLOCKS SUB-SCALE

These items are blocks to implementation.

1. Do staff require specific training to deliver the intervention?

Yes Partial No Unable to rate

Yes: *The intervention requires four hours or more of training*
Partial: *The intervention requires up to four hours of training*
No: *The intervention does not require any specific training*
Unable to rate: *Not enough information provided to rate item*

2. Is the intervention complex?

Yes Partial No Unable to rate

Yes: *The intervention is made up of more than three separate components*
Partial: *The intervention contains two or three separate components*
No: *The intervention only has one component*
Unable to rate: *Not enough information provided to rate item*

3. Is the intervention time consuming to provide?

Yes Partial No Unable to rate

Yes: *The intervention requires two hours or more per week of work (per client)*
Partial: *The intervention requires half an hour or more but less than two hours of work per week (per client)*
No: *The intervention requires less than half an hour per week (per client)*
Unable to rate: *Not enough information provided to rate item*

4. Does the intervention include/require ongoing support and supervision?

Yes Partial No Unable to rate

Yes: *The intervention requires an extra weekly supervision or support session*
Partial: *The intervention requires an additional monthly supervision or support session*
No: *The intervention does not require any additional support sessions or supervision*
Unable to rate: *Not enough information provided to rate item*

5. Does the intervention require additional human resources?

Yes Partial No Unable to rate

Yes: *Either the whole team is required to provide the intervention or professionals not in the standard multidisciplinary team are needed.*
Partial: *More than one member of staff are involved in providing the intervention*
No: *The intervention can be provided by one member of staff*
Unable to rate: *Not enough information provided to rate item*

6. Does the intervention require additional material resources?

Yes Partial No Unable to rate

Yes: *The intervention requires sizeable resources or special equipment which staff would not usually have access to e.g. a specially equipped room, instruments, art materials*
Partial: *The intervention requires additional but readily available resources e.g. computers, workbooks*
No: *The intervention does not require any additional resources that staff would not usually have access to*
Unable to rate: *Not enough information provided to rate item*

7. Is the intervention costly?

Yes Partial No Unable to rate

Yes: *The intervention is likely to be too costly to provide without extra funding*
Partial: *The intervention is likely to require other costs to be de-prioritised*
No: *The intervention cost is low*
Unable to rate: *Not enough information provided to rate item*

8. Are there known serious or adverse events associated with the intervention?

Yes Partial No Unable to rate

Yes: *There are known serious adverse events associated with the intervention*
Partial: *There are known adverse events associated with the intervention*
No: *There are no known serious or adverse events associated with the intervention*
Unable to rate: *Not enough information provided to rate item*

ENABLERS SUB-SCALE
These items are enablers of implementation.

9. Is the intervention applicable to the population of interest (e.g. adults using community mental health teams)

Yes Partial No Unable to rate

Yes: *The intervention has been designed for the population of interest*
Partial: *The intervention has been designed for a general mental health population or can be adapted to be applicable to the population of interest*
No: *The intervention is not applicable to the population of interest*
Unable to rate: *Not enough information provided to rate item*

10. Is the intervention manualised?

Yes Partial No Unable to rate

Yes: *All components of the intervention are manualised*
Partial: *Some components of the intervention are manualised*
No: *The intervention is not manualised*
Unable to rate: *Not enough information provided to rate item*

11. Is the intervention flexible (i.e. can it be tailored to the context and situation)?

Yes Partial No Unable to rate

Yes: *The intervention is flexible and can be tailored to the context and situation*
Partial: *Elements of the intervention can be tailored to the context and situation*
No: *The intervention cannot be tailored to the specific context*
Unable to rate: *Not enough information provided to rate item*

12. Is the intervention likely to be effective (i.e. evidence based and expected to produce positive outcomes)?

Yes *Partial* *No* *Unable to rate*

Yes: *There is an established evidence base regarding the effectiveness of the intervention (e.g. clinical trials)*
Partial: *There is some evidence for the effectiveness of the intervention (e.g. case studies but no clinical trials)*
No: *There is no evidence base for the intervention*
Unable to rate: *Not enough information provided to rate item*

13. Is the intervention cost saving?

Yes Partial No Unable to rate

Yes: *The intervention has been demonstrated to save costs*
Partial: *The intervention has been demonstrated to be cost-neutral*
No: *The intervention incurs more costs*
Unable to rate: *Not enough information provided to rate item*

14. Do the intended goals of the intervention match the prioritised goals of the NHS?

Yes Partial No Unable to rate

Yes: *The primary aims of the intervention match valued NHS outcomes e.g. improving mental health and wellbeing, supporting clinical and personal recovery, promoting good physical health, improving service satisfaction, reducing stigma and discrimination [Taken from No Health Without Mental Health, 2011, Department of Health]*
Partial: *The secondary aims of the intervention match the current valued outcomes*
No: *The primary and secondary aims of the intervention do not match the current valued outcomes of the NHS*
Unable to rate: *Not enough information provided to rate item*

Appendix 2.11

GLASGOW OUTCOME at DISCHARGE SCALE (GODS) v6/12/12

Participant code: _____

Date: _____

Consciousness		Enter No	
1a	Is the brain injured person conscious eg: able to obey simple commands, write, say any words or commun communicate by other means? • Could the absence of response be due to sedation? [Yes / No]* • Has the person been diagnosed as being in a vegetative state [Yes / No]* *Note: Corroborate with nursing staff.		1 – No 2 - Yes
Independence in the unit/ward			
2 a a a a	Does the person require nursing care or supervision every day for some activities of daily living? • For a 'No' answer they should be able to look after themselves for 24 hours although they need not actually look after themselves. • Independence includes the ability to plan for and carry out the following activities: getting washed, putting on clean clothes, able to prepare food for themselves (eg in the OT kitchen or during home leave), can appropriately deal with visitors/other patients and handle minor crises. • They should be able to carry out the above activities **without needing prompting**, supervision or reminding and should be believed to be capable of being left alone safely overnight. • They should not be a danger to themselves or others.		1 – No 2 - Yes
2 b	Do they need frequent help or someone to be around for most of the time? • For a 'No' answer they should be thought able to look after themselves for up to 8 hours during the day if necessary, although they need not actually look after themselves.		1 – No (Upper SD) 2 – Yes (Lower SD)
2 c	Was assistance at home essential before the injury?		1 – No 2 - Yes
2 d	Is the person confused or disorientated? • Has this been assessed using a PTA scale y/n : If yes name of scale: and score [ ] • Could confusion or disorientation be a result of sedation? [Yes / No] • If the person is confused or disorientated for any reason, assume the answer is YES to 2a		1 – No (Upper SD) 2 – Yes (Lower SD)

2e	Does the person's behaviour cause severe disruption or difficulties with ward staff, visitors, other patients or carers • No: May be antisocial, irritable or passive/apathetic but are not a danger to self or others and do not require immediate or urgent attention • Yes: Severely disruptive or difficult and can be a danger to self or others. Requires immediate or urgent staff intervention and special measures to minimise risk such as additional staffing or regular sedation.		1 – No (Upper SD) 2 – Yes (Lower SD
Independence outside the unit/ward			
3a	Are they able to shop without assistance? • For example at the hospital shop could they plan what to buy, handle money appropriately and purchase a list of items successfully without assistance		1 – No (Upper SD) 2 - Yes
3b	Were they able to shop without assistance before the injury?		1 – No 2 – Yes
4a	Are they able to travel outside the unit/ward safely without assistance? • They may walk, self propel a wheelchair, drive or use public transport to get around. Examples include visiting the hospital shop independently and safely or travelling home and returning on pass successfully and safely. Use of a taxi is sufficient if the person can phone for it themselves and instruct the driver.		1 – No (Upper SD) 2 - Yes
4b	Were they able to travel without assistance before the injury?		1 – No 2 - Yes
Work			
5a	Are they thought to be able to work to their previous capacity? • This pertains to ability to return to work within a week of discharge, and specifically to the advice they would be given at discharge. If they were working before, then their capacity for work should be at the same level. If they were seeking work before, then the injury should not have adversely affected their chances of obtaining work or the level of work for which they are eligible. If the patient was a student before their injury then their capacity for study should not have been adversely affected.		1 – No 2 - Yes
5b	How restricted do you think they are? a) Reduced work capacity b) Able to work only in a sheltered workshop or non-competitive job, or unable to work		1 = a (Upper MD) 2 = b (Lower MD)
5c	Were they either working or seeking employment before the injury (answer 'Yes') or were they doing neither (answer 'No')		1 – No 2 - Yes
Social and leisure activities			

6a	Are they able to participate in regular social and leisure activities in the ward? • This includes interacting socially and appropriately with other patients, therapists, staff and visitors. It includes taking an interest in others and in television or radio or newspapers or other reading. If they do not participate in the majority of social or leisure activities or therapy because of loss of interest or motivation then this is also considered a disability. • The person should be engaging in the activity intellectually and a judgement needs to be made this regard; eg check simply by asking them what they are/ have recently been watching, reading or listening to.		1 – No 2 - Yes
6b	What is the extent of restriction of their social and leisure capabilities? a) Mild: spend half the waking day or more demonstrating some social or intellectual interest b) Moderate: spend less than half the waking day demonstrating some social or intellectual interest c) Severe: rarely if ever, demonstrate an intellectual or social interest		1 = a (Lower GR) 2 = b (Upper MD) 3 = c (Lower MD
6c	Did they engage in regular social and leisure activities outside the home before the injury?		1 – No 2 - Yes
Social relationships			
7a	Are there psychological problems which result in disruption or difficulties in social relationships with ward staff, family, visitors, other patients or carers • Typical post brain injury personality changes: quick temper, irritability, aggression, anxiety, insensitivity to others, mood swings and depression, and unreasonable or childish behaviour		1 – No 2 - Yes
7b	What is the impact of the psychological problems? a) Occasional problems that do not have any severe or persisting impact. b) Problems are evident, but are tolerable and occur less than daily. Causes strain but this is intermittent. c) A cause of continual and severe strain and upset on a daily basis. Could lead or has led to breakdown in family relationships.		1 = a (Lower GR) 2 = b (Upper MD) 3 = c (Lower MD)
7c	Were there problems of this kind before the injury? • If there were some problems before the injury but these have become remarkably worse since the injury then answer 'No' to 7c		1 – No 2 - Yes
Return to normal life			

8a	Are there any other current problems relating to the injury which have a negative impact on daily life? • Other typical problems reported after brain injury: headaches, dizziness, tiredness, sensitivity to noise or light, slowness, memory failures, and concentration difficulties		1 – No (Upper GR) 2 – Yes (Lower GR)
8b	Were similar problems present before the injury? • If there were some problems before injury, but these have become markedly worse since the injury then answer 'No' to 8b		1 – No 2 - Yes

Appendix 2.12 Information sheet for Psychology Staff

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 Psychology staff

You are being invited to take part in this pilot study assessing the use of ACT with Traumatic Brain Injury (TBI) sufferers. 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. 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 will involve administering an ACT intervention to suitable service users based at BIRT Graham Anderson House.
- You will also be involved in recruitment of participants. We will provide you with a checklist of inclusion/exclusion criteria to facilitate this process. For each service user considered for participation we would ask that you complete the checklist identifying what inclusion/exclusion criteria were met or not met for that person.
- Your participation would involve delivering ACT to groups of four participants for six weekly sessions. The details of treatment protocol will be provided during training should you choose to take part. Regular supervision will be offered to you by Dr Ross White.
- On completion of intervention you will be invited to complete a short questionnaire, which should take no longer than 10 minutes, seeking feedback with regard barriers to implementing the intervention.
- You will also be invited to attend a one hour focus group in order to provide feedback with regard the study procedures and your experience of having been involved. This will be audio recorded.

What happens to information collected?

Your identity 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 published in a scientific journal.

What are the possible effects on you?

Taking part in this study requires considerable commitment and it may become challenging for you to manage an already significant workload with the demands of this research. If you feel overwhelmed by the tasks involved please contact any of researchers (details provided below) and we will discuss an appropriate solution.

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
Institute of Health and Wellbeing
1055 Great Western Road
Glasgow G12 0XH
n.o'meara.1@research.gla.ac.uk

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

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 2.13 Consent Form for Psychology Staff

Consent Form for Psychology Staff

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

Version Number: 2
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
1055 Great Western Road
Glasgow G12 0XH

Please initial the BOX

I confirm that I have read and understand the information sheet for psychology staff, version 2, 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 I can withdraw my data from the research database at any time.	☐
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 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 2.14 Information Sheet for Care 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 Intervention Site

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
Institute of Health and Wellbeing
1055 Great Western Road
Glasgow G12 0XH
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

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 2.15 Consent Form for Care Staff at Intervention Site

Consent Form for Care Staff at Intervention Site

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

Version number: 2
Date: 19/11/2014

Contact details: Niamh O'Meara
University of Glasgow
Institute of Health and Wellbeing
1055 Great Western Road
Glasgow G12 0XH

Claire Moynan
University of Glasgow
Institute of Health
1055 Great Western Road
Glasgow G12 0XH

Email: n.o'meara.1@research.gla.ac.uk 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.	☐

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Name of Participant	Date	Signature
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Name of Witness	Date	Signature

1 copy to staff, 1 copy to researcher

Appendix 2.16 Information Sheet for Care Staff at Comparison 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 at Comparison Site

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
Institute of Health and Wellbeing
1055 Great Western Road
Glasgow G12 0XH
n.o'meara.1@research.gla.ac.uk

Claire Moynan
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Institute of Health and Wellbeing
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Research Supervisors:

Professor Tom McMillan
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1055 Great Western Road
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Dr Hamish McLeod
University of Glasgow
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1055 Great Western Road
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Hamish.McLeod@glasgow.ac.uk

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

Appendix 2.17 Consent Form for Care Staff at Comparison Centre

Consent Form for Care Staff at Comparison Centre

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

Version number: 2
Date: 19/11/2014

Contact details: Niamh O'Meara
University of Glasgow
Institute of Health and Wellbeing
1055 Great Western Road
Glasgow G12 0XH

Claire Moynan
University of Glasgow
Institute of Health
1055 Great Western Road
Glasgow G12 0XH

Email: n.o'meara.1@research.gla.ac.uk 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 2, 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.	☐

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Name of Participant	Date	Signature
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Name of Witness	Date	Signature

1 copy to staff, 1 copy to researcher

Appendix 2.18 Information Sheet for Clients 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
University of Glasgow
Institute of Health and Wellbeing
1055 Great Western Road
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Claire Moynan
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Email: n.o'meara.1@research.gla.ac.uk
c.moynan.1@research.gla.ac.uk

Information Sheet for Clients at Intervention Site

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?
You will be invited to take part in a six week Acceptance and Commitment Therapy (ACT) intervention. This treatment will be in addition to the treatment you usually receive. The main goal of ACT is to help people make room for painful feelings as opposed to trying to get rid of them. 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 and will explain ACT to you in more detail should you choose to take part. Should you choose to take part there will be six weekly sessions of ACT, each sessions is two hours long (break included). You will be asked to complete questionnaires on two occasions; before your first therapy session and after your final therapy session. The questionnaires will take approximately 40 minutes to complete. After this we will invite you to attend a small Focus Group lasting no longer than one hour. The purpose of this group is to get your verbal feedback about being involved in the study. The Focus Group will be recorded so that what is said 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 include 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 choose 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 care plan outlining your participation in the study will be shared with your care team. If you would like to see an example of the care plan 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 or the appropriate authorities to ensure the safety of you and the public.

What are the possible effects on you?
During the ACT group you may experience a number of strong emotions. These emotions could be positive or negative. Should you experience a negative emotional reaction 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 2.19 Consent Form for Clients at Intervention S

Consent Form for clients at Intervention Site

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

Version Number: 2
Date: 11/11/2014

Contact details: Niamh O'Meara
University of Glasgow
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Claire Moynan
University of Glasgow
Institute of Health
1055 Great Western Road
Glasgow G12 0XH

Email: n.o'meara.1@research.gla.ac.uk 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.	☐

Name of Participant	Date	Signature
Name of Witness	Date	Signature

Appendix 2.20 Information Sheet for Clients at Comparison Site

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

Version number: 1
Date: 12/11/2014

Contact details: Niamh O'Meara
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Information Sheet for Clients at Comparison Site

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
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1055 Great Western Road
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Hamish.McLeod@glasgow.ac.uk

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

Appendix 2.21 Consent Form for Clients at Comparison Site

Consent Form for Clients at Comparison Site

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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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.	☐

Name of Participant	Date	Signature
Name of Witness	Date	Signature

Appendix 2.22

Version number: 2
Date: 19/11/2014

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

Letter to Care staff team at Intervention Site.

To whom it may concern

Re: (*insert client name*)

The above named patient has agreed to partake in research investigating the use of Acceptance and Commitment Therapy (ACT) with people who have suffered a severe Traumatic Brain Injury (sTBI). This research aims to pilot an ACT intervention study in order to inform the quality and design of a large scale study. We are completing this research for part completion of our clinical psychology doctorate degree at the University of Glasgow.

Client X has been assigned to the treatment group. Their participation will involve taking part in a six week ACT intervention, completing some questionnaires prior to and post intervention, and attending a focus group in order to provide feedback with regard their experience of having been involved. Please see **Client X** file for a description of how this research is incorporated into their care plan. The West of Scotland Research Ethics Committee have reviewed the study protocol and given approval to proceed. The study protocol has also been assessed as having met internal ethical standards at BIRT.

If you have any questions with regard this research or require any additional information please do not hesitate to contact any member of the research team listed below.

Yours sincerely

Claire Moynan
Trainee Clinical Psychologist
_____

Niamh O'Meara
Trainee Clinical Psychologist
_____

Contact details

Niamh O'Meara
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Appendix: 2.23

Version number: 2
Date: 19/11/2014

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

Letter to care staff team at comparison site.

To whom it may concern

Re: (*insert client name*)

The above named patient has agreed to partake in research investigating the use of Acceptance and Commitment Therapy (ACT) with people who have suffered a severe Traumatic Brain Injury (sTBI). This research aims to pilot an ACT intervention study in order to inform the quality and design of a large scale study. We are completing this research for part completion of our clinical psychology doctorate degree at the University of Glasgow.

Client X has been assigned to the treatment as usual (comparison) group. Their participation will involve completing questionnaires at two different time points and participation in a focus group to give feedback with regard their experience of having been involved in the study. The West of Scotland Research Ethics Committee have reviewed the study protocol and given approval to proceed. The study protocol has also been assessed as having met internal ethical standards at BIRT.

If you have any questions with regard this research or require any additional information please do not hesitate to contact any member of the research team listed below.

Yours sincerely

Claire Moynan
Trainee Clinical Psychologist

Niamh O'Meara
Trainee Clinical Psychologist

Contact details:Niamh O'Meara
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Appendix 2.24 Recruitment form

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 2.25 Reporting Serious Adverse Events

REACT –Recovery Enhancement from TBI using ACT. A pilot study.
Date: 26/10/2014
Version number: 1

STANDARD OPERATING PROCEDURES FOR REPORTING SERIOUS ADVERSE EVENTS

Definition of a serious adverse event

The National Research Ethics Service (NRES) defines a serious adverse event (SAE) as an untoward occurrence that:

(a) Results in death;
(b) Is life threatening;
(c) Requires voluntary hospitalisation or prolongation of existing voluntary hospitalisation;
(d) Required involuntary hospitalisation or prolongation of existing involuntary hospitalisation;
(e) Results in persistent or significant disability or incapacity;
(f) Consists of a congenital anomaly or birth defect; or
(g) Is otherwise considered medically significant by the investigator.

In this pilot study we will also monitor the occurrence of the following events:

- Self-harm
- Harm to others

Guidance for reporting a serious adverse event in this pilot trial

The following steps will be taken should an SAE occur:

(a) The clinician will discuss the event in supervision as soon as possible.
(b) The clinician will complete the "serious adverse event form" (see below) either in supervision or soon afterwards. The clinician will send the form to the Chief Investigator (CI) within three days
(c) The clinician will communicate the event to the rest of the research team.
(d) The clinician reporting the SAE will discuss the event with the CI to determine whether the SAE is considered independent or related to trial procedures. Where there is any indication that the SAE is related to trial participation, guidance will be sought, and a report will be submitted to the

relevant REC committee within 15 days of the CI becoming aware of the event.

Serious Adverse Event reporting form

Serious Adverse Event (SAE)

Participant:

Date of SAE:

Month at which the SAE took place:

Location:

Death ☐	Life threatening ☐	Involuntary hospitalisation or *prolongation* Of existing involuntary hospitalisation ☐	Self-harm ☐	Other (please describe) ☐
Persistent or significant disability or incapacity ☐	Congenital anomaly or Birth defect ☐	Voluntary hospitalisation or *prolongation* Of existing voluntary hospitalisation ☐	Harm to others ☐	

Please describe the circumstances of the event:

Please describe the likely relatedness of this event to the trial.

Please describe whether this event was considered a risk prior to commencement of the trial.

Report completed by

Name:

Designation:

Signature:

Date:

Appendix 2.26 Focus group questions

Focus group questions – ACT recipients

- What was your experience of taking part in therapy?
- Were the outcome measures that you were asked to complete; comprehensible? Appropriate? Well defined? Well presented?
- Have you any thoughts with regard the recruitment and consent process. Appropriate? Satisfactory information provided? Were you approached sensitively?
- What do you think was the greatest benefits you noticed, if any, following therapy?
- Did you experience any adverse effects having taken part?
- Have you any recommendations to improve the protocol?

Focus group questions –Care staff not involved in ACT intervention

- What do you think were the greatest benefits for clients having taken part in therapy, if any?
- What are you views with regard the recruitment and consent process? Was it appropriate? Was satisfactory information provided? Were clients approached sensitively?
- What are your views with regard service user experience of participation in intervention?
- Did you observe any ethical issues which you felt were not addressed?
- Did you notice any adverse side effects?
- Have you any recommendations to improve the protocol?

Focus group questions –Participants in comparison group

- How do you feel about being allocated to comparison group and not receiving potentially beneficial treatment

Focus group questions –Psychology staff involved in intervention

- What was your experience of training?
- What was your experience of using of treatment manual?
- Did you encounter any difficulties during recruitment and intervention?
- Have you any recommendations to improve the protocol?