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University  
of Glasgow

**A Feasibility Study of Acceptance and Commitment Therapy for  
Recovery from Complex Trauma**

CLINICAL RESEARCH PORTFOLIO

Volume 1

(Volume 2 bound separately)

**Jennifer Megson BSc Honours, MSc**

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

Institute of Health and Wellbeing  
College of Medical, Veterinary and Life Sciences  
University of Glasgow

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**CHAPTER ONE**  
**SYSTEMATIC REVIEW**

A Systematic Review of Cognitive-Behavioural Therapies for a  
Complex Trauma Population: Identifying Risk of Bias

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Declaration of interests: None

See **Appendix 1** for a summary of author instructions for submission to the  
Journal of Consulting and Clinical Psychology

Word count (including abstract and references): 7966

## Abstract

**Background:** The term 'complex trauma' has been coined in clinician and research literature to refer to prolonged and repeated traumatic events events. There have been many diagnoses given to people who have suffered a history of complex trauma, one of which is Complex Post Traumatic Stress Disorder (CPTSD) (Herman, 1992). An array of different interventions has been developed to address complex trauma. The purpose of the current review is to provide an up-to-date summary of studies that have tested the effectiveness of Cognitive Behavioural Therapy (CBT) interventions for the treatment of CPTSD in adults.

**Objectives:** This systematic review aimed to evaluate papers published in peer-reviewed journals that reported on randomised controlled trials (RCTs) examining the effectiveness of CBT as a complex trauma intervention that had been published in the past 10 years. In particular, the review aimed to investigate potential sources of bias in the included studies.

**Method:** A literature search of papers published in the last 10 years (2004-2014) was conducted using the keywords *complex trauma; complex post-traumatic stress disorder; domestic violence; chronic interpersonal violence; domestic abuse; child abuse; sexual abuse; emotional abuse; physical abuse; spouse abuse; battered women; battered child syndrome; CBT; cognitive behav\* therap\**. The following databases were searched:

MEDLINE, EMBASE and PsycINFO. Studies were included if they were published in English; peer-reviewed publications; employed a quantitative methodology; were randomised controlled trials; participants had a history of complex trauma; target interventions were those based on the cognitive-behavioural approach. The Cochrane Collaboration *risk of bias* approach (2011) was used to measure sources of bias.

**Main results:** Fourteen out of four hundred and twenty-nine studies that were identified via database and reference list searches were included in this review based on the content-specific eligibility criteria. A total of 1703 participants were randomised across the fourteen studies, with a mix of male (n = 282) and female (n = 1294) participants in the final samples. The most common outcome measures used across the studies were the Clinical-Administered PTSD Scale (CAPS, used in 6 studies); Beck Depression Inventory (BDI, used in 2 studies); Beck Depression Inventory – 2<sup>nd</sup> Edition (BDI-II, used in 2 studies) and PTSD Diagnostic Scale-Interview (PDS-I, used in 3 studies). Generally, large effect sizes (d=0.8-1.84, g=1.9-2.9) were only reported by the studies in which the target cognitive-behavioural intervention was compared to a control condition or treatment as usual (TAU). No significant superiority was found when CBT interventions were compared with an alternative psychotherapeutic intervention. The limitation that was most frequently reported across included studies (n = 7) was that of a small sample size.

All studies were rated as 'low risk' for short-term attrition bias and the majority were rated as 'low risk' for detection bias. The majority of included studies were rated as being at an 'unclear risk' for selection bias. Cultural bias was noted in the 'other bias' domain, with four studies being rated as a 'high risk' of bias.

**Discussion and Conclusion:** There are strong effect sizes for CBT interventions in the treatment of symptoms characteristic of CPTSD when compared to control conditions; however effect sizes are weaker when CBT interventions were compared to other psychotherapeutic interventions. Larger sample sizes may help to strengthen effect sizes and possibly lead to more conclusive findings, and more diverse samples will allow for an increase in the generalizability of results. In order for future research studies to be as reliable and valid as possible, the risk of bias in the domains outlined by *The Cochrane Collaboration (2008)* should be considered in the planning and implementation stages and clearly reported in the final paper.

## **Background and Rationale**

Complex trauma involves traumatic stressors that (1) are repetitive or prolonged; (2) involve direct harm and / or neglect and abandonment by caregivers or ostensibly responsible adults; (3) occur in vulnerable times in the survivors' life, such as early childhood, and (4) have potential to severely compromise a child's development (Courtois & Ford, 2009).

Courtois & Ford (2009) highlight that it is the timing of the occurrence of the traumatic events (during the critical stages of development in childhood when self-identify and self-regulation are being formed) as well as the nature of the events (specifically the betrayal of the developing child's security and trust in core relationships resulting in disrupted attachment security) that distinguishes complex trauma from all other forms of psychological trauma. The consequences of complex trauma can involve a range of psychological and behavioural difficulties including: emotion regulation difficulties; dissociation; disturbed self-identity; relationship difficulties; substance misuse; low self-esteem; and somatic distress (Courtois & Ford, 2009).

There have been many diagnoses given to people who have suffered a history of complex trauma as defined above, one of which is Complex Post Traumatic Stress Disorder (CPTSD). CPTSD differs from Post-Traumatic Stress Disorder (PTSD) in that it results from multiple, prolonged traumatic experiences, whereas PTSD can result from exposure to a single traumatic event, for example a car crash. Herman (1992) outlines a diagnostic conceptualisation of CPTSD which consists of seven areas

characteristic of early interpersonal trauma: alterations in the regulation of affective impulses; alterations in attention and consciousness; alterations in self-perception; alterations in perception of the perpetrator; alterations in relationship to others; somatisation and/or medical problems, and alterations in systems of meaning.

In light of the biopsychosocial nature of CPTSD, an array of different interventions has been developed to address complex trauma. Cognitive Behavioural Therapy (CBT) for complex traumatic stress disorders (Courtios & Ford, 2009) is one such treatment which has been adapted from cognitive behavioural interventions for single-event PTSD, such as Prolonged Exposure (Foa, Hembree, Rothbaum, 2007) and Cognitive Processing Therapy (Resick & Schnicke, 1993). The purpose of the current review is to provide an up-to-date summary of studies that have tested the effectiveness of cognitive behavioural therapies for the treatment of CPTSD in adults.

### *Previous reviews*

The most recent review on interventions for complex trauma in the adult population was conducted by Cloitre (2009) who reviewed the effectiveness of psychotherapies for posttraumatic stress disorder. The review included single-event PTSD populations as well as complex trauma populations, including chronic interpersonal violence; childhood sexual abuse; domestic violence; political detainees; genocide witnesses;

refugees with PTSD; combat; adult sexual and physical assault, and terrorism and civil conflict. Cloitre (2009) concluded that, in chronically traumatised populations, cognitive-behavioural interventions have been successful. The publication dates of the studies on cognitive-behavioural interventions for the complex trauma populations mentioned above range from 1997 to 2008. It was noted by the author that Cloitre (2009) did not provide a sound methodology that would allow for precise reproduction of their review; more specifically the search strategy was not outlined. In addition, Cloitre (2009) did not include the use of The Cochrane Collaboration's *risk of bias* tool (2011) to rate the quality of included studies, which is now recommended by Cochrane handbook for systematic reviews of interventions (version 5.1.0) (2011) when reviewing randomised controlled trials. The *risk of bias* framework was used in the current review. In contrast to Cloitre's (2009) review including both single-event and complex trauma populations, the current review includes complex trauma only and the inclusion criteria for screening potential studies is based solely on Courtois & Ford's (2009) definition of complex trauma as stated in the opening paragraph.

### **Objectives**

This systematic review aimed to evaluate current peer-reviewed randomised controlled trials examining the effectiveness of interventions based on cognitive behavioural Therapy (CBT) as a complex trauma intervention published in the past 10 years. The review aimed to investigate potential sources of bias in the included studies. In addition,

the review aimed to provide an opportunity to reflect on how research into the effectiveness of CBT interventions as complex trauma interventions can be improved in the future.

## **Method**

### **Eligibility Criteria**

*Inclusion criteria:* Studies were included if they were published in English; peer-reviewed publications; employed a quantitative methodology; were randomised controlled trials; participants had a history of complex trauma, as defined by Courtois and Ford (2009) (different terminology may be used; see 'key words'); target interventions were cognitive behavioural therapies; and were published over the last 10 years (from 2004 to 2014).

*Exclusion criteria:* Studies were excluded if they were: published in non-English language journals; employed a qualitative methodology; non-peer reviewed publications; book chapters; review papers or PhD theses; single case studies; participants did not have a history of complex trauma, as defined by Courtois and Ford (2009); focused on single event PTSD populations only; non-randomised control trials; and published prior to 2004.

### **Search Strategy**

#### *Computerised Search*

The following databases were searched for relevant studies on the 17<sup>th</sup> January 2014 and 9<sup>th</sup> February 2014: MEDLINE, EMBASE and PsychINFO

The following key-words were used for the computerised search:

*Trauma* key words (complex trauma; complex post-traumatic stress disorder; domestic violence; chronic interpersonal violence; domestic abuse; child abuse; sexual abuse; emotional abuse; physical abuse; spouse abuse; battered women; battered child syndrome), combined with *intervention* key words (CBT; cognitive behav\* therap\*). See Appendix 2 for database-specific search strategies and the number of studies included from each search.

#### *Hand Search*

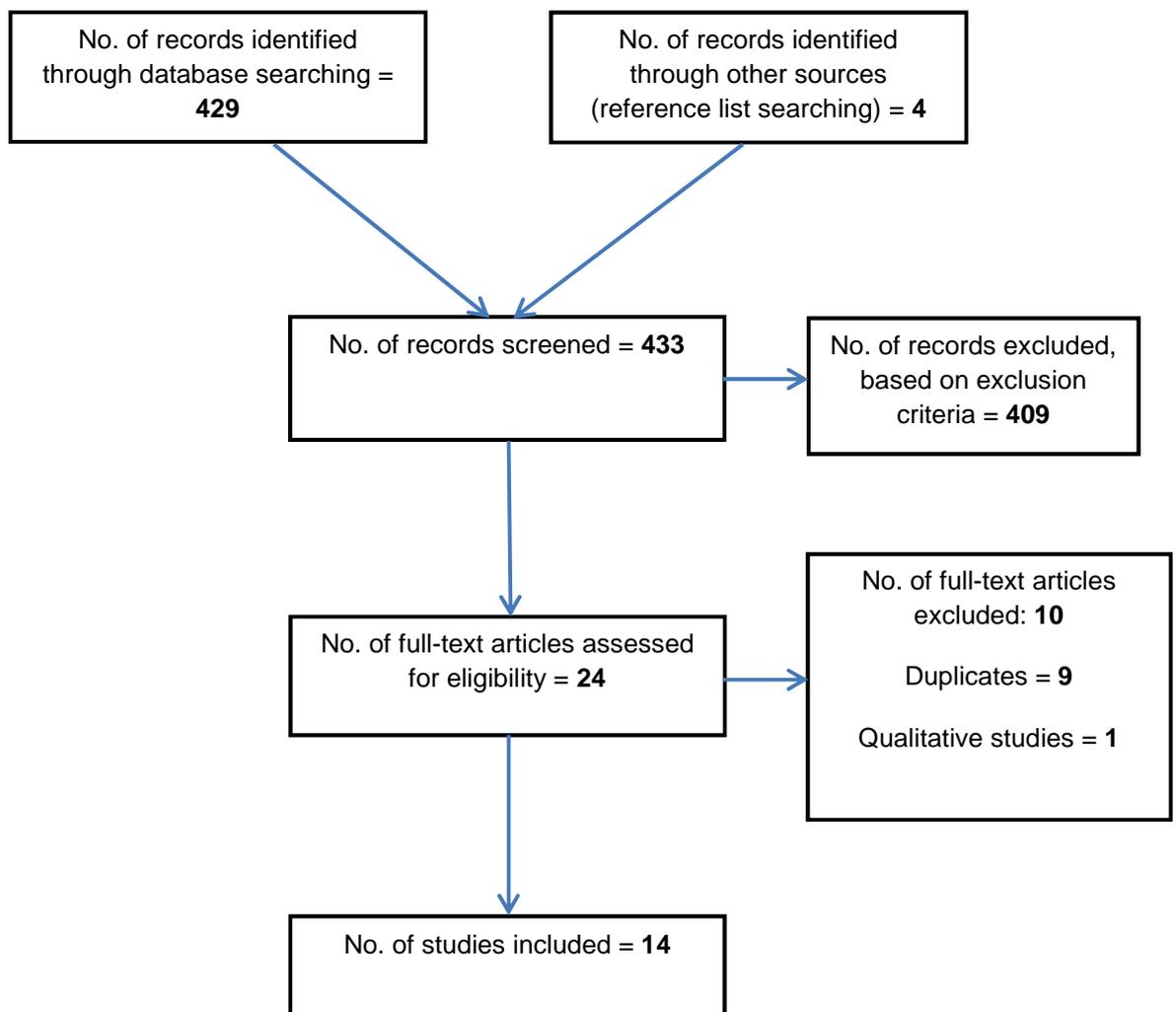
Abstracts from relevant journals were examined to determine whether papers met eligibility criteria, such as the Journal of Aggression, Maltreatment & Trauma (incorporates Journal of Psychological Trauma), Childhood Abuse & Neglect – The International Journal, and the Journal of Traumatic Stress.

## Reference Searching

The reference sections of papers that were identified by the computerised database searches were inspected to identify additional studies to be included in the review.

The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram of study selection (The PRISMA Group, 2009) provides a summary of the process used to select the studies included in this review (See Figure 1).

**Figure. 1** Flow diagram of study selection



## Rating of Included Studies

Included studies were evaluated according to The Cochrane Collaboration's *risk of bias* tool (2011). PRISMA (The PRISMA Group, 2009) introduced *risk of bias* as a different approach to systematically critiquing research in place of the previous approach of critiquing *methodological quality* that previous authors have used. They highlight the importance of distinguishing between quality and risk of bias and that when conducting a systematic review, the latter should be the focus of evaluating and reporting included studies.

Historically there have been three ways by which studies can be evaluated: scales, checklists, and individual components. PRISMA (2009) cautions against the use of scales based on theoretical grounds and emerging empirical evidence. Juni, Witschi, Bloch, & Egger (1999) report that the use of summary scores resulting from scales can be problematic and instead suggest that appropriate methodological components, such as allocation concealment, blinding of outcomes, and handling of withdrawals, should be assessed. Greenland & O'Rourke (2001) provide support for this, stating that summary scores derived from scales are poor predictors of study results and that they produce skewed estimates of effect. PRISMA (2009) highlights that checklists pose the same problem as scales. Instead of scales and checklists, PRISMA (2009) encourages the use of the Cochrane *risk of bias* tool which is a component approach to evaluating risk of bias in studies and is based on domains for which there is good empirical evidence.

The Cochrane *risk of bias* tool comprises five items: sequence generation, allocation concealment, blinding, incomplete outcome data, and selective outcome reporting. Each item was included based on the empirical evidence for its biasing influence on the estimated effectiveness of an intervention in randomised trials. The tool also includes an item named 'other sources of bias', incorporating items such as topic (peculiarity of a research topic) or something specific to the study design. When conducting a systematic review, the reviewer is advised to think about aspects of the study quality that may have an effect on the results (PRISMA, 2009). The Cochrane Handbook for Systematic Reviews of Interventions (2011) was referred to for guidance on how to apply the Cochrane *risk of bias* tool. See Appendix 3 for a summary of the types of bias.

## **Results**

See Table 1.

### *The Included Studies*

The literature search generated a total of 429 references and a total of 14 studies met the content-specific eligibility criteria; see Appendix 2 for database-specific numbers. The process of selecting the included studies is described in Figure 1: The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram of study selection (The PRISMA Group, 2009).

## *Participants*

The total number of participants randomised across the fourteen studies was 1703. There was a mix of male ( $n = 282$ ) and female ( $n = 1294$ ) participants in the final samples. The age range of the participants was 18-70 years. The studies were conducted in a range of different countries: ten were conducted in the USA (Chard, 2005; Cloitre, Stovall-McClough, Nooner, Zorbas, Cherry, Jackson, et al., 2010; Feske, 2008; McDonagh, Friedman, McHugo, Ford, Sengupta, Mueser, et al., 2005; Kubany, Hill, Owens, Iannce-Spencer, McCraig, Tremayne, et al., 2004; Resick, O'Brien, Uhlmansiek, Clum, Galovski, Scher & Young-Xu, 2008; Resick, Williams, Suvak, Monson & Gradus, 2012; Sikkema, Hansen, Kochman, Tarakeshwar, Neufeld, Meade, et al., 2007; Sikkema, Wilson, Hansen, Kochman, Neufeld, Ghebremichael, et al., 2008; Wyatt, Longshore, Chin, Carmona, Loeb, Myers, et al., 2004), two were conducted in Canada (Brotto, Seal & Rellini, 2012; Harkness, Bagby & Kennedy, 2012), one was conducted in The Netherlands (Dorrepal, Thomas, Smit, van Balkom, Veltman, Hoogendoorn, et al., 2012), and one was conducted in Germany (Jung & Steil, 2013).

In terms of the duration of post-intervention follow-up assessments, there was a range of 3-12 months (mean 5.55 months;  $SD = 1.73$ ) across six studies (Chard, 2005; Cloitre et al., 2010; Feske, 2008; McDonagh et al., 2005; Kubany, Hill, Owens, et al., 2004; Resick, et al., 2008; Sikkema et al., 2008). Resick, Williams, Suvak, Monson & Graduz (2012) conducted a

study of long-term outcomes in which they evaluated durations of follow-up assessments ranging from 5-10 years (mean 6.15 years; SD = 1.22).

### *Interventions*

Table 1 provides a summary of the interventions and comparators used in the studies included in this review.

The most popular forms of intervention being evaluated were Cognitive Behavioural Therapy (CBT, used in 3 studies: Brotto et al., 2012; Harkness et al., 2012; McDonagh et al., 2005), with a median number of individual sessions of 14, and Cognitive Processing Therapy (CPT, used in 3 studies: Chard, 2005; Resick et al., 2008; Resick et al., 2012), with a median number of 12 individual sessions and 17 group sessions (group sessions only in Chard, 2005).

The most frequently used form of comparator for the CBT interventions was a 'waiting list control group' (used in 6 studies: Chard, 2005; Jung & Steil, 2013; McDonagh et al., 2005; Kubany et al., 2004; Sikkema et al., 2007; Wyatt et al., 2004). Less frequently used comparators were a 'time-matched support group' (used in 2 studies: Sikkema et al., 2008 and Sikkema et al., 2007) and different versions of the CBT intervention (i.e. 'Skills Training in Affect and Interpersonal Regulation' [STAIR]), paired with either supportive counselling or exposure (used in 1 study: Cloitre et al., 2010).

## *Outcomes*

Table 1 provides details of the various measures used in the studies. The most commonly used measures were the Clinical-Administered PTSD Scale (CAPS, used in 6 studies: Chard, 2005; Jung & Steil, 2013; McDonagh et al., 2005; Kubany et al., 2004; Resick et al., 2008; Resick et al., 2012), Beck Depression Inventory (used in 2 studies: Feske, 2008; Kubany et al., 2004); Beck Depression Inventory – 2<sup>nd</sup> Edition (Chard, 2005; Resick et al., 2008) and the PTSD Diagnostic Scale Interview (PDS-I, used in 3 studies: Feske, 2008; Jung & Steil, 2013; Resick et al., 2008). Effect sizes for the CAPS ranged from  $d=1.07-1.8$ ,  $g=2.4$  (post-test) and  $d=0.93-2.18$  (follow-up), for the BDI ranged from  $d=0.89$ ,  $g=2.0$  (post-test) and  $d=1.03$  (follow-up), the BDI-II effect sizes ranged from  $d=1.42$ ,  $g=1.0-1.2$  and  $g=1.1-1.3$  (follow-up), and effect sizes for the PDS-I ranged from  $d=0.84-1.19$ ,  $g=0.9-1.1$  (post-test) and  $d=0.91-1.20$ ,  $g=0.8-1.2$  (follow-up).

In general, large effect sizes ( $d=0.8-1.84$ ,  $g=1.9-2.9$ ) were only reported by the studies in which the CBT intervention was not compared with another specified form of intervention (e.g. when the comparator was 'wait-list', or 'treatment as usual'). An exception to this was the study by Cloitre et al. (2010). They obtained medium to large effect sizes when directly comparing two different versions of the CBT intervention (STAIR with Exposure; STAIR with support; support with Exposure). In the studies that employed other psychotherapeutic interventions, the cognitive behavioural intervention did not appear to produce large effect sizes, and no significant differences were found in the studies comparing the target intervention

with an alternative psychotherapeutic intervention (Brotto et al, 2012, Mindfulness Based Therapy; Harkness et al, 2012, Interpersonal Therapy; McDonagh et al., 2005, Present-Centred Therapy; Resick et al., 2008, Written Accounts). See Table 1 for the full range of small, medium and large effects sizes.

### *Limitations*

The limitation that was most frequently reported across included studies was that of a small sample size (n=7: Brotto et al., 2012; Chard, 2005; Feske, 2008; Harkness et al., 2012; Jung & Steil, 2013; Sikkema et al., 2008; Wyatt et al., 2004) restricting generalizability of the results. Further limitations reported were: high attrition rates (n=3: McDonagh et al., 2005; Sikkema et al., 2007; Sikkema et al., 2008), cultural bias (n=2: Chard, 2005; Resick et al., 2012), no comparison with other therapies (n=2: Chard, 2005; Dorrepaal et al., 2012), and no control group as a comparator (n=2: Brotto et al., 2012; Jung & Steil, 2013). See Table 1 for the full range of reported limitations across all studies.

### **Risk of Bias**

See Table 2. All included papers were evaluated by the author. Thirty percent of the included papers were randomly selected and independently second-rated by a final-year Trainee Clinical Psychologist to assess for inter-rater reliability, resulting in a 98% agreement rate and any disagreements resolved in a consensus meeting of the two evaluators.

### *Sequence Generation and Allocation Concealment*

Three out of fourteen studies (Cloitre et al., 2010; Dorrepaal et al., 2012; Harkness et al., 2012) reported their process of the generation of the randomisation sequence as well as adequately described allocation concealment, therefore were rated as 'low risk of bias'. The remaining eleven out of fourteen studies (>78%) did not specify the process of randomisation or whether or not allocation post-randomisation was concealed and therefore were rated as having an 'unclear bias'.

### *Blinding*

Nine out of fourteen studies (Chard, 2005; Cloitre et al., 2010; Dorrepaal et al., 2012; Harkness et al., 2012; Jung & Steil, 2013; McDonagh et al., 2005; Kubany et al., 2004; Resick et al., 2008; Resick et al., 2012) described blinded outcome assessment which were therefore rated as having a 'low risk' of detection bias. One study (Feske, 2008) described non-blinded outcome assessment and was therefore rated as having a 'high risk' of detection bias. The remaining studies did not describe blinding of outcome measurement and were therefore rated as having an 'unclear risk' of detection bias.

**Table 1** Summary of Included Studies

Study and method	Included participants	Intervention / Conditions	Reported effect sizes for PTSD or CPTSD symptoms*	Reported limitations
1. Brotto, Seal & Rellini (2012) Canada RCT	Fluent English; sexually active in past 4 years; anxiety leading to sexual distress; history of childhood sexual abuse (CSA)  20 randomised  Female  22-54 years old  Euro-Canadian (85%); African Canadian (5%); Biracial (10%)	Cognitive Behavioural Therapy (CBT)  Mindfulness-Based Therapy (MBT)	Significant main effect of treatment, no significant difference between interventions: $d=1.08$  MBT group; Significant change in concordance between genital & subjective arousal, compared with CBT group: $d=1.46$	No wait-list or control for comparison  Small sample size  Poor ecological validity of the setting  Lacking trauma history, effects may have been dependent on baseline trauma symptoms  Sample was only recruited through advertisements, therefore it may not be representative of the population of women who would seek help for such difficulties
2. Chard (2005) USA RCT	PTSD; 1 incident and memory of CSA  71 randomised  Female  18-56 years old  African American (14%); White (81.4%); Hispanic (Latin, Mexican) American (3.5%); Other (1%)	Cognitive Processing Therapy for Sexual Abuse Survivors (CPT-SA)  Minimal Attention Wait-List (WL)	CAPS-SX: $d=1.52$ ; MPSS: $d=1.55$ ; BDI-II: $d=1.42$ ; DES-II: $d=0.91$ (between groups)	Small Sample size  Culture bias  Lack of assessments that encompass symptoms characteristic of CPTSD  No comparison with another therapy

**Table 1** *continued*

Study and method	Included participants	Intervention / Conditions	Reported effect sizes for PTSD or CPTSD symptoms*	Reported limitations
3. Cloitre, Stovall-McClough, Nooner, Zorbas, Cherry, Jackson, et al. (2010)	PTSD related to CSA or physical abuse before 18 years of age	Skills Training in Affect and Interpersonal Regulation (STAIR) and Exposure	PSS-SR: $d=0.73$ and $d=0.95$ (3 and 6-month follow-up respectively, for STAIR/Exposure compared with Support/Exposure)	Support/Exposure results may not be representative of exposure therapy as it is typically practiced. The counselling may have contributed to good outcome.
USA	104 randomised	STAIR and Support		
RCT	Female 18-65 years old  Caucasian (36%); African American (28%); Hispanic (26%); Other (10%)	Support (counselling) and Exposure	NMRS: $d=0.45$ and $d=0.50$ (3 and 6-month follow-up respectively, for STAIR/Exposure compared with Support/Exposure)  IIP: $d=0.63$ and $d=0.77$ (3 and 6-month follow-up respectively, for STAIR/Exposure compared with Support/Exposure)  STAI-S: $d=1.18$ and $d=0.92$ (3 and 6-month follow-up respectively, for STAIR/Exposure compared with Support/Exposure)  STAEI: $d=0.45$ (all time points, for STAIR/Exposure compared with Support/Exposure)  ISEL: $d=0.76$ (6-month follow-up, for STAIR/Exposure compared with Support/Exposure), $d=0.67$ (6-month follow-up, for STAIR/Support compared with Support/Exposure)	

**Table 1** *continued*

Study and method	Included participants	Intervention / Conditions	Reported effect sizes for PTSD or CPTSD symptoms*	Reported limitations
4. Dorrepaal, Thomas, Smit, van Balkom, Veltman, Hoogendoorn, et al. (2012)	PTSD; CPTSD; history of sexual and/or physical abuse	Stabilising Group Treatment based on CBT	DTS and SIDES: $d \geq 0.80$ and $d \geq 0.50$ , respectively (within groups, pre to post-treatment)	Heterogeneity of treatment history and TAU may have biased the results
The Netherlands	71 randomised	Treatment as Usual (TAU) tailored to the individual	No significant between-group difference	Non-blinded nature of the study may have overestimated treatment effects
RCT	Gender not specified  Mean age: 40.3 years  Ethnicity not reported			Gold standard treatment was not used as comparison
5. Feske (2008)	Chronic PTSD related to sexual or physical assault; if on psychotropic medications, stable dose	Prolonged Exposure (PE)  TAU (standard treatment, focussed on depression and interpersonal difficulties)	PDS-I, BAI, BDI: $d = 0.80$ to $1.20$ (between group, 4-month post-test and 6-month follow-up)  BSQ, AEI, and BSI: $d = 0.73$ to $1.23$ (between group, 4-month post-test and 6-month follow-up)	Limited sample size  Motivation possibly driven by compensation  Exclusion criteria may be too restrictive, therefore not truly representative of the population in question
USA	21 randomised			
RCT	Female  29-55 years old  African American (95.2%); Caucasian (4.8%)			

**Table 1** *continued*

Study and method	Included participants	Intervention / Conditions	Reported effect sizes for PTSD or CPTSD symptoms*	Reported limitations
6. Harkness, Bagby & Kennedy (2012)  Canada  RCT	Major Depressive Disorder (MDD); free of anti-depressant medication (ADM); no electroconvulsive therapy (ECT) for 6 months; minimum 8 years of education; fluent in reading English  203 randomised  Female (n=129) Male (n=74)  18-60 years old  Ethics did not approve collection of ethnicity data	CBT  Interpersonal Therapy (IPT)  Anti-Depressant Medication (ADM)	HAM-D: p=0.04, OR=3.61 (4 times more likely to respond in CBT and ADM conditions than in IPT condition in patients with history of childhood maltreatment. Multiply imputation analysis.)  HAM-D: p=0.008, OR=7.87 (8 times more likely to respond in CBT and ADM conditions than in IPT condition. Completer sample)  No significant difference in response rate between CBT and ADM conditions.	Small completer sample, limiting generalisability  No ethnicity data  Recruited primarily from advertisements, questioning the generalisability of results to treatment-seeking and/or referred outpatients  Excluded Borderline Personality Disorder which is associated with trauma history, again questioning how representative the current results are of those with a history of childhood maltreatment
7. Jung & Steil (2013)  Germany  RCT	PTSD related to CSA and a feeling of being contaminated (FBC)  34 randomised  Female  19-61 years old  Caucasian (89%) Asian (11%)	Cognitive Restructuring and Imagery Modification (CRIM)  WL	FBC: Intensity – d=0.75 (T1), d=1.52 (T2) Vividness – d=0.47 (T1), d=1.28 (T2) Uncontrollability – d=1.03 (T1), d=1.77 (T2) Distress – d=1.27 (T1), d=1.80 (T2)  CAPS: d=0.93 (T2)  PDS: d=0.84 (T1), d=0.91 (T2) RSES: d=0.76 (T1), d=0.72 (T2)  All between-group effects.	Small sample size  Short follow-up (5 weeks)  Lack of active control group  More than half the participants were receiving other psychological treatment (which were interrupted, however need to consider delayed effects)  Querying treatment effects of individual therapist traits and expertise. No data on treatment fidelity collected.

**Table 1** *continued*

Study and method	Included participants	Intervention / Conditions	Reported effect sizes for PTSD or CPTSD symptoms*	Reported limitations
8. Kubany, Hill, Owens, Iannace-Spencer, McCraig, Tremayne, et al. (2004)	Out of an abusive relationship for over 30 days; not been stalked or physically abused by anyone for over 30 days; partner abuse-related PTSD; moderate abuse-related guilt as identified by the Global Guilt Scale; no substance misuse; not suffering schizophrenia or bipolar	Cognitive Trauma Therapy for Battered Women with PTSD (CTT-BW)  Delayed CTT-BW	CAPS: $g=2.4$  DEQ: $g=2.4$  BDI: $g=2.0$  TRGI: Global Guilt – $g=2.9$ Guilt Cognitions – $g=1.9$ Distress – $g=2.6$  RSES: $g=2.4$	Not generalisable to females currently in abusive relationships  Exclusion of females suffering none to mild abuse-related guilt as identified by the Global Guilt Scale  Lack of inter-rater reliability checks on the CAPS
HAWAII  RCT	125 randomised  Female  18-70 years old  White (n=66); Native Hawaiian (n=11); Filipino (n=9); Japanese (n=8); Black (n=6); Samoan (n=11); American Indian (n=2); Other or mixed ethnicity (n=17)		PFQ-Guilt and Shame: $g=1.9$ (completer analysis)  Delayed CTT-BW exhibited comparable effect sizes  ITT analysis exhibited comparable effect sizes	

**Table 1** *continued*

Study and method	Included participants	Intervention / Conditions	Reported effect sizes for PTSD or CPTSD symptoms*	Reported limitations
9. McDonagh, Friedman, McHugo, Ford, Sengupta, Mueser, et al. (2005)	PTSD; history of CSA; at least 1 clear memory of CSA	CBT	CAPS: CBT vs WL – d=0.50 and 1.07 (ITT and completer analysis respectively, post-test)	Comparisons between CBT and the other two groups are less scientifically sound than those comparing PCT and WL due to higher drop-out rates in the CBT condition
USA	74 randomised	Present-Centred Therapy (PCT)	PCT vs WL – d=0.89 (both ITT and completer analysis, post-test)	
RCT	Female	WL	TSI: CBT vs WL – d=1.64 PCT vs WL – d=1.27 (post-test, completer analysis)	Lack of competency ratings for the trial therapists
	Mean age: 39.8-42 years (range between groups)		STAI: CBT vs WL – d=1.21 PCT vs WL – d=0.67 (post-test, completer analysis)	
	White (90-96%); African American (0-5%); Native American (0-10%); Other (0-4%)(range between groups)		CBT produced comparable effect sizes to PCT at FU, WL not used as comparison at FU	
			No significant difference between treatment groups	

**Table 1** *continued*

Study and method	Included participants	Intervention / Conditions	Reported effect sizes for PTSD or CPTSD symptoms*	Reported limitations
10. Resick, O'Brien Uhlmansiek, Clum, Galovski, Scher & Young-Xu (2008)  USA  RCT	Literate; not currently suffering psychosis; no suicidal intent; abstinent from substance misuse for 6 months; not currently in an abusive relationship or being stalked; history of childhood physical or sexual assault; PTSD; 3 months post-trauma; stable on medication  162 randomised  Female  Mean age: 35.4 years  White (62%); African American (34%); Hispanic (3%); Other (1%)	Cognitive Processing Therapy (CPT)  Written Accounts (WA)  Cognitive Therapy only (CPT-C)	CAPS: CPT – $d=-1.68$ , $d=-2.03$ WA – $d=-1.54$ , $d=-1.98$ CPT-C – $d=1.82$ , $d=2.18$ (ITT and Completers analysis over time respectively, within groups.)  PDS: CPT – $g=1.1$ , $1.2$ (ITT) $g=0.9$ , $0.8$ (completers) WA – $g=0.7$ , $1.0$ (ITT) $g=0.7$ , $0.9$ (completers) CPT-C – $g=1.1$ , $1.1$ (ITT), $g=0.9$ , $0.9$ (Post-test and 6-month FU respectively, within groups.)  BDI-II: CPT – $g=1.0$ , $1.2$ (ITT) $g=1.0$ , $1.1$ (completers) WA – $g=0.7$ , $1.0$ (ITT) $g=0.7$ , $0.8$ (completers) CPT-C – $g=1.2$ , $1.3$ (ITT) $g=1.2$ , $1.1$ (Post-test and 6-month FU respectively, within groups.)  (No significant between-group differences found on any measures)	Inclusion of only female participants  Limited power provided by the three time points (pre-treatment, post-treatment, and FU) to detect differences between three active treatments for a sample size of 150  Alteration of the WA component of CPT so that it was a stand-alone protocol, may have made it less viable

**Table 1** *continued*

Study and method	Included participants	Intervention / Conditions	Reported effect sizes for PTSD or CPTSD symptoms*	Reported limitations
11. Resick, Williams, Suvak, Monson & Graduz (2012)	Experienced one rape a minimum of 3 months prior to seeking treatment; on a stable dose of medication if taking; not suffering psychosis; no suicidal intent or current substance misuse	CPT PE	No significant difference between groups on following measures during the LTFU period (mean 6.15 years): PSS, CAPS, BDI  On PSS, change in the PE group only approached significance.	Female only  Narrow range of ethnicities  LTFU was not pre-planned and FU data as not collected at a single, uniform time
USA				
RCT				
	171 randomised		(This is the LTFU study. In the original trial there were no significant between-group differences, however significant within-group differences were found in CAPS, PSS, and BDI.)	
	Female			
	Mean age: 31.99 years (ITT), 38.27 years (LTFU)			
	African American (25.1%, 20.6%); Caucasian (70.8%, 73.6%); Hispanic (1.2%, 0.8%); Asian (0.6%, 0.8%); Native American (1.2%, 0.8%); Other (1.2%, 3.2%) (ITT and LTFU respectively)			

**Table 1** *continued*

Study and method	Included participants	Intervention / Conditions	Reported effect sizes for PTSD or CPTSD symptoms*	Reported limitations
12. Sikkema, Hansen, Kochman, Tarakeshwar, Neufeld, Meade, et al. (2007)	HIV-infected; histories of CSA; no higher than mild to moderate levels of depression if present	HIV and Trauma Coping Group	IES Intrusion subscale: Coping Group vs WL – d=0.49 (pre to post change)	Only 60% of participants received the full intervention
USA		HIV Time-Matched Support Group	IES Avoidance subscale: Coping Group vs Support Group – d=0.34 (pre to post change, final treatment condition with all WL randomised into treatment condition)	High attrition rates
RCT	253 randomised Female (n=107) Male (n=91) (Final sample)  Mean age: 42.5 years  Caucasian (11.3%); African American (68.8%); Hispanic/Latino (16%); Other (4.1%)	WL Control		Unable to recruit a sufficient number of heterosexual men  Post outcomes are limited when compared with WL as mental health treatment effects may fade over time

**Table 1** *continued*

Study and method	Included participants	Intervention / Conditions	Reported effect sizes for PTSD or CPTSD symptoms*	Reported limitations
13. Sikkema, Wilson, Hansen, Kochman, Neufeld, Ghebremichael, et al. (2008)	HIV-positive adult ( 18); history of CSA; no presence of impaired mental status; no suicidal intention or severe depression	HIV and Trauma Coping Group  HIV Time-Matched Support Group	Sexual Behaviour: d=0.38, 0.32, 0.38 (4-, 8-, 12-month FU, respectively, between-group)	High attrition rates  Effect size at 12-month FU for reduction in in transmission risk with HIV-negative or serostatus unknown partners in Coping Group diminished (related to attrition/smaller sample size?)  Unable to recruit a sufficient number of heterosexual men  Findings are based on self-reported sexual activities (reliability?)
USA				
RCT	247 randomised  Female (n=62, 67) Male (n=61, 56) (Coping Group and Support Group respectively)  Mean age: 41.82, 42.70 years old (Coping Group and Support Group respectively)  African American (65%, 71.1%); Hispanic (21.1%, 12.3%); White (10.6%, 9%); Other (3.3%, 6.6%) (Coping Group and Support Group respectively)			

**Table 1** *continued*

Study and method	Included participants	Intervention / Conditions	Reported effect sizes for PTSD or CPTSD symptoms*	Reported limitations
14. Wyatt, Longshore, Chin, Carmona, Loeb, Myers, et al. (2004)	Adult ( 18); HIV-positive; sexually active in past year; history of CSA;	Enhanced Sexual Health Intervention (ESHI)	Sexual Risk Reduction: No significant differences	Small sample size
USA	147 randomised	Attention Control/WL	Medication Adherence: Significant difference between High Attenders in ESHI compared with WL ( $p < .05$ , $OR=4.09$ . 4 times more likely to adhere to medication in Higher Attenders in ESHI condition than in WL condition)	Amount of contact between conditions was not controlled for
RCT	Female  25-65 years old  African American (51%); Latina (49%)			Self-report adherence measures may over-report actual levels of adherence

A Cohen's  $d$  and Hedge's  $g$  effect size between 0.2 and 0.5 is small, between 0.5 and 0.8 is medium, and an effect size  $> 0.8$  is large (Cohen, 1988). Hedge's  $g$  effect size between T0 = baseline, T1 = post-test, T2 = follow-up. Anger Expression Questionnaire (AEI); Beck Anxiety Inventory (BAI); Beck Depression Inventory (BDI); Beck Depression Inventory-2<sup>nd</sup> edition (BDI-II); Body Sensations Questionnaire (BSQ); Brief Symptom Inventory (BSI); Clinical-Administered PTSD Scale: one-week symptom status version (CAPS-SX); Complex Post Traumatic Stress Disorder (CPTSD); Davidson Trauma Scale (DTS); Dissociative Experiences Scale-II (DES-II); Distressing Event Questionnaire (DEQ); Feeling of Being Contaminated (FBC); Hamilton Depression Rating Scale (HAM-D); Impact of Events Scale (IES); Inventory of Interpersonal Problems (IIP); Interpersonal Support Evaluation List (ISEL); Intent-to-treat (ITT); Long-Term Follow-Up (LTFU); Modified PTSD Symptom Scale (MPSS); Negative Mood Regulation Scale (NMRS); Personal Feelings Questionnaire (PFQ); Post Traumatic Stress Disorder (PTSD); PTSD Diagnostic Scale-Interview (PDS-I); PTSD Symptom Scale-Self Report (PSS-SR); Randomised Controlled Trial (RCT); Rosenberg Self-Esteem Scale (RSES); State-Trait Anxiety Inventory-S (STAI-S); State-Trait Anger Expression Inventory (STAEI); Structured Interview for Disorders of Extreme Stress (SIDES); Trauma-Related Guilt Inventory (TRGI); Trauma Symptom Inventory (TSI)

\*Effect sizes from significant results only are reported

### *Incomplete outcome data*

Attrition bias was addressed by evaluating the reporting of short-term (2-6 weeks) and long-term (>6 weeks) outcome data. All studies were rated as being at 'low risk' of attrition bias based on their reporting of short-term outcome data and all but three studies reported intent-to-treat (ITT) analyses as a way of managing drop-out data: Brotto et al. (2012) reported 0% attrition; Feske (2008) reported the number of drop-outs from the study to be too small to allow for statistical comparison; and Harkness et al. (2012) performed multiple imputation [MI] to account for attrition. Four out of fourteen studies were rated as being at 'unclear risk' of long-term attrition bias: Brotto et al. (2008); Dorrepaal et al. (2012); Sikkema et al. (2007); and Wyatt et al. (2004) did not address this outcome. The remaining studies were assigned a rating of being at 'low risk' of long-term attrition bias.

### *Selective reporting*

Due to the time constraints of this review, it was not possible to contact study authors to request access to study protocols. Consequently, 100% of the studies were assigned the 'unclear bias' for the 'selective outcome reporting' domain.

### *Other potential sources of bias*

In regards to the 'other bias' domain, four out of fourteen studies (Brotto et al., 2012; Chard, 2005; Jung & Steil, 2013; McDonagh et al., 2005) were rated as at 'high risk' of being culturally biased (lack of consideration for cultural differences in research, resulting in the lack of generalizability to cultures other than those that were in the study sample) in terms of their samples, which reduces the generalizability of the results. Feske (2008) was rated as having a 'low risk' of cultural bias even though the ethnicity of the sample was 95% African American as the study author outlined that this was the target population and therefore was in line with the aim of the study.

**Table 2** 'Risk of Bias' summary: review author's judgements about each risk of bias item for each included study

Reference	Domain						
	Sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias) (Short Term 2-6 weeks)	Incomplete outcome data (attrition bias) (Long Term > 6 weeks)	Selective outcome reporting (reporting bias)	Other source of bias (culture)
1. Brotto, Seal & Rellini (2012)	?	?	?	+	?	?	-
2. Chard (2005)	?	?	+	+	+	?	-
3. Cloitre, Stovall-McClough, Nooner, Zorbas, Cherry, Jackson, et al. (2010)	+	+	+	+	+	?	+
4. Dorrepaal, Thomas, Smit, van Balkom, Veltman, Hoogendoorn, et al. (2012)	+	+	+	+	?	?	?
5. Feske (2008)	?	?	-	+	+	?	+
6. Harkness, Bagby & Kennedy (2012)	+	+	+	+	+	?	?
7. Jung & Steil (2013)	?	?	+	+	+	?	-
8. Kubany, Hill, Owens, Iannace-Spencer, McCraig, Tremayne, et al. (2004)	?	?	+	+	+	?	+

 Low risk = 
  High risk = 
  Unclear risk =

Table 2 continued

Reference	Domain						
	Sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias) (Short Term 2-6 weeks)	Incomplete outcome data (attrition bias) (Long Term > 6 weeks)	Selective outcome reporting (reporting bias)	Other source of bias (culture)
9. McDonagh, Friedman, McHugo, Ford, Sengupta, Mueser, et al. (2005)	?	?	+	+	+	?	-
10. Resick, O'Brien Uhlmansiek, Clum, Galovski, Scher & Young-Xu (2008)	?	?	+	+	+	?	+
11. Resick, Williams, Suvak, Monson & Graduz (2012)	?	?	+	+	+	?	+
12. Sikkema, Hansen, Kochman, Tarakeshwar, Neufeld, Meade, et al. (2007)	?	?	?	+	?	?	+
13. Sikkema, Wilson, Hansen, Kochman, Neufeld, Ghebremichael, et al. (2008)	?	?	?	+	+	?	+
14. Wyatt, Longshore, Chin, Carmona, Loeb, Myers, et al. (2004)	?	?	?	+	?	?	+

Low risk = High risk = Unclear risk =

## Discussion

This review aimed to evaluate current peer-reviewed randomised controlled trials examining the effectiveness of Cognitive Behavioural Therapy (CBT) interventions for complex trauma published in the past 10 years. The review also aimed to investigate potential sources of bias in the included studies. As such, the review aimed to provide an opportunity to reflect on how research into the effectiveness of CBT interventions as complex trauma interventions can be improved in the future.

A previous review by Cloitre (2009) exhibited some methodological failings that make it difficult to reproduce and puts into question the validity and reliability of the results extracted from the included studies. More specifically, the review's search strategy was not reported rendering the review difficult to reproduce, and the gold standard method of evaluating randomised controlled trials as stated by PRISMA (The PRISMA Group, 2009) was not employed to evaluate included studies. PRISMA (2009) highlighted that *risk of bias* should be the focus of evaluating and reporting included studies in order to make informed deductions about any aspects of study quality that may have an effect on the results.

The current review indicated that the most common forms of intervention were Cognitive Behavioural Therapy and Cognitive Processing Therapy. The most common comparator used in the included studies was a wait-list

control group. In regards to measuring outcome, two PTSD-specific measures (CAPS and PDS-I) and measures of depression severity (BDI and BDI-II) were most commonly used.

It is apparent from this review that there are strong effect sizes for CBT interventions in the treatment of symptoms characteristic of Complex Post-Traumatic Stress Disorder (CPTSD) when compared to control conditions; however effect sizes are weaker and results are less conclusive when CBT interventions are compared to other psychotherapeutic interventions. This is in line with a previous review conducted by Cloitre (2009) who reported that cognitive-behavioural treatments have shown to be more effective when compared to waitlist, supportive counselling, non-specific therapies and treatment as usual. In addition, as with the current review, Cloitre (2009) reported that cognitive behavioural approaches have shown to be successful in the treatment of populations who have experienced chronic interpersonal violence and childhood abuse, however that when comparing cognitive therapy (with or without reprocessing) to trauma-focussed therapies such as EMDR (eye movement desensitisation and reprocessing), results are inconclusive .

Evaluating for *risk of bias* in included studies is a process by which the reviewer is advised to think about aspects of the study quality that may have an effect on the results (PRISMA, 2009). An example of a well

conducted study identified in the current review is the study by Cloitre, et al. (2010) which scored 'low' in risk of bias in six out of the seven domains being evaluated. The study clearly described the process of sequence generation and allocation concealment, reported blinding of outcome assessments, adequately reported the management of attrition in short-term and long-term outcome data, and obtained an ethnically diverse sample. The only domain that the study was rated as having an 'unclear risk' in was 'selective outcome reporting', however all studies were allocated this rating in line with the guidance provided by The Cochrane Collaboration (2011). Harkness et al. (2012) received the same ratings as Cloitre et al. (2010), apart from in the 'cultural bias' domain in which they were allocated a rating of 'unclear bias' due to the absence of ethnicity data; they did explain, however, that they did not receive ethical approval to collect such data.

Domains in which the majority of studies failed to score a rating of 'low risk of bias' were the 'sequence generation' and 'allocation concealment'. Eleven out of fourteen studies were allocated a rating of 'unclear bias' in both domains due to reporting insufficient detail on the randomisation process and on whether or not those allocations resulting from randomisation were concealed from those significant to the study.

### *Limitations of the current review*

A key limitation is the lack of inter-rater reliability in the process of screening the abstracts for inclusion in the current review; 100% of the abstracts were screened by the author and none were second-screened by an independent evaluator.

In regards to rating the *risk of bias* in included studies, 'selective reporting' bias was not reported. This means that systematic differences between reported and unreported findings were not addressed. As previously stated, due to the time constraints of this review, it was not possible to contact study authors to request access to study protocols.

An additional limitation of the current review is that it was not possible to synthesise the results in order to reliably report on the effectiveness of cognitive behavioural therapies on the recovery from complex trauma. This may be attributed to the overall heterogeneity of the included studies, for example in terms of the variety of intervention type; study sample selection; comparator; and outcome measures. This heterogeneity may be a reflection of the multiplicity of symptoms that characterise CPTSD, which is also reflected in the variety of outcome measures across the included studies.

Finally, the current review was looking into the effectiveness of interventions based on the cognitive-behavioural framework; however it did not explore the active ingredients within each intervention to identify which cognitive and/or behavioural component had the most influence on the effectiveness.

### **Recommendations and Conclusion**

As a result of this review, a number of recommendations can be made that will serve to enhance future research into the efficacy of interventions based on cognitive behavioural theories for the treatment of Complex Post-traumatic Stress Disorder. Firstly, it is difficult to synthesise the outcomes of various individual studies that compare cognitive-behavioural approaches with different therapies, therefore it is recommended that it may be more advantageous to have an adequate number of studies for each comparison to allow for the reporting of more conclusive findings on the effectiveness of CBT interventions compared to alternative psychotherapeutic approaches in the treatment of CPTSD. Secondly, the same recommendation is applied to the use of outcome measures; a consensus on measures that best reflect the symptoms characteristic of CPTSD would greatly help to reduce the heterogeneity of future studies and therefore aid the synthesis of results to produce more conclusive findings. In addition, larger sample sizes would help to strengthen effect sizes and possibly lead to more conclusive findings, and more diverse samples will allow for an increase in the generalizability of results.

Following on from the final limitation, it is suggested that future reviews focus on exploring active ingredients within target interventions in order to identify the more effective components which in turn may inform the development of new interventions.

Finally, in order for future studies to produce as reliable and valid results as possible, and for reviewers to make well-informed decisions about the aspects of study quality that may have an effect on results, the risk of bias in the domains outlined by The Cochrane Collaboration (2008) should be considered in the planning and implementation stages and clearly reported in the final paper.

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**CHAPTER TWO**  
**MAJOR RESEARCH PROJECT**

A Feasibility Study of Acceptance and Commitment Therapy for  
Recovery from Complex Trauma

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## Lay Summary

**Background:** The term 'complex trauma' has been created to refer to prolonged and repeated traumatic events. There are 3 phases of treatment for recovery from complex trauma (Herman, 1992). *Phase 1:* establish safety; *phase 2:* address difficult memories, and *phase 3:* reconnect with the community. Acceptance and Commitment Therapy (ACT) is a Cognitive and Behavioural Therapy developed by Hayes, Strosahl, & Wilson (1999). It uses strategies to help people to notice and accept thoughts and emotions without getting caught up in them. ACT helps individuals to explore what they value in life and to help people to behave in a way that is consistent with these values.

**Aims of the study:** This study aimed to find out if individuals could be identified and recruited into a study of ACT for *phase 3* of a complex trauma intervention and if a novel ACT intervention was acceptable for individuals in *phase 3* of treatment. This study also aimed to find out what outcome measures would be appropriate for assessing the efficacy of an ACT intervention for emotional difficulties associated with complex trauma.

**What the study involved:** This study was conducted in 2 stages. In stage 1, eleven people who were in or near *phase 3* of their treatment with the Greater Glasgow and Clyde (GG&C) Psychological Trauma Service were

recruited to attend a 4-session ACT group and two follow-up individual sessions.

Assessments measuring general mental health, psychological flexibility, value-consistent behaviour, and sense of coherence (feeling of confidence that the environment is predictable and that things will work out as we can be expected) were completed at the beginning, middle and end of the overall intervention; the results of which were assessed to identify any change in answers between the time points.

Stage 2 was developed in response to difficulties with recruitment at stage 1 and involved carrying out interviews with seven GG&C Psychological Trauma Service clinicians. The purpose of conducting the interviews was to gain an understanding of why the recruitment difficulties had occurred and to find out what changes could be made to improve recruitment in future studies.

**Results:** In stage 1, five out of the eleven participants completed questionnaires at the three time points. One participant showed significant improvement in general mental health, and one participant showed significant improvement in both sense of coherence and cognitive fusion (feeling stuck to or 'fused' with our thoughts).

Information from the interviews conducted in stage 2 helped to provide an understanding of the recruitment difficulties and to plan for improved future studies.

**Conclusion:** Recruitment difficulties emerged in stage 1 that made it difficult to make conclusions about the acceptability of the ACT intervention with a complex trauma population, or about the questionnaires that were used. Information from the interviews has been used to inform suggestions for how such difficulties can be managed in order to plan for future research.

## Scientific Abstract

**Objectives:** Following the Medical Research Council (MRC, 2008) guidelines relating to feasibility studies of complex interventions, *stage 1* of this study was an uncontrolled trial investigating recruitment, acceptability of intervention and potential outcome measures for a novel *phase 3* Complex Trauma intervention based on Acceptance and Commitment Therapy. *Stage 2* investigated barriers to participation in 'stage 1' by conducting interviews with the GG&C Psychological Trauma Service clinicians.

**Methods:** Stage 1 – *Participants:* Eleven participants were recruited from the NHS Greater Glasgow & Clyde Psychological Trauma Service. Nine participants completed baseline assessments. The following measures were used to assess outcome: General Health Questionnaire (12 item version; GHQ-12) and Sense of Coherence – Orientation to Life Questionnaire (13 item version; SoC-13); Acceptance and Action Questionnaire-2<sup>nd</sup> edition (AAQ-II), Cognitive Fusion Questionnaire (CFQ), and Valuing Questionnaire (8 item version; VQ). The Working Alliance Inventory (short-form revised; WAI-SR) was used to measure therapeutic alliance. *Procedure:* Participants took part in a novel ACT intervention comprising 4 group sessions and 2 individual sessions. Measures were completed pre-intervention, post-group and on completion of the full intervention. *Data Analysis:* Clinically significant cut-offs and Reliable Change Indexes (RCIs) were used to investigate clinically significant change. Stage 2 – *Participants:* Seven of the 14 (50%) GG&C

Psychological Trauma Service clinicians were recruited to the study.

*Procedure:* Interviews were conducted with the clinicians to address the recruitment difficulties that emerged in *stage 1*. *Data Analysis:* Framework Analysis was used to analyse data from the interviews.

**Results:** Stage 1 – Five (45.5%) of the 11 recruited participants completed the final assessment. One of the 5 (20%) participants showed clinically significant improvement in general mental health. One of 5 (20%) who completed final assessment exhibited clinically significant improvement on levels of cognitive fusion and sense of coherence. Stage 2 – Analysis of the interviews produced 14 ‘robust’ themes, which have provided insight into the recruitment difficulties.

**Conclusion:** Investigating recruitment was one of the key objectives of this feasibility study. It emerged as a substantial barrier and impacted on the extent to which conclusions can be drawn about the acceptability of the ACT intervention or the assessment measures. It is proposed that a more refined feasibility study is developed that addresses such barriers and that will be better equipped to inform larger-scale pilot trials.

**Keywords:** *Complex Trauma; Acceptance and Commitment Therapy; Feasibility Study*

## Introduction

Complex trauma involves traumatic stressors that (1) are repetitive or prolonged; (2) involve direct harm and / or neglect and abandonment by caregivers or ostensibly responsible adults; (3) occur in vulnerable times in the survivors' life, such as early childhood, and (4) have potential to severely compromise a child's development (Courtois & Ford 2009). Complex trauma can lead to mental health difficulties including: Post-Traumatic Stress Disorder (PTSD); emotional regulation difficulties; dissociation; identity and relational disturbances; substance misuse; low self-esteem; somatic distress (Courtois and Ford, 2009). Herman (1992) coined the term Complex PTSD to conceptualise such difficulties. Research suggests that homelessness can be viewed as a traumatic experience, and being homeless increases the risk of further victimisation and re-traumatisation (Hopper, Bassuk, & Olivet, 2009).

A model of psychological intervention widely used in the treatment of complex trauma involves three phases of treatment (Herman, 1992). *Phase 1* involves establishing safety; *phase 2* involves remembrance and mourning, and *phase 3* aims to reconnect the client with society. Although no longer reaching criteria for a diagnosis of complex post-traumatic stress disorder is a pre-requisite for progressing to *phase 3*, individuals at this phase can be confused about their identity and values.

Various theories of human adaptation to stress and trauma have been developed. Linley (2003) proposed that one of the more empirically robust is Antonovsky's (1987) Sense of Coherence (SoC). SoC has three components: Comprehensibility – the extent to which events are perceived as making logical sense; Manageability – the extent to which a person feels they can cope; and Meaningfulness – how much a person feels that life makes sense, and challenges are worthy of commitment (Antonovsky, 1987). Research has consistently shown that a high SoC is associated with better adaptation to life stress and trauma (Flannery & Flannery, 1990).

Acceptance and Commitment Therapy (ACT) is a 'Third Wave' Cognitive and Behavioural Therapy developed by Hayes, Strosahl, & Wilson (1999). It uses acceptance-based strategies to help people to notice thoughts and emotions without getting caught up in reacting to them. ACT also helps individuals to explore what they value in life and to help people to adopt value-consistent behaviour. ACT draws a contrast between our agendas being set by struggling to move away from suffering or moving towards what is important in life. It is suggested that the 'values' and 'committed action' components of ACT may directly address such difficulties that individuals face in *phase 3*, as outlined by Herman (1992), which respectively focus on helping individuals clarify what gives their life meaning and purpose, and establish a pattern of behaviour that allows

them to repeatedly return to their values. Therefore, it could be a useful *phase 3* intervention for complex trauma.

There have been a number of outcome studies on the use of ACT with people experiencing a range of psychological disorders (Ruiz, 2010). ACT has shown to be effective in treating diverse symptoms associated with anxiety and depression (Lappalainen, Lehtonen, Skarp, Taubert, Ojanen, & Hayes, 2007); Generalised Anxiety (Roemer & Orsillo, 2007; Roemer, Orsillo, & Salters-Pedneault, 2008); addictive behaviours (Hayes, Wilson, Gifford, Bissett, Piasecki, Batten, et al. 2004); and impulsive, risk-taking behaviour in adolescents (Luciano, Salas, Martinez, Ruiz, & Blarrina, 2009). Single-case studies have also demonstrated preliminary efficacy for the use of ACT with individuals with PTSD and trauma-related difficulties meriting further exploration (Batten & Hayes, 2005; Orsillo & Batten, 2005; Twohig, 2009).

Herman (1992) suggests that different group interventions may be of benefit for those in *phase 3* and that the main aim should be to help the individual achieve commonality; to have a sense of belonging to a society; and to feel that “one’s own troubles are as a drop of rain in the sea” (Herman, 1992, pg. 236). There have also been various studies investigating the efficacy of ACT in a group format in the treatment of chronic pain (McCracken, Sato, & Taylor, 2013; Wetherell, Afari, Rutledge,

Sorrell, Stoddard, Petkus, et al., 2011); Social Phobia (Ossman, Wilson, Storaasli, & McNeill, 2006); Borderline Personality Disorder (Gratz & Gunderson, 2006); and for shame in substance use disorders (Luoma, Kohlenberg, Hayes, & Fletcher, 2012). To the author's knowledge, the efficacy of ACT as a group therapy with a complex trauma population has not yet been investigated.

The complex trauma population presents with a multitude of psychological and social difficulties. The above studies have reported that ACT is an effective intervention for a broad range of psychological difficulties. A functional process said to be underlying disorders resulting from complex trauma, such as PTSD and substance misuse, is experiential avoidance; a process that ACT was specifically developed to address (Batten, 2012). The current study seeks to investigate for the first time, the feasibility of using ACT as a *phase 3* complex trauma intervention.

When developing a complex intervention, as in the current study, adequate development and piloting work is of great importance (Medical Research Council - MRC, 2008). According to the MRC (2008) guidelines on developing complex interventions, the feasibility and piloting stages include: testing procedures for their acceptability, estimating the likely rates of recruitment and retention of participants, and calculation of appropriate sample sizes. These guidelines have informed the aims and

design of the current study. The study is divided into two stages. Stage 1 is a feasibility study investigating a novel ACT intervention that was developed specifically for the study. Stage 2 is a qualitative analysis of interviews with staff from the NHS GG&C Psychological Trauma Service about the process of referring people to the study.

### *Aims and Research Questions*

#### *Stage 1 – A feasibility study of an ACT intervention.*

Based on the MRC guidelines (2008), this feasibility study aimed to address issues including recruitment, the acceptability of the intervention and identifying treatment signals in potential outcome measures.

#### *Stage 2 – A qualitative analysis of interviews.*

Stage 2 aimed to obtain an understanding of the barriers to participation that became apparent during stage 1 of this study to inform the development of a more refined feasibility study by conducting interviews with the Psychological Trauma Service clinicians.

See Appendix 4 for the study flow chart.

## Stage 1

### Methods

#### *Design*

This study is a prospective uncontrolled feasibility trial of a novel ACT intervention for use in *phase 3* of treatment in complex trauma services.

#### *Participants*

*Inclusion criteria:* Individuals were included on the basis that they had a history of complex trauma, were either in *phase 3* of their treatment, were nearing the end of their treatment in *phase 1* and did not require *phase 2* interventions, or were nearing the end of their treatment in *phase 2*. All participants were aged 16 years old.

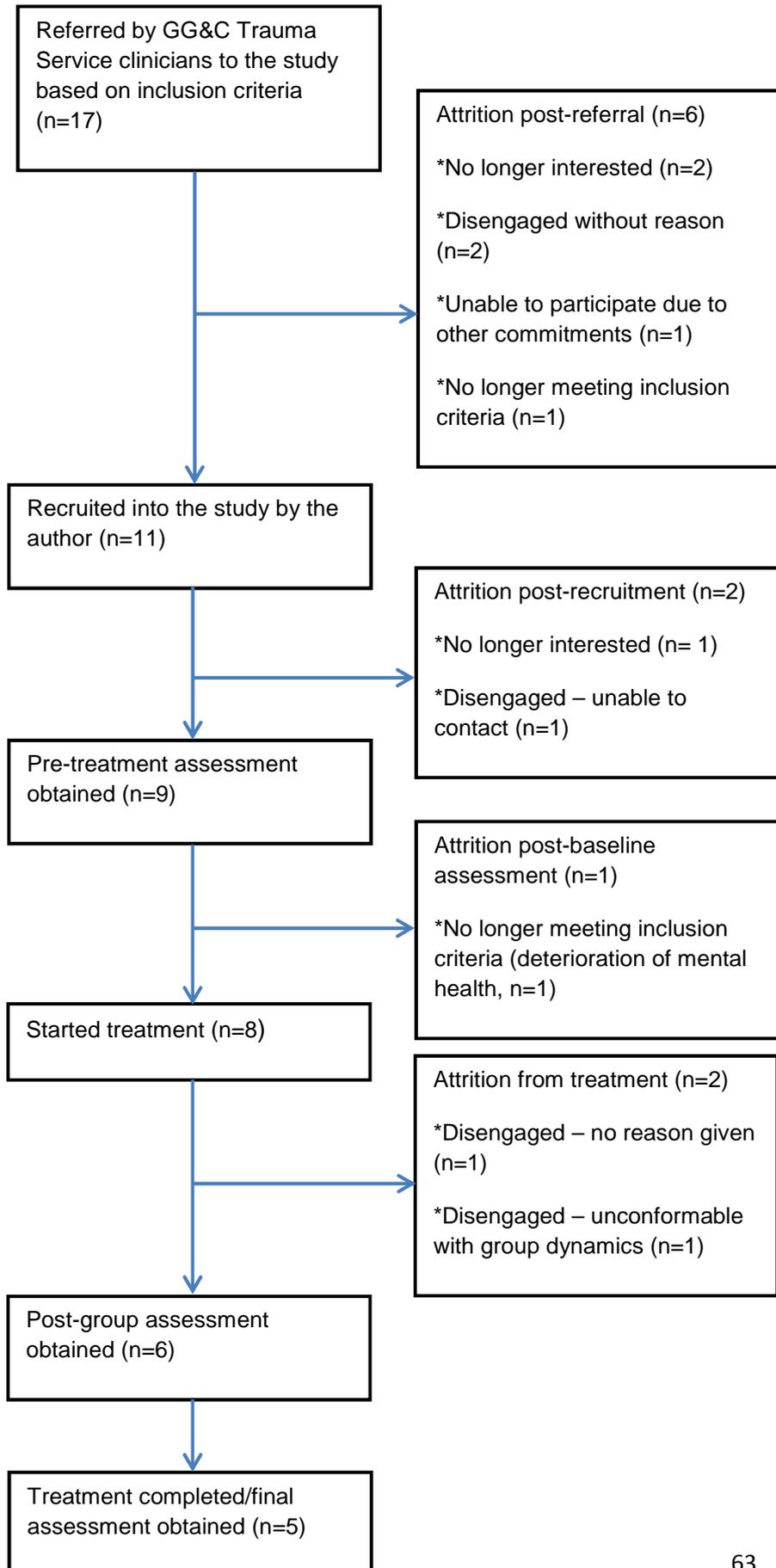
*Exclusion criteria:* Individuals were excluded if they were in *phase 1* or *2* of their treatment and were not nearing the transition from that phase, and if they had significant head injury or a learning disability.

Seventeen service users were referred to the study by clinicians from the NHS Greater Glasgow & Clyde (GG&C) Psychological Trauma Service. Eleven (64.7%) of these individuals consented to participating in the study from December 2013 to May 2014. Nine participants (81.8%) completed pre-treatment measures. Descriptive information about the participants can be viewed in Table 1. A further three (27.3%) participants dropped-out during the group stage, resulting in six (54.5%) participants completing

measures at the second time point. Five (45.5%) participants completed the final assessment.

Figure 1 describes the flow of participants through the study and Table 1 provides demographic characteristics of participants who completed pre-treatment measures.

**Figure 1** Flow diagram of the progress of participants through the feasibility study



**Table 1***Descriptive Characteristics of Participants*

Characteristic	Baseline Assessment Completed <i>n</i> = 9
Age: <i>M</i> ( <i>SD</i> )	39.22 (9.82)
Gender: <i>n</i> (%)	
Male	4 (44%)
Female	5 (56%)
Ethnicity: <i>n</i> (%)	
White British	8 (89%)
Black African	1 (11%)
Housing Status: <i>n</i> (%)	
Own Tenancy	2 (22%)
Temporary Furnished Flat	1 (11%)
Supported Accommodation	6 (67%)
Trauma History: <i>n</i> (%)	
Childhood	
Sexual Abuse:	6 (67%)
Physical Abuse:	5 (56%)
Emotional Abuse:	5 (56%)
Neglect:	3 (33%)
Sexual assault:	2 (22%)
Adult	
Domestic Violence	4 (44%)
Sexual Assault	3 (33%)
Physical assault	2 (22%)
Emotional Abuse	3 (33%)
Trafficked for sexual exploitation	1 (11%)

*Measures*

## Acceptability of Intervention Measure: Therapeutic Alliance

- The Working Alliance Inventory (Short Form Revised; WAI-SR; Hatcher & Gillaspay, 2006) is a 12-item self-report measure of therapeutic alliance, composed of three aspects: 1 – agreement between the patient and

therapist on the goals of the therapy (Goal); 2 – the patient's agreement with the therapist that the tasks of the therapy will address the problems the patient brings to treatment (Task), and 3 – the quality of the interpersonal bond between the patient and the therapist (Bond). The highest total score of 60 indicates a high working alliance and the lowest of 12 indicates a low working alliance. High internal consistency coefficient alphas and validity were reported by the authors (Hatcher & Gillaspay, 2006).

Outcome measures:

- The General Health Questionnaire-12 (Goldberg & Williams, 1988) is a 12-item measure of current mental health. Overall sensitivity and specificity ratings are high (83.4% and 76.3% respectively, Goldberg et al., 1997) with internal consistency ratings between 0.77-0.93 (Goldberg & Huxley, 1988). The 12-item version has been shown to be as effective as the 28-item version (Goldberg et al., 1997)
- The Sense of Coherence - Orientation to Life Questionnaire (SoC-13, Antonovsky, 1987); a 13-item scale with three factors: Comprehensibility, Manageability, and Meaningfulness. Internal consistency ratings range from 0.70 to 0.92, test-retest stability ranges from 0.69 to 0.78 (1 year), 0.64 (3 years), 0.42 to 0.45 (4 years), 0.59 to 0.67 (5 years) to 0.54 (10 years) (Eriksson & Lindstrom, 2005).

Therapy Specific Measures:

- The Acceptance and Action Questionnaire-II (AAQ-II; Bond, Hayes, Baer, Carpenter, Guenole, Orcutt, et al., 2011) is a 7-item measure of psychological flexibility. The mean internal consistency rating is 0.84. The 3- and 12-month test-retest reliability is .81 and .79, respectively (Bond et al., 2011). Sample items:
  - My painful experiences and memories make it difficult for me to live a life that I would value.
  - I worry about not being able to control my worries and feelings.
  - It seems like most people are handling their lives better than I am.
  
- The Cognitive Fusion Questionnaire (CFQ, Gillanders et al., 2010) is a 13-item self-report measure of cognitive fusion. It has a test-retest value of 0.88 and internal consistency ratings ranging from 0.85 to 0.89 (Gillanders, et al., 2010). Sample items:
  - I get so caught up in my thoughts that I am unable to do the things that I most want to do.
  - I find it easy to view my thoughts from a different perspective.
  - I tend to react very strongly to my thoughts.
  
- The Valuing Questionnaire-8 (VQ-8; Davies & Smout, 2011) measures value-consistent behaviour. It has 2 factors: “Progress”; how much people feel they lived by their values in the past week, and “Obstructed”; how much cognitive and emotional barriers restricted the enactment of values in the past week. The VQ-8 consists of 8 items that are rated on a 7-point

scale. The internal consistency for the four 'Progress' items is 0.86 and for the four 'Obstructed' items is 0.83. Sample items:

- I made progress in the areas of my life I care most about.
- I was proud of how I lived my life.
- I was basically on "auto-pilot" most of the time.

The Client Service Receipt Inventory (CSRI; Beecham & Knapp, 2001) was included. The CSRI is a questionnaire for collecting retrospective information about study participant's use of health and social care service, accommodation and living situation, income, employment and benefits. The outcome and therapy-specific measures were completed at the following time points:

- 1) Pre-treatment (1<sup>st</sup> assessment)
- 2) On completion of the ACT group sessions (2<sup>nd</sup> assessment)
- 3) On completion of the full ACT intervention (final assessment).

N.B. The Working Alliance Inventory-short form revised and the Client Service Receipt Inventory were completed at the final assessment stage only.

### *Intervention*

The intervention was a novel group-based 4-session Acceptance and Commitment Therapy (ACT) group followed by two one-to-one sessions developed by the author and her academic supervisor (an experienced ACT Therapist). This protocol (see Appendix 5) was based on a protocol by Lloyd, Bond, & Flaxman (2013). The key ACT processes of mindful

acceptance, defusion, and values clarification were used to enhance participants' ability to pursue value-based goals and actions. Prior to the intervention commencing, the author attended a 2-day ACT workshop facilitated by accredited ACT trainers. In addition, the academic supervisor delivered ACT training to the service's clinicians. This training was provided in order to facilitate clinicians referring to the study and to up-skill the clinicians who co-facilitated the group with the author. To ensure ACT consistent practice, the academic supervisor co-facilitated and supervised the running of the first group with the author.

### *Procedure*

The research procedures were approved by the West of Scotland NHS Research Ethics Committee No. 3 (ref: 13/WS/0278) and R&D approval (ref: GN13CP407) was granted from NHS Greater Glasgow and Clyde. The author attended NHSGG&C Good Clinical Practice Training prior to the research procedures commencing.

The author attended an allocations meeting and a business meeting at the GG&C Psychological Trauma Service to provide the clinicians with information about the study. Service users in *phase 3* of treatment, or nearing the end of *phases 1* or *2*, each had a clinician who provided them with an information sheet (see Appendix 6) containing information about the study. Each service user was given the opportunity to meet with the author at least 24 hours after receiving the information sheet to allow them

time to consider participation. This meeting gave the service user an opportunity to raise any questions about the study. During the meeting the service user decided whether or not they wished to take part in the study. For those who decided to participate, the author obtained informed consent by asking the service user to sign a consent form (see Appendix 7). Participants were informed that they could withdraw at any time without their care being affected.

The group sessions were delivered by the author over four sessions with a co-facilitator. The two individual sessions that followed the group sessions were used to explore values specific to the individuals. Overall, each participant was required to participate in six sessions over a period of seven weeks.

It had been the intention to recruit eight participants to a group, based on 'eight' being reported as the ideal number of participants for a group (Yalom, 1995), and therefore four groups were scheduled in order to try to recruit a sufficient number of participants. The study, however, came up against significant recruitment difficulties, and the ACT intervention could only be delivered to three groups. For each participant who dropped-out from the study, the author informed the referring clinician and attempted to make contact with each participant via letter correspondence and telephone.

### *Data Analysis*

The study did not obtain sufficient data to explore intervention signals via inferential statistics. Instead clinically significant change was addressed for each individual participant on the GHQ-12, AAQ-II, CFQ and the SoC-13.

Jacobson and Truax (1991) state that changes on outcome measures achieve clinical significance if the following two criteria were met:

1. The change in outcome score was reliable according to the *Reliable Change Index* (RCI) ( $RCI < -1.96$  or  $> 1.96$ )
2. Scores transitioned from being above clinical cut-off at baseline to below clinical cut-offs at post-baseline.

N.B. For the SoC and VQ, scores needed to transition from being below clinical cut-off at baseline to above clinical cut-off at post-baseline.

Jacobson and Truax's (1991) method was used to calculate the Reliable Change Index (RCI) for the aforementioned measures to determine whether the magnitude of change for a given participant was statistically reliable. These calculations were based on estimates of test-retest reliability for the:

- GHQ-12 obtained by Hankins (2008) (Implied  $r^2$  0.73)
- AAQ-II obtained by Bond et al. (2011) ( $r = 0.80$ )
- CFQ obtained by Gillanders et al. (2010) ( $r = 0.88$ )
- SoC-13 obtained by Schnyder, Buchi, Sensky, & Klaghofer (2000) ( $r = 0.70$ )

To the author's knowledge, there is yet to be test-retest values published for the VQ, consequently it was not possible to calculate the RCI for the VQ.

Clinically significant cut-off scores were determined for the GHQ-12, AAQ-II, CFQ, SoC-13 and VQ using the method outlined by Jacobson & Truax (1991). Normative data for the GHQ-12 (M = 10.6, SD = 4.9; Hankins, 2008) produced a value of 11.20. This score was rounded to the nearest whole number which meant that a cut-off score of 11 or above was indicative of clinically important levels of stress. Normative data for the AAQ-II (M = 18.51, SD = 7.05; Bond et al., 2011) produced a value of 22.17 which meant that a cut-off score of 22 or above was used to classify important levels of psychological inflexibility. For the CFQ, normative data (M = 41.53, SD = 11.57; Gillanders et al., 2010) produced a value of 47.77, which meant that a cut-off score of 48 or above was used to indicate clinically important levels of cognitive fusion. Normative data for the SoC-13 (M = 66.56, SD = 10.2) produced a value of 61.19 which meant that a cut-off score of 61 or above was used to classify important levels of participant's sense of coherence. Finally, normative data for the VQ (M = 28.75, SD = 8.9; Davies & Smout, 2011) produced a value of 26.34, therefore a cut-off score of 26 or above was used to indicate clinically important levels of value-consistent behaviour. See Appendix 8 for both the RCI and clinical cut-off methods.

## Results

This study identified difficulties in recruiting individuals to a *phase 3* complex trauma ACT intervention. Seventeen people were referred over a six-month period. This amounts to a recruitment rate of approximately three per month. Only eleven (64.7%) consented to participate. Of those that consented only 45.5% completed the full intervention.

Table 2 summarises means and standard deviations for the measures over time. Relationships between the baseline scores on the GHQ-12, AAQ-II, CFQ, VQ and SoC were investigated using Spearman correlation coefficient. Preliminary analyses were performed to ensure no violation of the assumptions of normality and linearity. To control for the risk of Type I errors, the p-value of 0.05 was adjusted for the Bonferroni correction, resulting in the alpha level of 0.01 being used. A strong negative correlation between scores on the AAQ-II and SoC was reported,  $\rho = -.929$ ,  $n = 9$ ,  $p = 0.001$ , with high levels of sense of coherence associated with low levels of psychological inflexibility. No other significant relationships were reported.

As the WAI-SR was included as one of the indicators of the acceptability of the ACT intervention it is of interest to note that, from the data acquired ( $n = 5$ ), a mean score of 49 (SD = 7.96), range = 38-59, was obtained. The scores M = 16.2 (SD = 2.77), M = 17 (SD = 2.82), M = 15.8 (SD = 4.02) were obtained for the sub-scales Goal, Task, and Bond respectively.

**Table 2***Means (and standard deviations) Over Time*

	Baseline	2 <sup>nd</sup> assessment	Final assessment
Measures	( <i>n</i> = 9)	( <i>n</i> = 6)	( <i>n</i> = 5)
GHQ: <i>M</i> ( <i>SD</i> )	12.22 (8.28)	9.33 (10.98)	9.4 (7.02)
AAQ-II: <i>M</i> ( <i>SD</i> )	28 (11.57)	25.16 (12.26)	25.8 (8.75)
CFQ: <i>M</i> ( <i>SD</i> )	55.44 (12.69)	52.33 (10.03)	50.8 (14.46)
VQ: <i>M</i> ( <i>SD</i> )			
- <b>Total</b>	<b>24.44 (6.98)</b>	<b>30.16 (9.23)</b>	<b>29.8 (11.32)</b>
- Progression	15.44 (4.97)	17.66 (2.06)	18 (3.67)
- Obstruction	15.11 (2.14)	13.16 (3.54)	12.4 (8.08)
SoC-13: <i>M</i> ( <i>SD</i> )			
- <b>Total</b>	<b>54.37 (12.97)</b>	<b>47 (13.71)</b>	<b>51.8 (9.12)</b>
- Meaningful	18 (4.14)	17 (4.96)	18.8 (3.56)
- Comprehensibility	21.5 (5.39)	15.6 (6.80)	19 (4.12)
- Manageability	14.87 (4.58)	14.2 (3.70)	14 (4.74)
WAI – SR: <i>M</i> ( <i>SD</i> )			
- <b>Total</b>			<b>49 (7.96)</b>
- Goal			16.2 (2.77)
- Task			17 (2.82)
- Bond			15.8 (4.02)

General Health Questionnaire-12 (GHQ-12); Acceptance & Action Questionnaire-2<sup>nd</sup> Edition (AAQ-II); Cognitive Fusion Questionnaire (CFQ); Valuing Questionnaire (VQ); Sense of Coherence-13 (SoC-13); Working Alliance Inventory-Short form Revised (WAI-SR)

See Table 3 for a summary of scores above and below clinical cut-offs and the RCIs

### *Change in general mental health*

Two (40%) of the 5 individuals who completed final assessments had scores equal to and above the clinical cut-off on the GHQ-12 at baseline. One of these 2 participants (50%) showed clinically significant improvement at final assessment. Of the three participants who had

scores below the clinical cut-off at baseline, one (33%) showed clinically significant deterioration at final assessment.

The one participant who completed the post-group assessment and did not continue to final assessment had a score above the clinical cut-off on the GHQ-12 at baseline and showed clinically significant improvement at post-group assessment.

#### *Change in Sense of Coherence*

One of the 5 participants (20%) who completed final assessment had a score below clinical cut-off at baseline for this sample and exhibited clinically significant improvement. One of the same 5 participants (20%) had a score above the clinical cut-off at baseline and below at final assessment for this sample and exhibited a clinically significant deterioration.

#### *Change in Psychological Flexibility*

Three of the 5 participants (60%) who completed the final assessment had levels of psychological inflexibility that were above the clinical cut-off score for the sample at final assessment. One of the 2 participants (50%) who had levels of psychological inflexibility below the clinical cut-off at baseline exhibited a clinically significant increase in psychological inflexibility at final

assessment. Treatment signals on the AAQ-II for another one participant were suggestive of improvement; however their RCI value (1.55) did not indicate significance.

#### *Change in Cognitive Fusion*

Two of 5 participants (40%) who completed final assessment had scores that transitioned from above the clinical cut-off for this sample to below the clinical cut-off. One of those 2 (50%) exhibited clinically significant improvement in levels of cognitive fusion. One of the same 5 participants (20%) had a score that fell below the clinical cut-off at baseline then transitioned to above the clinical cut-off at final assessment, and exhibited clinical significant worsening in levels of cognitive fusion.

#### *Change in Valued Living*

Three of the 5 participants (60%) who completed the final assessment had scores below the clinical cut-off for this sample at baseline that transitioned to above the clinical cut-off at final assessment. This is suggestive of an improvement in value-consistent behaviour.

Three of the 5 (60%) participants who completed final assessment did not exhibit clinically significant change, as defined by Jacobson & Truax (1991), on any of the measures.

**Table 3***Clinically Significant Change for Participants Completing Post-Group Assessment (n = 1) or Final Assessment (n = 5)*

Participant	Measure	Baseline	Post-Group Assessment	Final Assessment	RCI	Below clinical cut-off score at post-group or final assessment	Clinical significant change*
1	GHQ-12	1		21	-5	No	No
	SoC-13	68		49	2.68	Yes	No
	AAQ-II	16		34	-3.48	No	No
	CFQ	47		59	-2.67	No	No
	VQ	34		26	-	No	-
2	GHQ-12	11		3	1.86	Yes	No
	SoC-13	50		65	-2.11	No	Yes**
	AAQ-II	25		17	1.55	Yes	No
	CFQ	57		36	4.67	Yes	Yes**
	VQ	25		46	-	No	-
3	GHQ-12	8		8	0	Yes	No
	SoC-13	38		43	-0.70	No	No
	AAQ-II	38		35	0.58	No	No
	CFQ	74		67	1.56	No	No
	VQ	20		24	-	Yes	-

\*Clinical significant change as defined by Jacobson &amp; Truax (1991)

\*\*Denotes clinically significant *improvement*

**Table 3** *continued*

Participant	Measure	Baseline	Post-Group Assessment	Final Assessment	RCI	Below clinical cut-off score at post-group or final assessment	Clinical significant change*
4	GHQ-12	4		10	-1.4	Yes	No
	SoC-13	56		45	1.55	Yes	No
	AAQ-II	28		26	0.38	No	No
	CFQ	46		57	-2.45	No	No
	VQ	17		17	-	Yes	-
5	GHQ-12	15		5	2.33	Yes	Yes**
	SoC-13	58		57	0.14	Yes	No
	AAQ-II	21		17	0.77	Yes	No
	CFQ	41		35	1.34	Yes	No
	VQ	23		36	-	No	-
6	GHQ-12	19	9		2.33	Yes	Yes**
	SoC-13	37	32		0.14	Yes	No
	AAQ-II	39	44		0.97	No	No
	CFQ	65	64		0.22	No	No
	VQ	18	27		-	No	-

\*Clinical significant change as defined by Jacobson & Truax (1991)

\*\*Denotes clinically significant *improvement*

## Discussion

This non-controlled feasibility study of Acceptance and Commitment Therapy (ACT) for *phase 3* complex trauma treatment was guided by the MRC (2008) guidelines on developing complex interventions. It aimed to explore parameters of interest including recruitment, acceptability of intervention, and treatment signals in potential outcome measures.

This study identified difficulties in recruiting individuals to the *phase 3* complex trauma ACT intervention, with a recruitment rate that was lower than had initially been expected.

The reasons for the high attrition rate in this feasibility study remain largely unclear as interviews with participants who did not complete the trial were not conducted. However, one participant who dropped-out of the first group offered some informal feedback. This participant was in a mixed-gender group and reported that group dynamics were intimidating and attributed this to a member of the opposite sex. As a result, the following two groups were gender-specific. It is of interest to note that none of the five participants who attended these groups dropped-out. The attrition rate observed in the current study (54.5%) does appear to be high compared with those reported in other studies investigating ACT as a group intervention referred to earlier in the *Introduction*, which report various different attrition rates: 8% (n = 12; Gratz & Gunderson, 2006); 12% (n =

49; Wetherell et al., 2011); 17.7% (n = 68; Luoma, Kohlberg, Hayes, & Fletcher, 2012); 27.1% (n = 37; McCracken, Sato, & Taylor, 2013). This study's attrition rate is comparable, however, to Ossman, Wilson, Storaasli, & McNeill (2006) who reported a 45.5% (n = 22) attrition rate. It is noteworthy that all of these studies had larger sample sizes than this one and therefore the comparison may not be a fair one.

Due to the difficulties with recruitment and retention and the associated small sample size, it was not possible to conduct inferential statistics to evaluate *statistically* significant treatment signals in outcome measures. However, *clinically* significant changes were investigated. The clinically significant improvement in general mental health that was indicated for two participants, the clinically significant improvement in sense of coherence and cognitive fusion for another participant, and the two participants exhibiting scores that were close to clinically significant improvement in psychological flexibility may be perceived as encouraging indications of potential treatment signals.

It is important to highlight that one participant did experience a significant increase in levels of stress, psychological inflexibility, and cognitive fusion, and clinically significant decreases in levels of value-consistent behaviour and sense of coherence. The reasons for this remain unclear. Whereas the possibility that this was something to do with the intervention cannot

be ruled out; it is possible that it was due to external factors such as a significant life transition, more specifically moving from supported accommodation to an independent tenancy. This participant in question was being supported by a keyworker in the community at the time of participation in this study.

It is apparent that 60% of participants who completed final assessment did not show any clinically significant change, as defined by Jacobson & Truax (1991), on the measures. Therefore, definitive conclusions regarding the appropriateness of assessment measures included in this study cannot be made. Perhaps a longer follow-up period is required to evidence such appropriateness, as well as the therapeutic value of the intervention.

In regards to the acceptability of the intervention, the majority of the scores indicated a relatively strong therapeutic alliance, with sub-scores indicating relatively high levels of satisfaction with the goals and tasks set throughout the intervention as well as the bond that developed between the participants and the facilitators. This may be seen as a further indicator in favour of the acceptability of the ACT intervention. One participant's scores did indicate a weaker alliance, the same aforementioned participant who exhibited deterioration on all measures. As previously mentioned, the reason for this outcome remains unclear.

Overall, the *stage 1* results highlight the need for further research to determine the feasibility of using ACT as an intervention for complex trauma. In particular, the recruitment of larger sample sizes would allow for firmer conclusions to be made regarding the appropriateness of the assessment measures and acceptability of the intervention. Despite the challenges associated with recruitment, the findings of this feasibility study in conjunction with single case studies that demonstrated efficacy for the use of ACT with individuals with PTSD and trauma-related difficulties (Batten & Hayes, 2005; Orsillo & Batten, 2005, and Twohig, 2009) suggest that further exploration is merited.

## **Stage 2**

### **Methods**

#### *Design*

Following the qualitative method of Framework Analysis (Ritchie & Spencer, 1994) a preconceived framework was developed based on issues that arose during the first stage of this study, forming a semi-structured interview. Data from the interviews was subsequently analysed.

#### *Participants*

All clinicians of the GG&C Psychological Trauma Service were contacted via email by the author to enquire about their interest in and availability to participate in this stage of the study. An information sheet (see appendix 9) was attached to inform the clinicians of *stage 2* of the study. Seven out of 14 clinicians (50%) opted to participate.

### *Procedure*

A substantial amendment was submitted to and approved by the West of Scotland NHS Research Ethics Committee No. 3 (ref: 13/WS/0278) and R&D (ref: GN13CP407) with the proposed addition of qualitative methodology as detailed below. This was to address the recruitment difficulties in *stage 1*.

A preconceived framework grounded in this study was used to create a semi-structured interview. The data obtained was used to support the quantitative information obtained in the assessment measures detailed previously. Interviews lasted approximately 15 minutes, and all were transcribed (transcriptions available on request) by the author. See Appendix 10 for the interview schedule.

Each clinician signed a consent form (see Appendix 11) prior to participating in the interview. From the interviews it emerged that 6 out of 7 (85.7%) of the clinicians who were interviewed were able to refer to the study. It was the intention to have more of a balance of those who did and did not refer, however this was not possible due to the remaining 50% of clinicians not being available for participation within the time-frame.

### *Analysis*

Framework Analysis was conducted on the data from the interviews. According to Ward, Furber, Tierney & Swallow (2013), Framework Analysis can be shaped by existing ideas and is less focussed on

developing new theories, and it was developed to address specific questions. As the author and academic supervisor had specific questions in mind regarding the recruitment difficulties that arose during this study, this method of analysis was deemed most appropriate. The analysis was guided by four stages outlined by Ritchie & Spencer (1994):

Familiarisation, Indexing, Charting, and Mapping and Interpretation. All transcripts were analysed by the author. Twenty percent of the transcripts were also analysed by a final-year trainee clinical psychologist to assess for inter-rater reliability and to support the completion of data saturation. No disputes arose, wording of the themes identified by both evaluators were discussed and agreed upon.

In order to determine the robustness of this analysis, the author drew upon the quality evaluation guide for a similar method of qualitative analysis by Smith (2011), which stipulates that there must be sufficient evidence from the body of the transcript in order for a theme to be robust. From the seven transcripts in this study, quotes were required from at least three in order for a theme to be robust (Smith, 2011).

## **Results**

See Table 4 for a summary of key themes under each category of the pre-conceived framework that emerged from the interviews.

Fourteen 'robust' themes emerged from the data. See below for a summary of the themes and examples of supporting quotes, under the

categories and sub-categories from which they emerged. Information in brackets corresponds to the line and page number of individual transcripts. See Appendix 12 for charts containing all of the supporting quotes.

Under category 1 – **Clinician’s experience of the study**, sub-category

1.1 – **What helped recruitment**, two robust themes emerged:

1. ‘Clear referral process’

Clinician 4: *“Knowing there was a clear, a contact person, to contact to refer...”* (line 7, p.1)

2. ‘Provision of information’

Clinician 5: *“Aims were clearly laid out and explained...”* (lines 11 & 12, p.1)

Clinician 7: *“I was given clear information...”* (line 7, p.1)

One robust theme emerged under sub-category 1.2 – **What hindered recruitment**:

1. ‘Timing: inappropriate stage of therapy’

Clinician 5: *“With my case load it was timing, I just wasn’t quite at phase 3 with some...”* (line 16, p. 1)

Clinician 7: *“It was quite difficult to find people who were at phase 3...”* (lines 13 & 14, p.1)

Under category 2 – **ACT as a phase 3 intervention**, sub-category 2.1 – **Knowledge of ACT**, two robust themes emerged:

1. ‘Reasonable amount of knowledge’

Clinician 2: *"I feel like I know quite a bit, a reasonable amount..."*

(line 26, p.1)

Clinician 5: *"I have a reasonable knowledge..."* (line 24, p.1)

2. 'Attended training'

Clinician 3: *"I've had some training"* (line 48, p.2)

Clinician 4: *"I've been on a couple of training days..."* (lines 23 & 24)

Two robust themes emerged from sub-category 2.2 - **Suitability of ACT as a phase 3 intervention:**

1. 'Goodness of fit'

Clinician 2: *"Talking about values fits really well with phase 3"* (line 30, p.1)

Clinician 5: *"The theory... of ACT and the model I think potentially fit very well with this population and perhaps with the aims and goals that we would have at phase 3"* (lines 27, 28, & 29, p.1)

2. 'Suitable for application in all phases'

Clinician 1: *"I'm wondering if there's scope for it to be used... (in other phases) other than solely being a phase 3 intervention"* (lines 40 & 41, p.2)

Clinician 4: *"I also think it could be used in phase 1..."* (lines 31 & 32, p.1)

Two robust themes emerged under sub-category 2.3 – **Challenges faced by service-users transitioning between phase 2 and phase 3:**

1. 'Readiness: apprehension'

Clinician 1: "*There's something about confidence at being discharged*" (line 44, p.2)

Clinician 2: "*Moving forwards felt scary*" (line 39, p.2)

2. 'Separation Anxiety: ending the therapeutic relationship'

Clinician 6: "*A difficulty might be the ending of a therapeutic relationship...*" (lines 77 & 78, p.2)

Clinician 5: "*For many individuals, ending with a therapist can be difficult...*" (line 35, p.2)

Under category 3 - **The future of phase 3 interventions**, sub-category 3.1 – **Hopes and visions for the future of phase 3 interventions**, two robust themes emerged:

1. 'Encourage independence from the service'

Clinician 1: "*Moving away from specialist homelessness services into community services...*" (lines 63 & 64, p.2)

Clinician 7: "*What will achieve that connectivity, or connection that we're looking for... so that people feel confident to leave our service*" (lines 46 & 47, p.2)

2. 'Clarification of phase 3 for the clinician'

Clinician 3: "*A little bit more clarity... you know what do we expect from ourselves...*" (lines 79 & 80, p. 8)

Clinician 5: "*I think a clear rationale in our heads of when... the phase 3 work needs to be done in the service... or when is it making links with the third sector...*" (lines 50, 51, & 52, p.2)

One robust theme emerged under sub-category 3.2 – **Engagement of service-users in phase 3:**

1. 'Planning'

Clinician 3: "*How you agree stage 3, the time scales for it, what it will focus on and when it will end...*" (lines 91 & 92, p.3)

Clinician 5: "*I think planning, eh, for that transition to phase 3 early on...*" (lines 57 & 58, p.2)

Clinician 7: "*Discharge planning and treatment planning from the start of therapy...*" (lines 60 & 61, p.2)

Finally, two robust themes emerged under category 4 – **Other comments:**

1. 'Value of the study'

Clinician 3: "*I think it's been something that's been valuable for our service...*" (line 96, p.3)

Clinician 4: "*It seems to have been really valuable...*" (lines 85 & 86, p.3)

2. 'Commitment to future research'

Clinician 3: "*I hope we can build on the work you have done.*" (Line 98, p.3)

Clinician 6: "*It'll be interesting to see how it might go again in the future... something for us to focus on in the future...*" (lines 131, 132, & 133, p.3)

**Table 4** Summary of key themes from interviews with the GG&C Psychological Trauma Service clinicians

Category	Subcategory	Themes
1. Clinician's experience of the study	1.1. What helped recruitment	Clear referral process* Provision of information* Timing: appropriate stage of therapy
	1.2. What hindered recruitment	Timing: inappropriate stage of therapy* Group setting: intimidating prospect
2. ACT as a phase 3 intervention	2.1. Knowledge of ACT	Reasonable amount of knowledge* Training attendance*
	2.2. Suitability of ACT as a phase 3 intervention	Goodness of fit* Suitable for application in all phases*
	2.3. Challenges faced by service-users transitioning between phase 2 and phase 3	Readiness: apprehension* 'Separation Anxiety': ending the therapeutic relationship*
3. Future of phase 3 interventions	3.1. Hopes and vision for the future of phase 3	Encourage independence from the service (GG&C Psychological Trauma Service)* Clarification of phase 3 for the clinician* Group setting
	3.2. Engagement of service users in phase 3	Planning* Boundaries
Other comments		Value of the study* Commitment to future research* Mixed-gender groups

**\*'Robust' themes that emerged from 3 interview**

## Discussion

*Stage 2* aimed to obtain an understanding of the barriers to participation that became apparent during *stage 1* of this study, which in turn will help inform the development of a more refined feasibility study. The results of the framework analysis have provided valuable information on what helped and hindered recruitment to the study, what barriers service users and clinicians encountered with the phase-based treatment, and changes that can be made that can address such barriers.

In the opinions of the clinicians, one of the main hindrances to recruitment was the stage of therapy that clients were at, with the majority being in *phase 1* or *2* and not being ready for the transition to *phase 3*. Taking this issue of transitioning from *phase 2* to *phase 3* further, the themes of 'Separation Anxiety: ending of the therapeutic relationship' and 'Readiness: apprehension about moving on' emerged from the interviews, both were mostly attributed to the client; with clinicians highlighting that the client may be anxious about the therapeutic relationship ending or about moving on. It is of interest to note, however, that two clinicians highlighted that this can be bi-directional and that clinicians can share such anxieties regarding endings. One clinician stated, "*I know that as therapists we can feed into that as well ok?*" (Clinician 1, lines 45 & 46, p. 2) and another commented, "*We can have our own anxiety about that too*" (Clinician 3, line 40, p.2)

It would be of interest for future research to establish whether or not this is a common anxiety shared by the service's clinicians, which in turn may further clarify the low numbers of service users in phase 3, and therefore the low number of referrals to the study.

An issue already identified in the *stage 1 Discussion* section was the initial mixed-gender element of the group intervention and is one that some clinicians highlighted as being another hindrance to recruitment to and retention in the study. When asked for other comments, one clinician in particular stated, "*Having gender-specific groups straight away eliminates potential difficult dynamics...*" (Clinician 3, line83, p.3). Based on this, it can be suggested that gender-specific groups may encourage retention in future studies with this population.

Just as important as it was to explore the hindrances to recruitment, the issue of what helped recruitment was also addressed. It was made apparent that having a clear referral process and sufficient information on the study helped clinicians to engage in the recruitment process. It was also deemed important by the author to obtain clinician's professional opinions on the acceptability and suitability of the ACT intervention in order to establish whether or not this may have been a barrier to referring to the study. Results from the framework analysis showed that there was a consensus amongst the clinicians regarding the goodness of fit of the ACT

model within the complex trauma population and phase 3 of a complex trauma intervention.

### **General Discussion**

This research has sought to explore the feasibility of using ACT as a *phase 3* complex trauma intervention. Investigating recruitment was one of the key objectives of this feasibility study. The results of *stage 1* highlight that insufficient numbers were recruited to the study which has impacted on the extent to which definitive conclusions can be drawn about the appropriateness of the assessment measures or the therapeutic value and acceptability of the intervention. However, the interviews conducted in *stage 2* highlight how recruitment to and retention in future studies could be improved.

#### *Limitations*

There are a few key limitations of this study that have been identified by the author. In addition to acting as the lead researcher, the author also took on the role of the ACT therapist in all groups and individual sessions. Furthermore, due to the cancellation and re-scheduling of the groups, the psychology assistant who was administering the assessment measures ended up not being available for all of the assessment time points. As a result, the author had to administer some of the assessment measures, increasing the risk of response bias. In addition, the small sample size resulted in the study not facilitating the use of inferential statistics to

explore treatment signals in the outcome measures used. Regarding attrition, qualitative analyses were not used to interview non-completers and systematically investigate reasons for non-completion. An additional limitation identified by the author relates to the therapy-specific outcome measures used in *stage 1* of this study. It is suggested that the apparent overlapping nature of the constructs measured by the AAQ-8 and CFQ-13 (see '*Measures*' for sample items) puts into question the level of discriminant validity between both measures. Lastly, this study did not have a long-term follow-up assessment period which would have allowed for the exploration of delayed therapeutic effects.

### **Conclusion and suggestions for future research**

The up-scaling of this feasibility study is recommended by the author based on the MRC (2008) guidelines which suggest that the feasibility stage of research is an iterative process, and highlights that a number of studies may be required in order to progressively refine the design, prior to developing a full-scale evaluation. A key justification for developing a refined-feasibility study is the 0% attrition rate from the two gender-specific groups. This may be perceived as a sign of acceptability of the study which is worthwhile exploring further.

Stemming from the current study, a number of modifications can be suggested that could improve future feasibility and pilot research. To

reduce the risk of barriers to participation emerging as they did in the current study, it is suggested that clinicians plan for all phases of intervention from the very beginning of therapy to ensure the service user is as informed of the therapy pathway and is as prepared for discharge as possible. This may serve to make the ending of the therapeutic relationship and the transition from one phase to another, and then to discharge, easier and more manageable.

A further suggestion is that it could be arranged for service user's key clinicians to escort them to the first group session to allow for a smoother transition from an individual to a group setting. In addition, to aid the transition and to address the difficulty of forming new therapeutic relationships, it is suggested that the therapists facilitating the ACT intervention meet with the services users on more than one occasion in order to nurture the beginning of a new therapeutic relationship.

Further to the *stage 1 Discussion*, it is suggested that in the future feasibility study, gender-specific groups are offered. It will be of interest to then explore whether or not this has a significant effect on referrals and recruitment to the study.

In regards to the assessment process, future research could employ a follow-up assessment to assess for the longer-term effects of ACT on

psychological flexibility and values-based action. At follow-up, it may be of interest to assess the participant's perceived level of connectivity within society and the extent to which they feel integrated within their community, and the extent to which they attribute this to ACT-based processes.

To conclude, larger sample sizes are required in future studies in order to be able to obtain more conclusive outcomes on the appropriateness and effectiveness of ACT in facilitating recovery from complex trauma and to produce effect sizes in order to inform sample sizes for wider-scale trials. It is envisioned that by addressing the barriers and issues already discussed, and by making amendments accordingly, that recruitment to and retention in the next stage of research will be more successful.

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**CHAPTER THREE**  
**ADVANCED CLINICAL PRACTICE 1**  
**REFLECTIVE CRITICAL ACCOUNT (Abstract Only)**

Formulation: The Development of a Core Skill in Clinical  
Psychology

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<sup>1</sup> Mental Health and Wellbeing, Institute of Health and Wellbeing, University  
of Glasgow

## **Abstract**

### **Introduction**

The British Psychological Society, Division of Clinical Psychology (BPS, DCP, 2011) define formulation as, “both an event and a process, which summarises and integrates a broad range of biopsychosocial causal factors.” (pp. 4). Throughout my training I have referred to Johnstone and Dallos (2006) as guidance for developing my formulation competency and have found it very helpful when distinguishing between formulating using a Cognitive Behavioural approach and an Integrative approach.

To guide my reflection, I will be referring to The Integrated Developmental Model of Supervision (IDM, Stoltenberg, McNeill & Delworth, 1998) regarding the development of the competency over the two and a half years, and Gibb’s Reflective Cycle (1988) for specific situations.

I believe formulation is one of the key skills that distinguishes Clinical Psychologists from other mental health professionals and it is one that, through my own observation of processes within direct clinical work, I believe can have significant impact on a client’s recovery. As a result of my interest in and feelings about formulation, I have selected it as the focus for my first reflective account.

## **Reflection**

The process of reflecting on my training so far has evoked quite powerful feelings within me, as it has helped me to develop insight into how far I have come in general, but also with regards to my competence in formulating. This process has also helped me to see that the challenges I faced in first year with regards to formulation were completely different to the challenges I faced in second year and the challenges I am tackling now, in third year. In first year my main concern appeared to be focussed on getting through the assessment phase as quickly as possible so that I could move on to intervention in order to contain my obsession around finding an answer for each client and helping to 'fix' them so to speak, causing me to bypass developing a full formulation. In second year I felt more competent in the actual process of formulating, and I used it in order to understand how processes within the therapeutic environment can be used to help provide insight into the root of a client's difficulties and in turn enrich the intervention. Finally in third year, I am being faced with the challenge of formulating at a completely different level, one that I feel is as complex as the population I am working with, but one that I am embracing 100% as I am working in an area that I am very passionate about; an area that I believe I would like to dedicate my career to.

## **Conclusion**

I believe that formulation is a competency that I have embraced and developed significantly throughout my training, and it is one that I will continue to develop in my career as a qualified Clinical Psychologist.

**CHAPTER FOUR**  
**ADVANCED CLINICAL PRACTICE 2**  
**REFLECTIVE CRITICAL ACCOUNT (Abstract Only)**

From Resisting to Embracing: Accepting the Role of Research  
in Clinical Psychology

**Jennifer Megson<sup>1</sup>**

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of Glasgow

## **Abstract**

### **Introduction**

In the profession of Clinical Psychology, research plays an integral role, and it is pertinent that research is a continuous process. The role of research in clinical psychology is strengthened by the development of documents such as the 'The Matrix- A Guide to delivering evidence-based Psychological Therapies in Scotland' (2011), produced by the Scottish Government, which provides guidance on which evidence-based psychological therapies should be implemented for which mental health disorders and at what level. This document claims that it intends to continue to extend the evidence tables over time to give more comprehensive coverage, and to update the recommendations as new evidence becomes available; hence the need for on-going research.

My reflection is going to focus on research, and the process through which I have gone so far in order to develop the competencies required to obtain my Doctorate in Clinical Psychology (DClinPsy) qualification. To guide my reflection, I will be referring to The Integrated Developmental Model of Supervision (IDM, Stoltenberg, McNeill & Delworth, 1998) regarding the development of my research competencies throughout my training, and Gibb's Reflective Cycle (1988) for specific situations.

## **Reflection**

Now that I am in the last stretch of my training in the Doctorate in Clinical Psychology (DClin Psy), I can reflect that the focus of my stress has significantly changed year to year, and now I can confidently say that the focus is on the current status of my major research project (MRP). On reflection, I realise that I have gone through the process of acceptance with regards to conducting research as part of my training to the point that I am now embracing it and not just going through the motions with a sense of underlying resistance which I believe I was doing in first year and part of second year. I can now reflect that my somewhat negative feelings towards conducting research in first year were driven by a significant lack in confidence in my research abilities, paired with a mild disinterest in the area that I was focussing on for my service-based evaluation project (SBEP). By the time I had completed my SBEP in second year and shifted my focus to my MRP, I could feel my motivation and drive significantly increasing, which in turn helped me to challenge my lack of self-belief in my research abilities. Reduced confidence and self-belief does still appear from time to time, especially as I am approaching the end of the course. The difference now in my third and final year is that I know that I am more competent in conducting research than I was in first and second year, however my feelings can at times remain doubtful and clash with such knowledge.

## **Conclusion**

This reflection has been a significant learning experience for me, and has shown me that if I am working in an area in which I am genuinely interested, the drive and passion that comes with such interest will help me to challenge any self-doubt that is triggered when I come up against a piece of work that puts me out of my comfort zone. I now realise and appreciate the significant and pertinent role of research in clinical psychology, and genuinely hope that I am able to continue with research as I progress through my career as a qualified Clinical Psychologist.

## APPENDICES

**Appendix 1** *Summary of Author Instructions for Submission to the Journal of Consulting and Clinical Psychology*

## Journal of Consulting and Clinical Psychology<sup>®</sup>

### Cover Letter

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The cover letter accompanying the manuscript submission must include all authors' names and affiliations to avoid potential conflicts of interest in the review process. Addresses and phone numbers, as well as electronic mail addresses and fax numbers, if available, should be provided for all authors for possible use by the editorial office and later by the production office.

### Length and Style of Manuscripts

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Full-length manuscripts should not exceed 35 pages total (including cover page, abstract, text, references, tables, and figures), with margins of at least 1 inch on all sides and a standard font (e.g., Times New Roman) of 12 points (no smaller). The entire paper (text, references, tables, etc.) must be double spaced.

For papers that exceed 35 pages, authors must justify the extended length in their cover letter (e.g., reporting of multiple studies), and in no case should the paper exceed 45 pages total. Papers that do not conform to these guidelines may be returned without review.

The References section should immediately follow a page break.

### Title of Manuscript

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The title of a manuscript should be accurate, fully explanatory, and preferably no longer than 12 words. The title should reflect the content and population studied (e.g., "treatment of generalized anxiety disorders in adults").

### Abstract and Keywords

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Please include an Abstract of up to 250 words, presented in paragraph form. The Abstract should be typed on a separate page (page 2 of the manuscript), and must include each of the following sections:

- **Objective:** A brief statement of the purpose of the study

## Appendix 1 *continued*

- **Method:** A detailed summary of the participants (*N*, age, gender, ethnicity) as well as descriptions of the study design, measures (including names of measures), and procedures
- **Results:** A detailed summary of the primary findings that clearly articulate comparison groups (if relevant), and that indicate significance or confidence intervals for the main findings
- **Conclusions:** A description of the research and clinical implications of the findings

After the abstract, please supply up to five keywords or short phrases.

### Participants: Description and Informed Consent

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The Method section of each empirical report must contain a detailed description of the study participants, including (but not limited to) the following: age, gender, ethnicity, SES, clinical diagnoses and comorbidities (as appropriate), and any other relevant demographics.

In the Discussion section of the manuscript, authors should discuss the diversity of their study samples and the generalizability of their findings.

The Method section also must include a statement describing how informed consent was obtained from the participants (or their parents/guardians) and indicate that the study was conducted in compliance with an appropriate Internal Review Board.

### Measures

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The Method section of empirical reports must contain a sufficiently detailed description of the measures used so that the reader understands the item content, scoring procedures, and total scores or subscales. Evidence of reliability and validity with similar populations should be provided.

### Statistical Reporting of Clinical Significance

---

*JCCP* requires the statistical reporting of measures that convey clinical significance. Authors should report means and standard deviations for all continuous study variables and the effect sizes for the primary study findings. (If effect sizes are not available for a particular test, authors should convey this in their cover letter at the time of submission.)

## Appendix 1 *continued*

In addition, when reporting the results of interventions, authors should include indicators of clinically significant change. Authors may use one of several approaches that have been recommended for capturing clinical significance, including (but not limited to) the reliable change index (i.e., whether the amount of change displayed by a treated individual is large enough to be meaningful; see Jacobson et al., *Journal of Consulting and Clinical Psychology*, 1999), the extent to which dysfunctional individuals show movement into the functional distribution (see Jacobson & Truax, *Journal of Consulting and Clinical Psychology*, 1991), or other normative comparisons (see Kendall et al., *Journal of Consulting and Clinical Psychology*, 1999).

### Discussion of Clinical Implications

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Articles must include a discussion of the clinical implications of the study findings or analytic review. The Discussion section should contain a clear statement of the extent of clinical application of the current assessment, prevention, or treatment methods. The extent of application to clinical practice may range from suggestions that the data are too preliminary to support widespread dissemination to descriptions of existing manuals available from the authors or archived materials that would allow full implementation at present.

### Nonrandomized Trials

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For nonrandomized designs that often are used in public health and mental-health interventions, *JCCP* requires compliance with JARS.

### Manuscript Preparation

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Double-space all copy. Other formatting instructions, as well as instructions on preparing tables, figures, references, metrics, and abstracts, appear in the *Manual*.

### Tables

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Use Word's Insert Table function when you create tables. Using spaces or tabs in your table will create problems when the table is typeset and may result in errors.

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## Appendix 1 *continued*

### Submitting Supplemental Materials

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APA can place supplemental materials online, available via the published article in the PsycARTICLES® database. Please see [Supplementing Your Article With Online Material](#) for more details.

### References

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List references in alphabetical order. Each listed reference should be cited in text, and each text citation should be listed in the References section.

Examples of basic reference formats:

- **Journal Article:**  
Hughes, G., Desantis, A., & Waszak, F. (2013). Mechanisms of intentional binding and sensory attenuation: The role of temporal prediction, temporal control, identity prediction, and motor prediction. *Psychological Bulletin*, *139*, 133–151.  
<http://dx.doi.org/10.1037/a0028566>
- **Authored Book:**  
Rogers, T. T., & McClelland, J. L. (2004). *Semantic cognition: A parallel distributed processing approach*. Cambridge, MA: MIT Press.
- **Chapter in an Edited Book:**  
Gill, M. J., & Sypher, B. D. (2009). Workplace incivility and organizational trust. In P. Lutgen-Sandvik & B. D. Sypher (Eds.), *Destructive organizational communication: Processes, consequences, and constructive ways of organizing* (pp. 53–73). New York, NY: Taylor & Francis.

### Figures

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Graphics files are welcome if supplied as Tiff or EPS files. Multipanel figures (i.e., figures with parts labeled a, b, c, d, etc.) should be assembled into one file.

The minimum line weight for line art is 0.5 point for optimal printing.

When possible, please place symbol legends below the figure instead of to the side.

## Appendix 2 Database-specific Search Strategy

Date of search	Information source	Search terms	Limits	No. of results	No. of papers included based on criteria
17.1.14	Ovidsp MEDLINE(R)  In-Process & Other Non- Indexed Citations and Ovid MEDLINE(R)	Cognitive Therapy OR cbt OR cognitive behave* therap*  AND  complex trauma OR stress disorders, post- traumatic/ OR complex post-traumatic stress disorder, OR complex traumatic stress disorder OR Child Abuse, Sexual OR Child Abuse OR Child Neglect OR Child Physical Abuse OR Child Emotional Abuse OR Adult Survivors of Child Abuse OR Spouse Abuse OR Battered Women	English language, Adults, RCT, 2004-current	150	8
17.1.14	Ovidsp Embase  1947-Present, updated daily	Cognitive behavioural therapy OR cognitive therapy OR cognitive behavio* therap* OR behaviour therapy OR cbt  AND  Complex trauma OR posttraumatic stress disorder OR complex posttraumatic stress disorder OR complex traumatic stress disorder OR child abuse OR child sexual abuse OR battered child syndrome OR child physical abuse OR physical abuse OR child emotional abuse OR emotional abuse OR child neglect OR neglect OR Adult Survivors of Child Abuse OR spouse abuse OR partner violence OR battered women	English language, Adult, RCT, 2004-current, Embase	140	3  (7 initially, 4 were removed due to duplication of those from Ovid MEDLINE)

## Appendix 2 *continued*

Date of search	Information source	Search terms	Limits	No. of results	No. of papers included based on criteria
9.2.14	PsycINFO	Cognitive Behavior Therapy OR Cognitive Therapy OR Behavior Therapy  AND  Complex trauma OR complex post traumatic stress disorder OR post traumatic stress disorder OR child abuse OR child abuse victims OR adult child abuse victims OR childhood sexual abuse OR spouse abuse OR intimate partner violence OR domestic OR battered child syndrome OR battered woman syndrome	2004-2014, Peer reviewed journals, Adulthood (18yrs & older), English, Human	139	0  (4 initially however removed due to duplication of those found in Ovid MEDLINE and Embase)

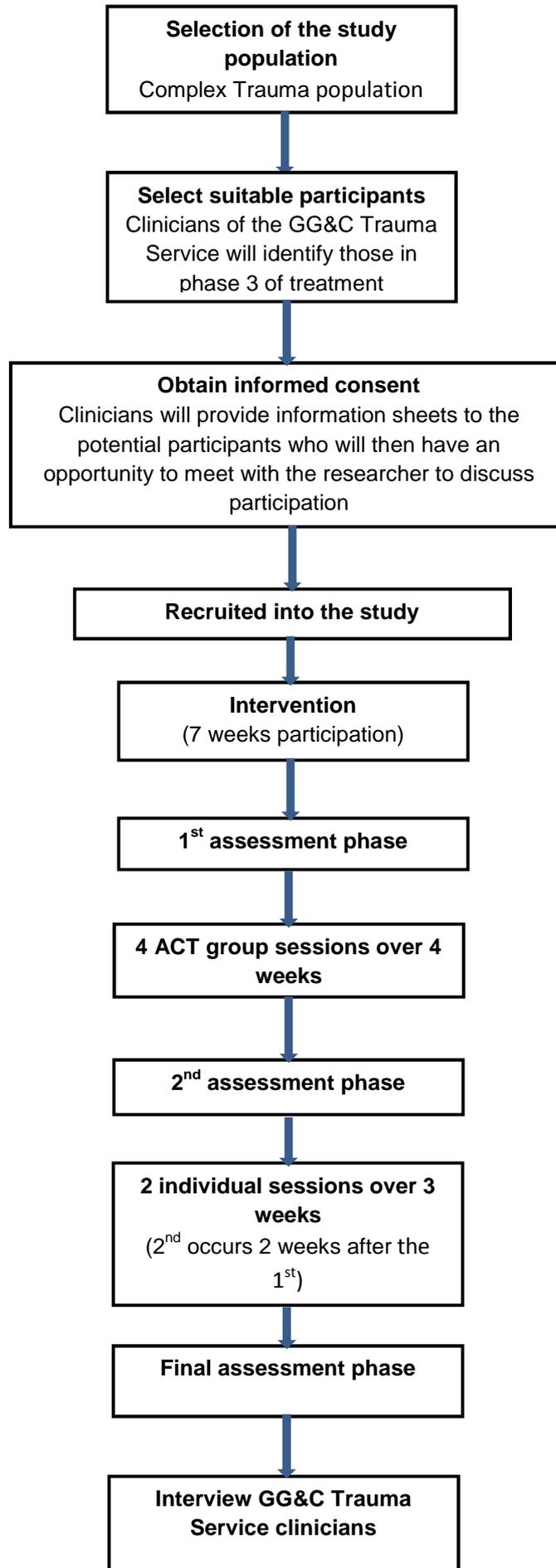
### Appendix 3 Summary of bias types

Type of bias	Description	Domain
Selection bias	Refers to systematic differences between baseline characteristics of the groups that are compared.	<p><b>Sequence generation</b> (allocation of participants to interventions must be based on a process of chance)</p> <p><b>Allocation concealment</b> (prevention of those significant to the study having knowledge of the allocations)</p>
Performance bias	Refers to systematic differences in the groups regarding care that is provided and/or exposure to factors other than the intervention of interest.	<p><b>Blinding of study participant and personnel</b> (not always possible, for example when exploring effects of a psychological therapy, participants will know whether or not they are receiving the treatment condition)</p>
Detection bias	Refers to systematic differences in how outcomes are determined between the groups being compared.	<p><b>Blinding of outcome assessors</b> (reduces the risk that knowledge of which intervention was received affects outcome, rather than the intervention itself)</p>
Attrition bias	Refers to systematic differences in withdrawals between groups being compared	<p><b>Incomplete outcome data – short term and long term</b> (it is important that the study author explains how such data is handled)</p>
Reporting bias	Refers to systematic differences between reported and unreported findings.	<p><b>Selective reporting</b> (it is more likely for significant than non-significant results to be published)</p>

### **Appendix 3** *continued*

Type of bias	Description	Domain
Other biases	Refers to biases that are relevant only in certain circumstances, for example in particular study designs or in particular clinical settings.	<b>Other bias</b>

#### Appendix 4 Study Flow Chart



## Appendix 5 ACT Group Protocol

### Group Session 1

#### **Mindful Acceptance**

Aims:

Introduction

Being Present / Acceptance

#### 2pm Introduction

- Introduce self, modelling open stance from the start
- Thank participants for attending
- Direct participants to their hand-outs and the information within them (Contact numbers and session-specific information)
- Housekeeping (fire exits, toilets, etc...)
- Ground rules: Have own rules already prepared on other side of flip chart. Include “notice your reactions to others in the group, any urges you may have when others say something... just notice them...” Explain that everyone is different and will respond differently to content of the group, sometimes we may not agree with what is said, however we encourage you to simply notice this and allow for other’s opinions...
- Hope/expectations (**write expectations on flip chart to be referred back to during final group session**)

#### Session Content

##### 2.15pm Introduce Acceptance & Commitment Therapy

“ACT is a talking therapy which uses strategies to help people to notice thoughts and emotions without getting caught up in them. It helps individuals to explore what is important in their life and to behave in a way that is consistent with these values. During the next 4 group sessions we’re going to learn some skills called mindfulness skills that will help you to cope with painful thoughts and feelings far more effectively, in such a way that they have much less impact over you. We are also going to focus on putting your energy into doing things that improve your quality of life, things that are important to you, that you value.”

##### 2.20pm Focus on Mindfulness

Familiarise with concept of Mindfulness: Today we are going to focus on Mindfulness. Some of you may have already heard of it or already practiced it. Mindfulness is about being aware of the present moment, without judgement or worry for the past or the future, calmly and peacefully. It is...”

*“...a turning towards life... To live life as if each moment is important, as if each moment counted and could be worked with, even if it is a moment of pain, sadness, despair or fear.”* Jon Kabat-Zinn

“Our minds are natural problem solvers, and whilst at times it can be very helpful for our minds to be this way, for example when it rains it tells us to avoid getting wet by putting up our hood or using an umbrella, our minds can also spend a lot of time trying to find ways to avoid or get rid of unwanted thoughts or feelings. What might be the down side of getting caught up in trying to avoid thoughts or get rid of them? (Pause to allow for answers) When we get caught up in this kind of problem solving we are not being fully present and can therefore miss out on enjoying or appreciating life. **Use the door example, “what am I missing by standing on this side of the door, trying to keep it shut to avoid anything unpleasant/distressing/difficult?”**”

Practice being present: Mindful eating (M&Ms/fruit pastels). See Script 1

2.40pm Tea/coffee break

2.55pm Introducing ‘Passengers on the Bus’

“I’m wondering if we could take a moment to think of how ‘being present’ can apply to something that is probably quite familiar to most of us. If we think about a bus driver, let’s call him Fred. What does he need to do to drive the bus well? ... (Pause)... Concentrate on the road in front of him and use the mirrors to check behind, pay attention to other vehicles on the road, pedestrians, and signs on the road, actually drive the bus which involves changing gears, using the accelerator, clutch and brake, as well as pay attention to his passengers. This is the full breadth of his experience of driving the bus.” Allow time for answers.

“If Fred wasn’t ‘being present’, if he was only focussing on a dirty mark on his windscreen and nothing else that was going on around him, how effective would his driving be? Or if he was planning his dinner for that night, thinking about the house work he should have done the day before, what might he miss?”

“It’s important to note that being present doesn’t just refer to noticing only the pleasant things in life, but also accepting the presence of not so pleasant, difficult, or even distressing experiences. Mindfulness can be seen as an alternative to the on-going struggle to avoid difficult thoughts and emotions. It is important to not see it as giving in, but instead seeing it as a willingness to have all experiences and to live one’s life around these experiences.”

“One way that we can make contact with the present moment whilst allowing the presence of all experiences, pleasant and difficult, is by using something that we all have with us all of the time; our breath”.

3.05pm Contacting the Present Moment exercise with imaginal exposure to threat: See Script 2

### 3.20pm Homework:

- Do one activity mindfully & practise. Ask the participants to choose one in session and write it down on a post-it note so that they can place it somewhere that will remind them to do it. State that if they do not do it, simply notice that they don't do it, do not place a judgement on it.  
**Examples: brushing teeth, chopping vegetables/other food for dinner, eating a meal, washing hair, making a cup of tea, washing dishes, walking**
- Mindfulness of the Breath/Contacting the present moment with CD

Review session, participant's experience

Reiterate who to contact between sessions if required. Bring back any notes made about the between-session tasks.

### **Materials**

Flip chart / laptop / projector

Smarties/fruit pastels

Assessment measures

Hand-outs

CD

Travel expenses

Post-its

### **Script 1**

#### Mindfully Eating Smarties/fruit pastels (ACT Made Simple)

"Throughout this exercise, all sorts of thoughts and feelings will arise. Let them come and go, and keep your attention on the exercise. And whenever you notice that your attention has wandered, briefly note what distracted you, and then bring your attention back to the Smartie."

"Now take the Smartie, and observe it as if you're a curious scientist who has never seen a Smartie before... notice the shape and the colour... Notice the weight of it in your hand... and the feel of it against your fingers... notice its texture... now raise it to your nose and smell it... and now raise it to your mouth... notice the salivation... notice the urge to bite... and in a moment, don't do it yet, I'm going to ask you to bite it in half, keeping hold of one half and letting the other half drop onto your tongue."

“And so now, in ultra-slow motion, bite the Smartie in half, and notice what your teeth do... and let the Smartie sit there on your tongue for a moment... And I invite you to close your eyes now or fix them on a spot in front of you, to enhance the experience... and just notice any urges arising... and then gently explore the Smartie with your tongue, noticing the taste and texture... and now, in ultra-slow motion, eat the Smartie and notice what your teeth do... and your tongue... and your jaws... and notice the changing texture of the Smartie... and the sounds of chewing... and notice where you can taste the sweetness on your tongue... and when the urge to swallow the Smartie arises, just notice for a moment before acting on it... and when you do swallow it, notice the movement and the sound in your throat... and then notice where your tongue goes and what it does... and after you’ve swallowed the Smartie, take a moment to notice the way the taste gradually fades... but still faintly remains... and then, in your own time, eat the other half in any way you wish.”

### Debrief

“How was that experience?”

“What did you discover?”

“How do people usually eat Smarties?”

Relate to life in general: “life can be so much richer if when we spend more time paying attention to the present moment”

### **Script 2**

#### Contacting the Present Moment – Mindfulness of the Breath (ACT Made Simple)

“I invite you to find a comfortable position, and either close your eyes or keep them fixed on a spot in front of you... (short pause) notice any sounds you hear... (short pause) the feeling of chair on your back... (short pause) your feet against the floor...”(short pause)

“I invite you to bring your attention to your breathing. Imagine there is a balloon in your stomach, inflating with the in-breath and deflating with the out-breath, you might find it helpful to place your hand on your stomach to feel it rising and falling...” (10 second pause)

“Gently bring to mind a recent experience that may have upset you (short pause). It may have been something that happened recently or something that happened a while ago (short pause). As you allow thoughts about that experience come into your awareness, you might feel some tension in your body. Notice where you feel that tension (short pause). If that tension was a colour, what colour would it be? (Short pause) Notice any urges you might have to run away from these feelings, any sense of restlessness you might have, and see if you can be willing just to sit with it” (10 second pause)

"I invite you to bring your attention back to your breathing, notice your stomach moving in and out with each breath... notice the feeling of the chair against your back, your feet on the ground...become aware of any sounds you hear... in your mind's eye, imagine what the room will look like when you open your eyes (short pause). When you're ready, gently open your eyes if they are closed and settle back into the room. Take a moment to notice your surroundings..."

### Debrief

Explore participant's experience, are they willing to share with the group?

## Group Session 2

### **Mindful Acceptance**

Aims:

Acceptance & Defusion

### Recap ground rules

### Session Outline

2pm - Start with a short mindfulness exercise incorporating barriers they may have faced coming today (also acts as settling / grounding practice)

"We're going to do a short mindfulness exercise to help us to settle into today's session. I invite you to find a comfortable position in your chair, sit upright with your feet flat on the floor, your arms and legs uncrossed and your hands resting on your lap. Either close your eyes or fix your eyes on a spot in-front of you, whichever you prefer."

"Take a few deep breathes... Be aware of the air entering your lungs as you breathe in, and the air leaving your body as you breathe out, notice your stomach moving in and out with each breath (short pause)..."

"I now invite you to bring to mind something that may have made it difficult for you to come today, for example a negative thought about attending, a feeling of tiredness, or maybe you were rushing around trying to get here on time. See if you can just notice that thought or feeling for a moment... and take a moment to congratulate yourself on coming today, despite any barriers you may have come up against..."

"When you're ready, gradually bring your attention back to your breathing... notice your stomach moving in and out with each breath (short pause)... notice the feeling of the chair on your back, your feet on the ground...notice any sounds that you might hear (short pause)... in your mind's eye visualise how the room might look when you open your eyes, and when you're ready gently open your

eyes if they have been closed. Take a moment to notice your surroundings and settle back into the room...”

#### 2.05pm - Link content of session 1 with session 2

“Last week we focussed on contacting the present moment, how to let go of the ongoing struggle we may be experiencing and instead show a willingness to allow all experiences, including difficult and distressing thoughts and feelings. We asked you to choose one activity that you could do mindfully and gave you a CD of a mindfulness exercise. I’m wondering if anyone would like to share their experience? (if not, decide whether or not to share the activity I or co-facilitator chose)”

“Today we are going to spend some time exploring why difficult or distressing thoughts can very easily fill our minds and affect what we do in our daily lives. We will then talk about and practice some techniques that we can use to gain some distance from these difficult thoughts and reduce the effect they have on us.”

#### 2.15pm - Nature of our minds (leading on to fusion) – automatic thinking style

“Our minds very often have an automatic thinking style”, for example, if I say “Jack & Jill went up the...” (pause) “It’s raining cats and ...” (pause) “Humpty Dumpty sat on the ...” (pause) what do you notice your mind doing? Were you able to automatically complete the titles without really thinking about it?”

“Humans evaluate themselves all the time – more so than any other animal. The mind constantly makes evaluations, for example, “Am I good enough? Am I in danger?” and it makes comparisons, for example, “Am I as good as you? Am I stronger than you?” These comparisons can be quite painful. We might be tempted to try to turn them off. Sometimes we don’t want these painful thoughts going through our heads...”

“When you feel/are upset, what automatically comes into your mind?”

“Take a moment to think about a recent time that you were upset. How would you complete this sentence, “I am... ”? How about this sentence, “Other people think I am...”?”

“There’s actually a very good reason for why there is no shortage of negative thoughts in our minds...The human mind has evolved to think negatively. Let’s think back to our primitive ancestors, when people lived in caves, they lived in a world of constant danger – big animals with big teeth lurked around every corner. So back then, your mind had to constantly be on the lookout for danger, anticipating anything that could hurt you or harm you in any way. For example, “watch out, there could be a bear in that cave”. **What would have happened if our ancestors were not sensitive to threat?** Back then, if your mind didn’t warn you of danger, you wouldn’t have much of a chance of survival. This is what we have inherited from our ancestors, our minds are constantly trying to warn us of anything that could go wrong, for example, “you’ll screw up in the test”, “they

might reject you". This is normal, every mind does this. Our minds have evolved to think negatively, to protect us and keep us alive. Now this may be very useful in the short term, in specific situations, however how helpful is it to us in the long term? If we are caught up in thinking it all of the time?

2.25pm - Hands as Thoughts exercise See Script 3

2.40pm - Tea / coffee break

2.55pm - Fred and the Passengers

"Before the break we used our hands to signify difficult thoughts or feelings, and holding them right up close to our faces was an example of how getting caught up in or hooked by our thoughts can affect how we engage with the world around us. By gaining some distance from them, we are not allowing them to define us; instead we are showing a willingness to have them with us as we go about our day."

"Remember Fred the bus driver? Last week we discussed how important it is for him to be in contact with the present moment so that he can effectively and safely drive the bus, and we explored what could happen if he gets caught up in thoughts about the past or the future. What if the passengers that Fred has on his bus are his thoughts, for example one may be, "I'm not a good enough driver", what are the consequences of Fred getting caught up in that thought? If he keeps going over and over it, again and again, or he keeps trying to struggle with it, to throw it off the bus even though the more he tries the stronger the thought gets, what is he missing by being hooked by this thought?"

Passengers on the Bus hand-out

"Imagine that you are the bus driver and the passengers on your bus are your difficult thoughts, distressing memories, hurtful feelings. If you can remember the thought that came into your mind earlier on today, the one starting "I am..." or "others think I am..." I invite you to write it down, or another one that you feel you regularly struggle with, into one of the speech bubbles. This passenger is very good at hooking you, causing you to miss out on the here and now, stopping you from doing things that are important to you... Something interesting to note is that the simple process of writing down the difficult thought or feeling is a way of unhooking or distancing yourself from it"

3.05pm - Bubble wand exercise See Script 4

Defusion technique linking in with between-session task

"As mentioned before when we were writing our thoughts into the speech bubbles, simply writing thoughts down is a way to 'unhook' from them. Let's try doing something more to the thought once it is written down. You each have a piece of card there; I invite you to write down your thought on the card (pause). Now start a new line, and write "I'm having the thought that..." (pause), and then start a third line with, "I notice I'm having the thought that...". Now take a

moment to read the third line back to yourself and see if there are any differences to how line one and line three make you feel (pause). I wonder if anyone would like to share anything they noticed?" **Example on the flip chart**

3.20pm – Homework & review:

- Notice each time you become 'hooked' by your thoughts. If you manage to 'unhook', how did you do it? If you can, complete some more of your passenger's speech bubbles and bring back to next week's session.
- Practise 'Bubble Wand'

Review session 2, participant's experiences

### **Materials**

Flip chart sheet with group rules / laptop / projector

Hand-outs

Flip chart with example of Defusion technique

Pieces of card for Defusion technique

CD

Travel expenses

**Tea/coffee/water/biscuits**

### **Script 3**

Hands as Thoughts (ACT Made Simple, adapted)

"Imagine for a moment that your hands are your thoughts. I invite you to hold your hands together; palms open as if they're the pages of an open book. Now slowly and steadily raise your hands up toward your face. Keep going until they're covering your eyes. Then take a few seconds to look at the world around you through the gaps in between your fingers and notice how this affects your view of the world"

"Take a moment to think about what it would be like going around all day with your hands covering your eyes in this way. How much would it limit you? How much would you miss out on? How would it reduce your ability to respond to the world around you? This is like being hooked by your thoughts, we can become so caught up in our thoughts that we lose contact with many aspects of our present moment experience, and our thoughts have such a huge influence over our behaviour that our ability to act effectively is significantly reduced."

"I now invite you to lower your hands from your eyes very, very slowly. As the distance between your hands and your face increases, notice how much easier it

is to connect with the world around you. By doing this you are gaining some distance from your thoughts and feelings, unhooking from them. How much easier is it engage with the world around you without your hands covering your eyes? How much more information can you take in? How much more connected are you with the world around you?

#### **Script 4**

##### Bubble Wand Script

“Try to find a comfortable position in a chair, sit upright with your feet flat on the floor, your arms and legs uncrossed and your hands resting on your lap. Either close your eyes or fix your eyes on a spot in-front of you, whichever you prefer.”

“Close your eyes and take a few deep breathes... Be aware of the air entering your lungs as you breathe in, and the air leaving your body as you breathe out, notice your stomach moving in and out with each breath... Allow yourself to rest without drifting off to sleep”

“Now take a moment to bring into your awareness a recent time when you were upset. Perhaps it is a situation you have found yourself in recently... Really work to bring this experience into your full awareness... Make it as real as possible... As you work to visualise this situation, you may notice a wave of unpleasant changes sweeping over your body and your mind... As you notice any of these changes see if you can, with kindness, gently sit with those experiences...”

“As you remember the situation that has upset you, notice what automatically comes into your mind... How might you complete the following sentences...? *I am...? Or other people think I am...?* Notice the evaluations that your mind is giving you about how you were in this situation that upset you...”

“Now we want to go more deeply into this experience. Imagine you have a large bubble wand, like the kind children sometimes play with... Go ahead and fill the wand with bubble soap... Then, take your bubble wand and sweep it through your thought, trap the thought in a giant bubble... Then watch it as it slowly drifts upwards in the gentle breeze... There it goes, drifting higher and higher... keep watching as it drifts out of sight, and then take a few slow, deep breathes being aware of the air coming into your lungs as you breath in, and the air leaving your body as you breath out.”

“Now, for the next few minutes, take each thought that pops into your head, sweep the bubble wand through it, trap the thought in a giant bubble, label it and watch it drift upwards in the gentle breeze... there goes that thought... keep watching the bubbles, one by one, float higher and higher, until they are out of sight... Allow each bubble to float away at its own speed. There's no need to speed it up, allow it to float away in its own good time (pause)... there's no urgency, no need to force the bubbles away...”

“As you participate in this exercise, difficult feelings might arise, such as boredom or impatience, it's OK to acknowledge those feelings. Say to yourself, *there's a*

*feeling of boredom, or, there's a feeling of impatience.* Then sweep the bubble wand through it and watch the bubble float away... higher and higher..."

"When you're ready, gradually bring your attention back to your breathing... notice your stomach moving in and out with each breath... notice the feeling of the chair on your back, your feet on the ground...notice any sounds that you might hear... in your mind's eye visualise how the room might look when you open your eye, and when you're ready gently open your eyes if they have been closed. Take a moment to notice your surroundings and settle back into the room..."

### Group Session 3

#### **Values & Committed Action**

Aims:

Experiential Avoidance

Values

#### Recap ground rules

#### Session content

#### 2pm Start with a short mindfulness exercise

"We're going to do a short mindfulness exercise to help us to settle into today's session. I invite you to find a comfortable position in your chair, sit upright with your feet flat on the floor, your arms and legs uncrossed and your hands resting on your lap. Either close your eyes or fix your eyes on a spot in-front of you, whichever you prefer."

"Take a few deep breathes... Be aware of the air entering your lungs as you breathe in, and the air leaving your body as you breathe out, notice your stomach moving in and out with each breath (short pause)..."

"I now invite you to bring to mind something that may have made it difficult for you to come today, for example a negative thought about attending, a feeling of tiredness, or maybe you were rushing around trying to get here on time. See if you can just notice that thought or feeling for a moment... and take a moment to congratulate yourself on coming today, despite any barriers you may have come up against..."

"When you're ready, gradually bring your attention back to your breathing... notice your stomach moving in and out with each breath (short pause)... notice the feeling of the chair on your back, your feet on the ground...notice any sounds that you might hear (short pause)... in your mind's eye visualise how the room might look when you open your eyes, and when you're ready gently open your

eyes if they have been closed. Take a moment to notice your surroundings and settle back into the room...”

#### 2.05pm Link content of session 2 to session 3

“Last week we talked about being hooked by our difficult thoughts or feelings, and that by being caught up with them, it is difficult for us to meaningfully engage or interact with our environment, and we may miss something that is important to us. In-between sessions you were asked to notice each time you were hooked by a thought or feeling, and if you managed to unhook from it, notice how you did it. Did you manage to practice the “I notice I’m having the thought that...” technique? You were also asked to practice the ‘Bubble-Wand’ exercise. How did you find the exercise?”

#### 2.15pm Linking trauma experiences with avoidance, leading into values

“Today we are going to focus on the effect of distressing experiences and avoidance on how we live our lives. Firstly, let’s spend some time thinking about the effect of distressing experiences. The sudden and unwelcomed nature of such experiences, and/or feared outcomes associated with them, can lead to avoidance behaviour. What do you think this avoidance may cause?” **Wait for answers.**

“An individual can become hooked by the content of their thoughts and feelings, which in turn can guide choice and action. If you are hooked by your difficult thoughts and feelings, what do you think can this do?” **Wait for answers.**

Acknowledging the important role that threat did play in the participant’s lives.  
Hand out the Chinese finger cuffs: “You now each have a Chinese finger cuff. I invite you to place your index fingers into either side of it like this (demonstrate). Try to pull your fingers out, play about with it for a while... Have a think about what you notice.”

“At one point in a person’s life, avoidance of certain situations may help people to feel safe, however if the threat is no longer there then what will the avoidance do? **Pause to allow for answers.** Avoidance will no longer be serving the same function and it may cause the individual to miss opportunities to engage in meaningful, enjoyable activities. If we choose to stop struggling with our difficult thoughts and feelings, be willing to have them as a part of us instead of trying to pull away from them, maybe we can learn to have them with us whilst we move towards what we value in life.”

Flip chart: explore what is avoided and the costs and benefits of doing so, using the following headings: **Have an example prepared**

Threat What they do ST consequences LT consequences Workability  
(High or Low)

Acknowledge possible feelings of loss that may arise when linking suffering with values. “It may feel as though you have been struggling with your suffering for so long that you have missed out on living according to your values, what is important to you. Therefore, it is not unusual to experience feelings of sadness or loss when you begin to let go of the struggle.”

2.45pm Tea & coffee break

3pm Familiarise with concept of values (difference between values and goals)

“Before the break we made a list of what is being avoided and the consequences of this avoidance (gesture towards the flip chart). We can spend so much time trying to move away from our suffering instead of focussing on moving in our valued life direction. Maybe our suffering is telling us something important; maybe our suffering is a window through which we can see our values. I find it quite helpful to think of values as a sat-nav. **Put picture on power point slide and ask “what does a sat nav do? Help us with?”**

“A sat-nav gives us direction and keeps us on track when we’re travelling. As we move forward there may hazards to be aware of – speed cameras, one way streets – just like as we move forward towards our valued life direction there may be challenges to negotiate.”

“Our values do the same for the journey of life. We use them to choose the direction in which we want to move and to keep us on track as we go. Whereas a goal is something that we set and we work towards, a value guides us through life in an on-going way. For example, if the goal is be to stop smoking, the value is about living a healthier lifestyle. I wonder if you can take a moment to consider what has been motivating you to come to this group, take part in this research. Think about the value underlying the motivation...” **Invite participants to share their value.** “I invite you to write your value down on your ‘Passengers on the Bus’ hand out, if you don’t have it with you, write it down on your hand-outs and see if you can fill in the value bubble when you get home.”

“Let’s take a moment to think about Fred driving his bus with his passengers, his difficult thoughts and feelings, on board. He is driving his bus in his valued-life direction. A value of his may be to do his job well. However, if Fred is continuously struggling with his passengers, for example always taking his eyes off the road to look at his passengers in the rear-view mirror, constantly stopping the bus because they are telling him, “you’re a rubbish driver”, “you should never have become a bus driver”, what will this mean for him? What will this do? **Pause to allow for answers – conduct cost/benefit analysis with suggestions.** This will stop him from doing his job well, from looking in his valued-life direction. If Fred is able to get some distance from his passengers, maybe by simply noticing that they are thoughts and feelings, nothing more, and changing the way he reacts to them, maybe he can find a way to be willing to have them with him and take them on his journey...”

3.20pm Between-session tasks:

- Between now and next week, notice behaviours that are moving away from suffering and behaviours that are moving towards values. Notice if you are arguing with your passengers or looking in your valued life direction. You each have a sheet in case you would like to take a note of anything.
- Continue practice of mindfulness exercises. Use the practice sheet to note down which exercise you do and any thoughts or feelings you experience.
- Review session 3, participant's experiences

### **Materials**

Flip chart sheet with house rules / laptop / projector

Flip chart sheet already prepped for costs & benefits exercise

Hand-outs

Spare 'Passengers on the Bus' hand-out

Chinese finger cuffs

Travel expenses

**Tea/coffee/water/biscuits**

## Group Session 4

### **Values & Committed Action**

Aims:

Values & Goals

Recap ground rules (maybe not as prominent as other sessions as participants will be familiar with them)

### Session content

2pm - Start with a short mindfulness exercise incorporating barriers they may have faced coming today

"We're going to do a short mindfulness exercise to help us to settle into today's session. I invite you to find a comfortable position in your chair, sit upright with your feet flat on the floor, your arms and legs uncrossed and your hands resting on your lap. Either close your eyes or fix your eyes on a spot in-front of you, whichever you prefer."

"Take a few deep breathes... Be aware of the air entering your lungs as you breathe in, and the air leaving your body as you breathe out, notice your stomach moving in and out with each breath (short pause)..."

“I now invite you to bring to mind something that may have made it difficult for you to come today, for example a negative thought about attending, a feeling of tiredness, or maybe you were rushing around trying to get here on time. See if you can just notice that thought or feeling for a moment... and take a moment to congratulate yourself on coming today, despite any barriers you may have come up against...”

“When you’re ready, gradually bring your attention back to your breathing... notice your stomach moving in and out with each breath (short pause)... notice the feeling of the chair on your back, your feet on the ground...notice any sounds that you might hear (short pause)... in your mind’s eye visualise how the room might look when you open your eyes, and when you’re ready gently open your eyes if they have been closed. Take a moment to notice your surroundings and settle back into the room...”

#### 2.05pm – Review of last session and between-session tasks

“Last week we explored the difference between spending time and energy arguing with the passengers on the bus and spending time and energy moving in our valued-life direction. We differentiated values from goals, and compared values to a sat-nav. **In what way did we say our values and a sat-nav are similar? (allow time for answers)**

“Between last week and this week, you were asked to notice behaviours that were moving away from suffering, if you were arguing with your passengers/ getting caught up in them, putting a lot of energy into moving away from your suffering and engaging in the struggle, and those that were moving towards your values, where you were looking in your valued life direction. How did you get on with this? (Pause for answers) How have you been getting on with your mindfulness practice?”

“Today in our last group session we are going to spend time talking about what we can do in order to live by our values, and then we will bring everything from the last 3 sessions together. We will also invite you to complete the questionnaires that you completed at the start of the first group.”

#### 2.10pm – SMART

“We may be able to identify what it is that we do value in life but sometimes it can be difficult to know what to do in order to live by our values. The value is the direction in which we want to travel, it guides us on our journey, but we need to set some markers, some goals, to actually get anywhere. This is where committed action comes in, which means taking effective, meaningful action guided by our values.”

“To help with our committed action, we can set values-based goals. We don’t want to set goals that are too big, goals that we have a high chance of failing to achieve. So it is important to set goals that are SMART” **(have example pre-written on flipchart):**

**S = Specific:** Specify the action you will take – when and where you will do so, and who or what is involved. For example, this is a vague or non-specific goal: “I will spend more time with my kids”, whereas this is a specific goal: “I will take the kids to the park on Saturday afternoon to play football.”

**M = Meaningful:** If this goal is genuinely guided by your values as opposed to following a rigid rule, trying to please others, or trying to avoid some pain, then it will be personally meaningful. If it lacks a sense of meaning or purpose, check in and see if it is really guided by your values.

**A = Adaptive:** Does the goal help you to head in a direction that, as far as you can predict, is likely to improve, enrich, or enhance your quality of life?

**R = Realistic:** The goal should be realistically achievable. Take into account your health, competing demands on your time, financial status, and whether you have the skills to achieve it.

**T = Time-framed:** To increase the specificity of your goal, set a day, date and time for it. If this isn't possible, set as accurate a time frame as you possibly can.

“In our individual sessions, we will spend time thinking about short-term and long-term values-based goals, however I'd like you to take a moment to think of an immediate goal, something small, simple, and easy that you can do in the next twenty-four hours and write it down on this piece of paper / post-it” (invite participants to share their goal and give an example of one if they struggle)

2.25pm - Bring 'Passengers on the Bus' alive, invite one of the participants to act as the bus driver, if not ask the co-facilitator. The participants can then be the passengers.

“During the first 3 group sessions we discussed Fred the bus driver. We talked about the benefits of Fred being present whilst driving the bus, and how he can develop a willingness to allow his passengers to stay instead of continuously struggling with them so that he can travel in his valued-life direction. Along the way we've been asking you to think about being the bus driver and driving your bus in your valued-life direction, practicing increasing your contact with the present moment, identifying your passengers (difficult thoughts and emotions) and developing a willingness to have them in your life by learning how to simply notice them instead of interact with them and struggle with them. I'm wondering if one of you would like to share your experience as the bus driver. Share with us one of your values, maybe the one that has been motivating you drive your bus to this group, and the different passengers that you have on your bus? The rest of us can act as the passengers and you can practice how to react to them.” **If no one is keen to participate, one of the facilitators can be the bus driver. Practice 'being caught up' and 'allowing'...** Explore experiences.

2.55pm - Tea & coffee break

### 3.10pm - Reflect on the 4 group sessions

Summarise all 4 sessions. Refer back to expectations shared in session 1 (**have flipchart sheet from session 1**). See if participants will share opinions and main things they are taking away from the group.

Share this quote: "*It is never too late to be what you might have been*" George Elliot (19<sup>th</sup>-century British writer) **Slide and hand-out.**

Between –session tasks:

- "Between now and your individual sessions, think about one or two areas in your life that you would like to focus on. To help with this you could maybe choose from this list provided in your hand-outs (**have on slide**): Work, Health, Education, Social, Parenting, Relationships, Family, Finding meaning, Community, Environment, Leisure, Hopes. Please bring the sheet to individual session."
- Continue practice of mindfulness exercises.

#### **Materials**

Flip chart sheet with house rules / laptop / projector

Flip chart sheet with SMART goal example

Slide for SMART goals.

Hand-outs

Post-its

Flip chart sheet with expectations from session 1

Travel expenses

Tea/coffee/water/biscuits

#### **Assessment measures**

## **Appendix 6** *Participant Information Sheet*



Mental Health & Wellbeing  
Administration Building  
Gartnavel Royal Hospital  
1055 Great Western Road  
Glasgow  
G12 0XH

# A feasibility study of Acceptance and Commitment Therapy for recovery from Complex Trauma

## **Information Sheet**

We would like to invite you to take part in a research study which is being undertaken as an educational project. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish. Ask us if there is anything that is not clear or if you would like more information.

### **Who is conducting the research?**

The research is being carried out by Jen Megson from the University of Glasgow and the NHS Greater Glasgow & Clyde Trauma Service, Dr Ross White from the University of Glasgow, and Dr Lisa Reynolds from the NHS Greater Glasgow & Clyde (GG&C) Trauma Service.

### **What is the purpose of the study?**

The purpose of this study is to find out if an Acceptance and Commitment Therapy intervention is suitable for those who have suffered complex trauma and are nearing the end of their treatment with the GG&C Trauma Service.

Acceptance and Commitment Therapy (ACT) is a therapy that uses strategies to help people to notice and accept thoughts and emotions without getting caught up in them. ACT helps individuals to explore what they value in life and to help people to behave in a way that is consistent with these values.

People who have a history of complex trauma may end up feeling disconnected from their community and confused about their identity and values, even when the many other difficulties that they may have been addressing in treatment have been resolved or are more manageable, such as low self-esteem, depression, anxiety, post-traumatic stress disorder, difficulty managing intense emotions, and relationship difficulties. Because of this, we think that ACT may be a useful intervention for those who are nearing the end of their treatment in the GG&C Trauma service.

### **Why have I been invited?**

You have been invited to take part in this study because you are in the final phase of your treatment in the Greater Glasgow & Clyde Trauma Service.

### **Do I have to take part?**

No, 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. This will not affect the care you are currently receiving or any of your future treatment.

### **What does taking part involve?**

If you agree to take part, you will get the opportunity to participate in the ACT intervention. You will be asked to complete five short questionnaires with a member of the team at two different time points: at the start and

middle of the study and six short questionnaires at a third time point; at the end of the study.

You will be asked to complete the first set of questionnaires and then to attend four ACT group sessions which will be held once a week for four weeks and will be led by the main researcher and a member of the team. The group sessions will involve talking about what you value in life and what you can do to behave in a way that is in line with those values. They also involve practicing different exercises that will aim to help you to handle difficult thoughts and feelings that you may be experiencing. Once you have attended all four group sessions, you will be asked to complete the second set of questionnaires. You will then be asked to attend two individual sessions with the main researcher to discuss what you experienced in the group sessions, the first session will happen the week following the last group and the second session two weeks later. Finally, you will be asked to complete the third set of questionnaires. Altogether, the assessment phases; group intervention and individual sessions will take seven weeks.

Your GP will be informed of your participation at the beginning and end of the study. The lead researcher will require access to your case notes in order to record your attendance at the group and individual sessions.

Travel expenses will be provided for your travel to and from the site of the research.

### **What happens to the information?**

Your identity and personal information will be completely confidential and known only to the researchers and clinical team at the GG&C Trauma Service. The information obtained will remain confidential and stored within a locked filing cabinet. 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.

## **What are the possible disadvantages and risks of taking part?**

When filling out the questionnaires, difficult thoughts or feelings may arise when thinking of the answers. Similarly, you may experience some emotional distress when you are thinking of your life values and learning different ways to handle your difficult thoughts and feelings. If you do express feelings or thoughts of suicide it will be the responsibility of the researcher to inform a member of the GG&C Trauma Service clinical team so that you receive the appropriate support.

## **What are the possible benefits of taking part?**

It is hoped that by taking part in this research, you will be able to find out how to do things in your day-to-day life that support your values, what you feel is important to you, and learn different ways to cope with difficult thoughts and feelings that you can use in your daily life. Also, you will be providing valuable information regarding the usefulness of this intervention and if it is found to be useful, it will be offered to others.

## **Who has reviewed the study?**

This study has been reviewed by the West of Scotland Research Ethics Committee 3.

## **What will happen to the results of the research study?**

The results of this study will form part of a student dissertation at the University of Glasgow that will be marked. They may also be published in a peer-reviewed journal or presented at conferences. All results will be anonymised so you will not be identified in any report/publication.

## **If you have any further questions?**

We will give you a copy of the information sheet and signed consent form to keep. Please contact the main researcher (Jen Megson) for further

information. If you would like more information about the study and wish to speak to someone **not** closely linked to the study, please contact Professor Andrew Gumley (Research Advisor). Please find contact details below.

### **Contacts:**

Jen Megson, Trainee Clinical Psychologist & Main Researcher

Phone number: 0141 232 0114

Email address: [j.megson.1@research.gla.ac.uk](mailto:j.megson.1@research.gla.ac.uk)

Dr Ross White, University Teacher/Clinical Psychologist – Academic Supervisor

Phone number: 0141 211 3905

Email address: [Ross.White@glasgow.ac.uk](mailto:Ross.White@glasgow.ac.uk)

Dr Lisa Reynolds, Professional Lead – Field Supervisor

Phone number: 0141 232 0114

Email address: [Lisa.Reynolds@ggc.scot.nhs.uk](mailto:Lisa.Reynolds@ggc.scot.nhs.uk)

Professor Andrew Gumley - Research Advisor

Phone number: 0141 211 3939

Email address: [Andrew.Gumley@glasgow.ac.uk](mailto:Andrew.Gumley@glasgow.ac.uk)

### **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 main researcher in the first instance or one of her supervisors but the NHS complaints system is also available to you by telephone on: 0141 201 4500 or by email at:

[complaints@ggc.scot.nhs.uk](mailto:complaints@ggc.scot.nhs.uk)

*Thank you for your time and co-operation*

**Appendix 7 Participant Consent Form**



Mental Health & Wellbeing  
Administration Building  
Gartnavel Royal Hospital  
1055 Great Western Road  
Glasgow  
G12 0XH

Participant number:

**A feasibility study of Acceptance and Commitment Therapy for recovery from Complex Trauma**

**Consent Form**

**Please initial each box**

I confirm that I have read and understand the information sheet  
Dated \_\_\_\_\_ for the above study and have had the opportunity to ask  
questions.

I understand that my participation is voluntary and that I am free to  
withdraw at any time, without giving any reason, without my care or legal  
rights being affected.

I understand members of the research team will have access to the  
study data.

I understand that my GP will be contacted to inform them of my  
participation in and outcome of the study.

I understand that relevant sections of my care record and data  
collected during the study may be looked at by responsible individuals from the  
sponsor or host organisation or from regulatory authorities where it is relevant to  
taking part in this research.

I agree to take part in the above study.

-----  
Name of Participant

-----  
Date

-----  
Signature

-----  
Name of Researcher

-----  
Date

-----  
Signature

**1 copy to the participant, 1 copy to the researcher, 1 original for the participant's case-notes**

## **Appendix 8** *Clinical cut-off and RCI methods*

$$Cutoff = \frac{(S_1 \times X_2) + (S_2 \times X_1)}{S_1 + S_2}$$

Where  $X_1$ ,  $S_1$ ,  $X_2$ ,  $S_2$  specify the means and standard deviations of the participants with psychosis and a normative sample respectively.

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

Where  $X_1$  = baseline score;  $X_2$  = 3-month post-baseline score;  $S_1$  = the standard deviation at baseline; and  $r_{xx}$  = the test-retest reliability.

## Appendix 9 Clinician Participant Information Sheet



Mental Health & Wellbeing  
Administration Building  
Gartnavel Royal Hospital  
1055 Great Western Road  
Glasgow  
G12 0XH

### A feasibility study of Acceptance and Commitment Therapy for recovery from Complex Trauma

#### Information Sheet

We would like to invite you to take part in a research study which is being undertaken as an educational project. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish. Ask us if there is anything that is not clear or if you would like more information.

#### **Who is conducting the research?**

The research is being carried out by Jen Megson from the University of Glasgow and the NHS Greater Glasgow & Clyde Trauma Service, Dr Ross White from the University of Glasgow, and Dr Lisa Reynolds from the NHS Greater Glasgow & Clyde (GG&C) Trauma Service.

#### **What is the purpose of the study?**

The purpose of this study is to find out if an Acceptance and Commitment Therapy intervention is suitable for those who have suffered complex trauma and are nearing the end of their treatment with the GG&C Trauma Service.

Acceptance and Commitment Therapy (ACT) is a therapy that uses strategies to help people to notice and accept thoughts and emotions without getting caught up in them. ACT helps individuals to explore what they value in life and to help people to behave in a way that is consistent with these values.

People who have a history of complex trauma may end up feeling disconnected from their community and confused about their identity and values, even when the many other difficulties that they may have been addressing in treatment have been resolved or are more manageable, such as low self-esteem, depression, anxiety, post-traumatic stress disorder, difficulty managing intense emotions, and relationship difficulties. Because of this, we think that ACT may be a useful intervention for those who are nearing the end of their treatment in the GG&C Trauma service.

### **Why have I been invited?**

You have been invited to take part in this study because you are a clinician in the Greater Glasgow & Clyde Trauma Service working with service users who will potentially meet the inclusion criteria for this study, and your professional opinion regarding the ACT intervention will inform the outcome of this study.

### **Do I have to take part?**

No, 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 taking part involve?**

If you agree to take part, you will be asked to participate in an audio-recorded interview which will take no longer than 30 minutes. The information from the interview will be used to add meaning to the data obtained from the service users who participate in this study and to help plan the next stage of the research.

### **What happens to the information?**

Your identity and personal information will be completely confidential and known only to the researchers. The information obtained will remain confidential and stored laptop computer encrypted to NHS GG&C specifications accessible only to the Chief Investigator and main researcher. 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.

### **What are the possible disadvantages and risks of taking part?**

You will be required to provide 30 minutes of your time to participating in the interview. There are no identified risks to taking part.

### **What are the possible benefits of taking part?**

It is hoped that by taking part in this research, you will be able to add meaning to the data obtained from the service users who participate in this study, and help to provide an understanding of any barriers that the study may be faced with. As a result, it is hoped that your participation will help to plan future research in the GG&C Trauma Service and ACT community.

### **Who has reviewed the study?**

This study has been reviewed by the West of Scotland Research Ethics Committee 3.

### **What will happen to the results of the research study?**

The results of this study will form part of a student dissertation at the University of Glasgow that will be marked. They may also be published in a peer-reviewed journal or presented at conferences. All results will be anonymised so you will not be identified in any report/publication.

### **If you have any further questions?**

We will give you a copy of the information sheet and signed consent form to keep. Please contact the main researcher (Jen Megson) for further information. If you would like more information about the study and wish to speak to someone **not** closely linked to the study, please contact Professor Andrew Gumley (Research Advisor). Please find contact details below.

### **Contacts:**

Jen Megson, Trainee Clinical Psychologist & Main Researcher

Phone number: 0141 232 0114

Email address: [j.megson.1@research.gla.ac.uk](mailto:j.megson.1@research.gla.ac.uk)

Dr Ross White, University Teacher/Clinical Psychologist – Academic Supervisor

Phone number: 0141 211 3905

Email address: [Ross.White@glasgow.ac.uk](mailto:Ross.White@glasgow.ac.uk)

Dr Lisa Reynolds, Professional Lead – Field Supervisor

Phone number: 0141 232 0114

Email address: [Lisa.Reynolds@ggc.scot.nhs.uk](mailto:Lisa.Reynolds@ggc.scot.nhs.uk)

Professor Andrew Gumley - Research Advisor

Phone number: 0141 211 3939

Email address: [Andrew.Gumley@glasgow.ac.uk](mailto:Andrew.Gumley@glasgow.ac.uk)

### **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 main researcher in the first instance or one of her supervisors but the NHS complaints system is also available to you by telephone on: 0141 201 4500 or by email at:

[complaints@ggc.scot.nhs.uk](mailto:complaints@ggc.scot.nhs.uk)

*Thank you for your time and co-operation*

## Appendix 10 Interview Schedule



Mental Health & Wellbeing  
Administration Building  
Gartnavel Royal Hospital  
1055 Great Western Road  
Glasgow  
G12 0XH

A feasibility study of Acceptance and Commitment Therapy for recovery from  
Complex Trauma

Interview Schedule for clinicians of the GG&C Trauma Service

1. Clinicians experiences of the study
  - a. Were you able to refer individuals to the study?
  - b. If yes, what helped recruitment?
  - c. In your opinion, what hindered recruitment?
  
2. ACT as a Phase 3 intervention
  - a. How much do you know about ACT?
  - b. How suitable is ACT as a Phase 3 intervention?
  - c. What challenges might service users face when transitioning between Phase 2 and Phase 3?
  
3. Hopes/vision for the future of Phase 3 interventions
  - a. What are your hopes/is your vision for the future of Phase 3 interventions?
  - b. How might service users be better engaged in Phase 3 interventions?

Any other comments?

**Appendix 11 Clinician Participant Consent Form**



Mental Health & Wellbeing  
Administration Building  
Gartnavel Royal Hospital  
1055 Great Western Road  
Glasgow  
G12 0XH

Clinician participant number:

**A feasibility study of Acceptance and Commitment Therapy for recovery from Complex Trauma**

**Consent Form**

**Please initial each box**

I confirm that I have read and understand the information sheet dated \_\_\_\_\_ for the above study and have had the opportunity to ask questions.

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, legal rights being affected.

I understand members of the research team will have access to the study data.

I understand that the interview will be audio-recorded.

I understand that data collected during the study may be looked at by responsible individuals from the sponsor or host organisation or from regulatory authorities where it is relevant to taking part in this research.

I agree to take part in the above study.

-----  
Name of Clinician participant                      Date                      Signature

-----  
Name of Researcher                      Date                      Signature

**1 copy to the participant, 1 copy to the researcher, 1 original for the participant's case-notes**

## Appendix 12 Charts of quotes taken from the interviews

### Chart 1

Category	1. Clinicians experiences of the study	
Sub-category	1.1 What helped recruitment	1.2 What hindered recruitment
Clinician 1	All the information that you sent through beforehand... (line 7, p. 1) Completing the 2 mornings of ACT training... (lines 9 & 10, p. 1)	Timing... there was only a couple of people on my case load who I felt would be able to engage with the group... (lines 14 & 15, p. 1)
Clinician 2	I think the stage people were at (line 7, p. 1)... If you were close to discharging someone... the group fitted really nicely (lines 8, 9, & 10 p. 1)	They didn't like the idea of going somewhere different and the idea of starting a new thing... (lines 18 & 19, p. 1) The group element... maybe felt a bit too much for some people. (Lines 21 & 22, p. 1)
Clinician 3	Rather than looking at a list of criteria, I thought "what does this woman need at this point in her life and what would be a useful intervention for her?" (Lines 31, p. 1)	I actually found it quite difficult to find clients that I thought would fit with your criteria... (line 4, p. 1) The fact that it was labelled as 'Phase 3'... (line 41, p. 2)
Clinician 4	Knowing there was a clear, a contact person, to contact to refer... (line 7, p. 1) You having come and spoken about the study... and having emailed us the info so it was there... (lines 7 & 8, p. 1)	We had run a group in the previous year...some clients had been to that and they had had mixed experiences and I felt it wasn't appropriate for them, that it wasn't appropriate to ask them to attend another group... (lines 17, 18, & 19, p. 1)

**Appendix 12** *continued*

*Chart 1 continued*

Category	1. Clinicians experiences of the study	
Sub-category	1.1 What helped recruitment	1.2 What hindered recruitment
Clinician 5	Aims were clearly laid out and explained... (lines 11 & 12, p. 1)	With my case load it was timing, I just wasn't quite at Phase 3 with some... (line 16, p. 1) With the males I had in mind, I don't know if females might have found it difficult. (Lines 18 & 19, p. 1)
Clinician 6	Reminders... (line 12, p. 1) Having people at the appropriate stage I guess... (lines 14 & 15)	I felt some people said they would do it, but they had no intention of ever doing it, and I don't know if it was just a people pleasing... (lines 32 & 33, p. 1)
Clinician 7	I was given clear information... (line 7, p. 1) I think the training that the service received helped me identify people... (lines 7 & 8, p. 1) My own personal reading... (line 9, p. 1)	It was quite difficult to find people who were at Phase 3... I think a lot of the people that I'm seeing are mainly Phase 1 and 2... (lines 13 & 14, p. 1)

**Appendix 12** *continued*

*Chart 2*

Category	2. ACT as a Phase 3 intervention		
Sub-category	2.1 Knowledge of ACT	2.2 Suitability of ACT in Phase 3	2.3 Challenge of transitioning between Phase 2 and Phase 3
Clinician 1	I done a bit of reading... the training... and the info you sent... (line 26, p. 1)	I think it is suitable... (line 29, p. 1) The values part feels really important... (line 39, page 2) I'm wondering if there's scope for it to be used... ( <i>in other phases</i> ) other than solely being a Phase 3 ( <i>intervention</i> ) (lines 40 & 41)	There's something about confidence at being discharged... (line 44, p. 2) Moving on from the relationship with the therapist... I know that as therapists we can feed into that as well ok? (Line 45 & 46, p. 2) I think the main difficulty is discharge... (lines 55 & 56, p. 2)
Clinician 2	I feel like I know quite a bit, a reasonable amount... (line 26, p. 1)	I think it's really suitable. (Line 30, p. 1) Talking about values fits really well with Phase 3 (line 30, p. 1)	Anxiety about moving to Phase 3... (line 36, p. 2) Moving forwards felt scary... (line 39, p. 2) <i>We (clinician)</i> can have our own anxiety about that too (line 40, p. 2)

**Appendix 12 continued**

*Chart 2 continued*

Category	2. ACT as a Phase 3 intervention		
Sub-category	2.1 Knowledge of ACT	2.2 Suitability of ACT in Phase 3	2.3 Challenge of transitioning between Phase 2 and Phase 3
Clinician 3	I've had some training... (line 48, p. 2)	As an intervention for the trauma client group I think it's really valuable... (line 51, p. 2) I think it should thread right through ( <i>therapy</i> )... (lines 54 & 55, p. 2) I think it's something we should be doing throughout, and not limit it. (Lines 59 & 60, pg. 2)	I think it's more structure in clinician's minds... (lines 63 & 64, pg. 2) I think by trying to impose this Phase 1, 2, 3, we are creating an artificial reality... (line 67, p. 2) I think maybe what is needed, is a bit more definition around what stage 3 should involve. (Lines 72 & 73, pg. 2)
Clinician 4	A reasonable amount. (Line 23, p. 1) I've been on a couple of training days... done an e-course... (lines 23 & 24)	I think it is ( <i>suitable</i> ) particularly by that Phase... (line 28, p. 1) I think ACT is a very good framework. (Line 31, p. 1) I also think it could be used in Phase 1... (lines 31 & 32, p. 1)	It depends on the relationship that they've developed with you and they're scared if therapy's coming to an end... (lines 38 & 39, p. 2) A lot of people we see...they've been damaged within relationships and relationships are difficult for them... it might be difficult making that transition... (lines 41, 42, & 44, & 45, p. 2)

**Appendix 12** *continued*

*Chart 2 continued*

Category	2. ACT as a Phase 3 intervention		
Sub-category	2.1 Knowledge of ACT	2.2 Suitability of ACT in Phase 3	2.3 Challenge of transitioning between Phase 2 and Phase 3
Clinician 5	I have a reasonable knowledge... (line 24, p. 1)	The theory, em and, of ACT and the model I think potentially fit very well with this population and perhaps with the aims and goals that we would have at Phase 3... (lines 27, 28, & 29, p. 1)	For many individuals ending with a therapist can be difficult... (line 35, p. 2) Although they no longer have trauma symptomatology, they still find some of the realities of life very difficult and challenging... (lines 37 & 38, p. 2) Thinking about the future can feel very overwhelming. (Lines 42 & 43, p. 2)
Clinician 6	I've had training, the 2 days training... (lines 54 & 55, p. 2) I would say 60-70% ( <i>confident</i> )...	I think for some people it could be very suitable... (line 64, p. 2) I think for Phase 3 when you're trying to get them to reconnect and move on... it can be quite helpful. (Lines 68 & 69, p. 2)	A difficulty might be the ending of a therapeutic relationship... (lines 77 & 78, p. 2) A potential difficulty might have been because, A: it was a group and, B: it was a new therapist... (lines 81 & 82, p. 2)

**Appendix 12** *continued*

*Chart 2 continued*

Category	2. ACT as a Phase 3 intervention		
Sub-category	2.1 Knowledge of ACT	2.2 Suitability of ACT in Phase 3	2.3 Challenge of transitioning between Phase 2 and Phase 3
Clinician 7	Between a little and a moderate amount. (Lines 19 & 20, p. 1)	Theoretically I believe ACT should fit well to Phase 3 intervention... (line 23, p. 1)	Some clients feel that they no longer have trauma symptoms anymore so they no longer need any intervention... (lines 32 & 33, p. 2) Some clients, once their trauma symptoms are being worked on, they have a recurrence of previously unhelpful coping... which can hinder them moving on to Phase 3... (lines 33, 34, 35, & 36, p. 2)

**Appendix 12** *continued*

*Chart 3*

Category	3. Future of Phase 3 interventions	
Sub-category	3.1 Hopes and vision for Phase 3	3.2 How to improve engagement of service users in Phase 3
Clinician 1	Moving away from specialist homelessness services into community services... (lines 63 & 64, p. 2)	How we set it up from the beginning... (line 74, p. 3)
Clinician 2	<p>We want Phase 3 interventions that feel safe and acceptable to people, but also... involve doing things that are new... (lines 45 &amp; 46, p. 2)</p> <p>A group setting in Phase 3... makes a lot of sense... (lines 47 &amp; 48, p. 2)</p> <p>Something that... gives them (<i>service users</i>) the opportunity to use their skills in a safe place before they move on completely (lines 51, 52, &amp; 53, p. 2)</p>	<p>Our timing of it... (line 56, p. 2)</p> <p>How we talk about it and get the balance right... collaboratively pace it. (Lines 56 &amp; 57, p. 2)</p>
Clinician 3	<p>A little bit more clarity... you know what do we expect from ourselves and at what point do we hand over to community organisations ... (lines 79, 80, &amp; 81, pg. 3)</p> <p>What should stage 3 look like... that needs to be more clearly defined... (lines 82 &amp; 83, p. 3)</p>	How you agree stage 3, the time scales for it, what it will focus on and when it will end... (lines 91 & 92, p. 3)

**Appendix 12** *continued*

*Chart 3 continued*

Category	3. Future of Phase 3 interventions	
Sub-category	3.1 Hopes and vision for Phase 3	3.2 How to improve engagement of service users in Phase 3
Clinician 4	<p>More research... (line 53, p. 2)</p> <p>Things like this (ACT) can be really valuable... (58 &amp; 59, P. 2)</p>	<p>Autonomy, self-efficacy, "I can do something and make some change" (line 70, p. 2)</p> <p>Boundaries are made very explicit and clear... (line 79, p. 3)</p>
Clinician 5	<p>If we could have options of group interventions at Phase 3 I think that would be beneficial... (lines 47 &amp; 48, p. 2)</p> <p>I think a clear rationale in our heads of when... the phase 3 work need to be in the service... or when it is making links with the third sector or other services... (lines 50, 51, &amp; 52, p. 2)</p>	<p>I think planning, eh, for that transition to Phase 3 early on, right at the beginning... (lines 57 &amp; 58, p. 2)</p>
Clinician 6	<p>I would be quite keen to see the role of ACT... (lines 94 &amp; 95, p. 3)</p> <p>I would hope that it is a chance for patients to consolidate everything... feeling that it's been a kind of full circle journey... and it's been a planned ending... (lines 98, 99, 100, &amp; 101, p. 3)</p>	<p>I think it's important to have clear goals... (lines 117 &amp; 118, p. 3)</p>

**Appendix 12** *continued*

*Chart 3 continued*

Category	3. Future of Phase 3 interventions	
Sub-category	3.1 Hopes and vision for Phase 3	3.2 How to improve engagement of service users in Phase 3
Clinician 7	<p>If there is a role for mental health services at Phase 3, I would like to know which model is most palatable to the client group and service users... (lines 43, 44, &amp; 45, p. 2)</p> <p>What will achieve that connectivity, or connection that we're looking for... so that people feel confident to leave our service.(Lines 46 &amp; 47, p. 2)</p>	<p>I think that there's a role for the service...the clinician in terms of psychoeducation about the role of trauma service, the 3 phases... and if we can make that very clear to clients, from the really start of therapy... (lines 56, 57, &amp; 58, p. 2)</p> <p>Discharge planning and treatment planning from the start of therapy... (lines 60 &amp; 61, p. 2)</p> <p>Maintaining boundaries... (line 63, p. 2)</p> <p>Therapeutic relationship has to be monitored very closely... it's sometimes the attachment difficulties that people get stuck, both the therapist and the service user. (Lines 64, 64, &amp; 66, p. 2 &amp; 3)</p>

**Appendix 12** *continued*

*Chart 4*

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	Any other comments
Clinician 1	I don't think any of us anticipated recruitment being a difficulty (lines 91 & 92) It ( <i>the study</i> ) had meaning (line 94, p. 3)
Clinician 2	The group format combined with ACT for Phase 3 I think it brilliant... (line 60, p. 2) I think we should... try to work with the barriers, try to figure out how we can make this something... that people feel they can engage with... (lines 61, 62, 63, & 64, p. 2)
Clinician 3	I think it's been something that's been valuable for our service... (line 96, p. 3) I hope we can build on the work that you have done. (Line 98, p. 3) I forgot to mention, most of the people I see would not be able to attend a mixed-gender group... (lines 105, 106, & 107, p. 3)
Clinician 4	It's a very much needed study... (line 83, p. 3) ACT seems to have so much feasibility with the trauma population and it needs to be researched to show it actually can be helpful... (lines 83 & 84 p. 3) It seems to have been really valuable... (lines 85 & 86, p. 3) Having gender-specific groups straight away eliminates potential difficult dynamics... (lines 88 & 89, p. 3)
Clinician 5	( <i>none</i> )
Clinician 6	It'll be interesting to see how it might go again in the future without the time pressures you've been under... something for us to focus on in the future... (lines 131, 132, & 133, p. 3)
Clinician 7	This ( <i>study</i> )... was incredibly helpful to me in planning em, and thinking about what services we offer. (Lines 71 & 72, p. 3) It's a great example of when theory and practice em, are a mismatch sometimes... (line 72, p. 3) I think I will take this information from your study further and think about it. (Lines 77 & 78, p. 3)

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## Appendix 13 Original Ethics 'Favourable Opinion' Letter with Conditions

**WoSRES**  
**West of Scotland Research Ethics Service**



**West of Scotland REC 3**  
Ground Floor – The Tennent Institute  
Western Infirmary  
38 Church Street  
Glasgow G11 6NT  
[www.nhs.gov.uk](http://www.nhs.gov.uk)

Dr Ross White  
Clinical Psychologist and University Teacher  
University of Glasgow  
Mental Health and Well-being  
Admin Building  
Gartnavel Royal Hospital  
1055 Great Western Road  
Glasgow  
G12 0XH

Date 7<sup>th</sup> November 2013  
Your Ref  
Our Ref  
Direct line 0141 211 2123  
Fax 0141 211 1847  
E-mail [Liz.Jamieson@ggc.scot.nhs.uk](mailto:Liz.Jamieson@ggc.scot.nhs.uk)

Dear Dr White

**Study title:** A feasibility study of Acceptance and Commitment Therapy for recovery from Complex Trauma  
**REC reference:** 13/WS/0278  
**IRAS project ID:** 138592

The Research Ethics Committee reviewed the above application at the meeting held on 24 October 2013. Thank you to Miss Jennifer Megson for attending to discuss the application.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the Co-ordinator Mrs Liz Jamieson, [Liz.Jamieson@ggc.scot.nhs.uk](mailto:Liz.Jamieson@ggc.scot.nhs.uk).

### **Ethical issues raised by the Committee in private with responses from Miss Megson when invited into the meeting**

1) The Committee asked Miss Megson to explain the process of who gets what in the study. Miss Megson advised that Phase 3 of the study is not as structured as Phase 1 and 2. Patients would be seen weekly then reduced to every two weeks and then once a month. This would be to establish how they were getting on and to follow up goals set at the beginning. People who are going into the active group and receiving ACT will still receive this.

2) The Committee asked Miss Megson to explain how patients will be recruited to the study. Miss Megson advised that she would go along to the Allocations Meeting and explain the study to clinicians and provide copies of the Participant Information Sheet. The clinicians would have

## Appendix 13 *continued*

a list of those patients going into Phase 3 of their treatment. The Clinicians would then explain the study to suitable patients and give them an information sheet to take away. The patient would then contact their clinician if they are interested in hearing more about the study and a time would be arranged via their clinician to meet with Miss Megson. Miss Megson would then meet with the patient to discuss the study further and answer any questions. If the patient decided to take part consent would be taken.

3) The Committee asked the Investigator how long patients would have to decide if they wanted to take part in the study. Miss Megson advised that there would be a minimum of 24 hours at least or up to a week. Patients would not be followed up if they did not make contact.

### **Ethical opinion**

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

### **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).

### **Conditions of the favourable opinion**

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

1) The Participant Information Sheet requires to be amended as follows:

- The first paragraph should state that the study is being undertaken as an educational project.
- At 'Do I have to take part' the first word should be 'No'.
- At 'Who has reviewed the study' the name of the Ethics Committee is wrong. This should read West of Scotland Research Ethics Committee 3.
- At 'If you have a complaint etc' details of how to complain via the NHS Complaints system should be given.

2) The Consent Form requires to be amended as follows:

- The sentence 'I understand that this is a student project etc' should be deleted.

There is a mandatory paragraph which should be inserted for audit purposes as follows:

- *'I understand that relevant sections of my care record and data collected during the study may be looked at by responsible individuals from the sponsor or host organisation or from regulatory authorities where it is relevant to taking part in this research.'*

**You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation**

## Appendix 13 *continued*

with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

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

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

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

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

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

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

### Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

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

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

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett ([catherineblewett@nhs.net](mailto:catherineblewett@nhs.net)), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

**It is 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).**

### **Approved documents**

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
GP/Consultant Information Sheets	1	05 September 2013
Investigator CV		16 August 2013

## Appendix 13 *continued*

Other: CV Supervisor		
Other: Letter - Authority to proceed to Ethics		01 August 2013
Participant Consent Form	4	05 October 2013
Participant Information Sheet	4	01 October 2013
Protocol	3	30 September 2013
Questionnaire: Sense of Coherence		
Questionnaire: AAQ-11		
Questionnaire: CFQ13		
Questionnaire: Valuing Questionnaire		
Questionnaire: Working Alliance Inventory		
REC application		09 October 2013

### **Membership of the Committee**

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

### **Statement of compliance**

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

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

#### Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

## Appendix 13 *continued*

13/WS/0278

Please quote this number on all correspondence

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

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

Yours sincerely



**Liz Jamieson**  
Committee Co-ordinator  
On behalf of Dr Adam Burnel, Chair

Enclosures: List of names and professions of members who were present at the meeting  
"After ethical review – guidance for researchers"

Copy to: Miss Jennifer Megson  
Dr Erica Packard, NHS Greater Glasgow and Clyde

## Appendix 14 Ethics 'Acknowledgment of Conditions' Letter

**WoSRES**  
*West of Scotland Research Ethics Service*



**West of Scotland REC 3**

Ground Floor – The Tennent Institute  
Western Infirmary  
38 Church Street  
Glasgow G11 6NT  
[www.nhsqgc.org.uk](http://www.nhsqgc.org.uk)

Dr Ross White  
Clinical Psychologist and University Teacher  
University of Glasgow  
Mental Health and Well-being  
Admin Building - Gartnavel Royal Hospital  
1055 Great Western Road  
Glasgow  
G12 0XH

Date 15<sup>th</sup> November 2013  
Your Ref  
Our Ref  
Direct line 0141 211 2123  
Fax 0141 211 1847  
E-mail [Liz.Jamieson@ggc.scot.nhs.uk](mailto:Liz.Jamieson@ggc.scot.nhs.uk)

Dear Dr White

**Study title:** A feasibility study of Acceptance and Commitment Therapy for recovery from Complex Trauma  
**REC reference:** 13/WS/0278  
**IRAS project ID:** 138592

Thank you for your recent email. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 31 October 2013

### Documents received

The documents received were as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Participant Consent Form	5	07 November 2013
Participant Information Sheet	5	07 November 2013

### Approved documents

The final list of approved documentation for the study is therefore as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
GP/Consultant Information Sheets	1	05 September 2013
Investigator CV		16 August 2013

## Appendix 14 *continued*

Other: CV Supervisor		
Other: Letter - Authority to proceed to Ethics		01 August 2013
Participant Consent Form	5	07 November 2013
Participant Information Sheet	5	07 November 2013
Protocol	3	30 September 2013
Questionnaire: Sense of Coherence		
Questionnaire: AAQ-11		
Questionnaire: CFQ13		
Questionnaire: Valuing Questionnaire		
Questionnaire: Working Alliance Inventory		
REC application		09 October 2013

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

<b>13/WS/0278</b>	<b>Please quote this number on all correspondence</b>
-------------------	---

Yours sincerely



**Mrs Liz Jamieson**  
Committee Co-ordinator

Copy to: Miss Jennifer Megson  
Erica Packard, NHS GG&C – R&D

## Appendix 15 Ethics Substantial Amendment 'Favourable Opinion' Letter

**WoSRES**  
West of Scotland Research Ethics Service



**West of Scotland REC 3**  
Ground Floor – The Tennent Institute  
Western Infirmary  
38 Church Street  
Glasgow G11 6NT  
[www.nhsqgc.org.uk](http://www.nhsqgc.org.uk)

Dr Ross White  
Clinical Psychologist and University Teacher  
University of Glasgow  
Mental Health and Well-being  
Admin Building, Gartnavel Royal Hospital  
1055 Great Western Road, Glasgow  
G12 0XH

Date 19th June 2014  
Your Ref  
Our Ref  
Direct line 0141 211 2123  
Fax 0141 211 1847  
E-mail WOSREC3@ggc.scot.nhs.uk

Dear Dr White

<b>Study title:</b>	<b>A feasibility study of Acceptance and Commitment Therapy for recovery from Complex Trauma</b>
<b>REC reference:</b>	<b>13/WS/0278</b>
<b>Amendment number:</b>	<b>AM02</b>
<b>Amendment date:</b>	<b>04 June 2014</b>
<b>IRAS project ID:</b>	<b>138592</b>

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

### Ethical opinion

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

The amendment covered the addition of a qualitative aspect to the methodology in the form of an interview with NHS Greater Glasgow and Clyde Trauma Service Clinicians in order to obtain an understanding of the recruitment difficulties that this study has faced.

### Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Interview schedules or topic guides for participants	1	03 June 2014
Notice of Substantial Amendment (non-CTIMP)	AM02	04 June 2014
Participant consent form [Clinician]	1	03 June 2014
Participant information sheet (PIS) [Clinician]	1	03 June 2014
Research protocol or project proposal	5	03 June 2014

### Membership of the Committee

## Appendix 15 *continued*

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

### **R&D approval**

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

### **Statement of compliance**

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

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

<b>13/WS/0278:</b>	<b>Please quote this number on all correspondence</b>
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Yours sincerely



**Liz Jamieson**  
**REC Manager**  
**On behalf of Dr Adam Burnel, Chair**

Copy to: *Erica Packard, NHS GG&C*  
*Ms Jennifer Megson*

## **Appendix 16 Major Research Project Proposal**

### **Abstract**

#### *Background*

Complex trauma can involve problems such as emotional regulation difficulties; Post Traumatic Stress Disorder; dissociation; identity and relational disturbances; substance misuse; low self-esteem; somatic distress; and homelessness (Courtois and Ford, 2009). A model of intervention widely used in the treatment of complex trauma involves three phases of treatment (Herman, 1992). Phase 1: establishing safety; phase 2: remembrance and mourning, and phase 3: reconnecting the client with society. Although no longer reaching diagnosis for complex trauma, individuals at phase 3 can be confused about their identity and values.

Acceptance and Commitment Therapy (ACT) helps individuals to explore what they value in life and to adopt value-consistent behaviour, therefore could be useful for phase 3 in a complex trauma intervention.

#### *Aims*

Following the PICO framework (Oxman, Sackett, & Guyatt, 1993; Richardson, Wilson, Nishikawa, & Hayward, 1995) this study will look at the parameters of population recruitment, acceptability of a complex trauma intervention and suitable outcome measures in a complex trauma population.

### *Methods*

Participants (approximate n=32) will be recruited from the NHS Greater Glasgow & Clyde Trauma Service into a Prospective Outcome study exploring the feasibility of using ACT to facilitate recovery from complex trauma . Therapeutic alliance measure: The Working Alliance Inventory. Outcome measures: General Health Questionnaire-12 and Sense of Coherence – Orientation to Life Questionnaire-13. Therapeutic measures: Acceptance and Action Questionnaire-II, Cognitive Fusion Scale, and Valuing Questionnaire-8. A Client Service Receipt Inventory will be completed for each participant.

### *Applications*

To establish whether or not the ACT group intervention will be appropriate for a complex trauma population, and to contribute to the literature on the effectiveness of ACT interventions and on interventions for complex trauma.

### **Introduction**

Complex trauma involves traumatic stressors that (1) are repetitive or prolonged; (2) involve direct harm and / or neglect and abandonment by caregivers or ostensibly responsible adults; (3) occur in vulnerable times in the survivors' life, such as early childhood, and (4) have potential to severely compromise a child's development (Courtois & Ford 2009). The consequences of complex trauma can involve emotional regulation

difficulties; Post Traumatic Stress Disorder; dissociation; identity and relational disturbances; substance misuse; low self-esteem; somatic distress; and homelessness (Courtois and Ford, 2009). Research suggests that homelessness can be viewed as a traumatic experience, and being homeless increases the risk of further victimisation and re-traumatisation (Hopper, Bassuk, & Olivet, 2009).

A model of intervention widely used in the treatment of complex trauma involves three phases of treatment (Herman, 1992). Phase 1 involves establishing safety; phase 2 involves remembrance and mourning, and phase 3 aims to reconnect the client with society. Although no longer reaching diagnosis for complex trauma, individuals at phase 3 can be confused about their identity and values. Herman (1992) suggests that different group interventions may be of benefit for those in phase 3 and that the main aim should be to help the individual achieve commonality; to have a sense of belonging to a society; and to feel that “one’s own troubles are as a drop of rain in the sea” (Herman, 1992, pg. 236). Various theories of human adaptation to stress and trauma have been developed; one of the more empirically robust is Antonovsky’s (1987) Sense of Coherence (SOC) (Linley, 2003). SOC has three components: Comprehensibility – the extent to which events are perceived as making logical sense; Manageability – the extent to which a person feels they can cope; and Meaningfulness – how much a person feels that life makes sense, and challenges are worthy of commitment. Research has

consistently shown that a high SOC is associated with better adaptation to life stress and trauma (Flannery & Flannery, 1990).

Acceptance and Commitment Therapy (ACT) is a Third Wave Cognitive and Behavioural Therapy developed by Hayes, Strosahl, & Wilson (1999). It uses acceptance based strategies to help people to notice thoughts and emotions without getting caught up in reacting to them. ACT also helps individuals to explore what they value in life and to help people to adopt value-consistent behaviour. ACT draws a contrast between our agendas being set by struggling to move away from suffering or moving towards what is important in life. Therefore, it could be a useful phase 3 intervention for complex trauma.

There have been a number of outcome studies on the use of ACT with people experiencing a range of psychological disorders (Ruiz, 2010). ACT has shown to be effective in treating diverse symptoms associated with anxiety and depression (Lappalainen, Lehtonen, Skarp, Taubert, Ojanen, & Hayes, 2007); Generalised Anxiety (Roemer & Orsillo 2007; Roemer, Orsillo, & Salters-Pedneault, 2008); Borderline Personality Disorder (Gratz & Gunderson, 2006); addictive behaviours (Hayes, Wilson, Gifford, Bissett, Piasecki, Batten, et al. 2004); and impulsive, risk-taking behaviour in adolescents (Luciano, Salas, Martinez, Ruiz, & Blarrina, 2009).

The complex trauma population presents with a multitude of psychological and social difficulties. The above studies have reported that ACT is an effective intervention for similar difficulties and therefore it is likely that ACT will be a useful intervention for those in phase 3 of their treatment for complex trauma.

When developing a complex intervention, as in the current study, adequate development and piloting work is of great importance (Medical Research Council - MRC, 2008). According to the MRC (2008) guidelines on developing complex interventions, the feasibility and piloting stages include: testing procedures for their acceptability, estimating the likely rates of recruitment and retention of participants, and calculation of appropriate sample sizes. Such guidelines have informed the current study.

### **Aims and Research Questions**

The **PICO** framework (Oxman, Sackett, & Guyatt, 1993; Richardson, Wilson, Nishikawa, & Hayward, 1995) was used to develop the parameters of the study aims and objectives:

- Population: Could appropriate individuals be identified, consent to and be randomised to a trial of ACT for a phase 3 intervention in a complex trauma population as measured by:

- Recruitment numbers and Recruitment Rate (number/week of study)
- Intervention: Would ACT be an acceptable phase 3 intervention for a complex trauma population as measured by:
  - Attrition rate from the Intervention group
  - A standard measure of Therapeutic Alliance in the Intervention group
  - An interview schedule conducted with Greater Glasgow & Clyde Trauma Service clinicians
- Outcomes: To explore which outcome and therapy specific measures are useful in assessing the impact of ACT following complex trauma by determining the treatment signals in selected measures.

### Plan of Investigation

#### *Design*

This study is a Prospective Outcome study with non-Blinded Evaluation of Outcomes exploring the feasibility of using ACT to facilitate recovery from complex trauma. 'Prospective' and 'Outcome' refer to the process of collecting information over time to assess the relationship between the intervention and the outcome. It is non-blinded because the researcher will meet the participants to discuss participation in the study as well as run the intervention. A psychology assistant in the service will administer the assessment measures to decrease response bias.

### *Participants*

It is the intention to recruit 32 participants (16 intervention and 16 controls) from the NHS Greater Glasgow & Clyde (GG&C) Trauma Service who are in their 3<sup>rd</sup> phase of treatment for complex trauma. The Trauma Service is a NHS GG&C mental health service for adults with a history of complex trauma and follows the 3-phase treatment model.

### *Inclusion and Exclusion Criteria*

*Inclusion:* Those who are in phase 3 of their treatment in the GG&C Trauma Service and aged 16 years or over. Those who can access the English language without translation.

*Exclusion:* Those who are in phases 1 and 2 of treatment in the GG&C Trauma Service and less than 16 years of age. Those who cannot access the English language without translation.

### *Recruitment Procedures*

The researcher will attend an allocation meeting at the GG&C Trauma Service to provide the service's clinicians with information about the study. Service users in phase 3 of treatment will each have a clinician who will provide them with an information sheet containing information about the study. Each service user will be given the opportunity to meet with the researcher at least 24 hours after receiving the information sheet to allow them time to consider participation. This meeting will give the service user an opportunity to raise any questions about the study. During the meeting the service user will decide if they want to take part in the study. If the service user decides to participate then the researcher will then complete

the process of obtaining informed consent by asking the service user to sign a consent form. Once consent has been obtained, the service user will then take up the role of participant however will be informed that they do not have to take part or can withdraw at any time without affecting their care.

### *Intervention*

TAU as it exists in the Trauma Service:

- Continuing support from the key clinician
- Safety checks by the key clinician during each session
- Managing crisis as it arises
- Referrals to the voluntary sector.

Intervention is an ACT group based on a protocol developed by Lloyd, Bond, & Flaxman (2013) and will be conducted by the researcher over four sessions with a co-facilitator. After the group, each participant will receive two individual sessions to maximise the information passed on in the group. Overall, each participant is required to participate in six sessions over a period of seven weeks.

In one of the individual sessions, it is intended for a keyworker from community services already known by the participant to be present so that the keyworker can help the participant with applying skills developed during the intervention to life in the community.

### *Research Procedures*

Prior to the intervention commencing, the researcher will receive training in ACT.

An ideal group size will be 8 (Yalom, 1995); therefore, to meet the requirement of 32 participants as previously outlined in the 'Participants' section, the intervention will run on four occasions. Once 8 participants have been allocated to the first group, any participants remaining will be allocated to the next group and so on. The assessment measures will be completed at the following time points: a – pre-treatment (1<sup>st</sup> assessment), b – on completion of the ACT group intervention (2<sup>nd</sup> assessment), and c – on completion of the two individual sessions (final assessment). The Working Alliance Inventory will only be administered and the Client Service Receipt Inventory completed at the final assessment stage.

A mixture of qualitative and quantitative research methods is recommended by the MRC (2008) at the feasibility stage of research. Therefore, after the final ACT intervention has been delivered, clinicians of the GG&C Trauma Service will be interviewed in order to add meaning to the quantitative results obtained from the participants, and to help plan up-scaling of the research.

### *Assessment Measures*

#### *Quantitative*

Acceptability Measure: Therapeutic Alliance

- The Working Alliance Inventory (Short Form Revised; WAI-SR; Hatcher & Gillaspay, 2006) is a 12-item self-report measure of therapeutic alliance. High internal consistency coefficient alphas and validity were reported by the authors (Hatcher & Gillaspay, 2006).

#### Outcome measures:

- The General Health Questionnaire-12 (Goldberg & Williams, 1988) is a measure of current mental health. Overall sensitivity and specificity ratings are high (83.4% and 76.3% respectively, Goldberg et al., 1997) with internal consistency ratings between 0.77-0.93 (Goldberg & Huxley, 1988). The 12-item version has been shown to be as effective as the 28-item version (Goldberg et al., 1997)
- The Sense of Coherence - Orientation to Life Questionnaire (SOC-13, Antonovsky, 1987); a 13-item scale with three factors: Comprehensibility, Manageability, and Meaningfulness. Internal consistency ratings range from 0.70 to 0.92, test-retest stability ranges from 0.69 to 0.78 (1 year), 0.64 (3 years), 0.42 to 0.45 (4 years), 0.59 to 0.67 (5 years) to 0.54 (10 years) (Eriksson & Lindstrom, 2005).

#### Therapy Specific Measures:

- The Acceptance and Action Questionnaire-II (AAQ-II; Bond, Hayes, Baer, Carpenter, Guenole, Orcutt, et al., 2011) is a 7-item measure

of psychological flexibility. The mean internal consistency rating is 0.84. The 3- and 12-month test-retest reliability is .81 and .79, respectively (Bond et al., 2011).

- The Cognitive Fusion Questionnaire (CFQ, Gillanders, et al., 2010) is a 13-item self-report measure of cognitive fusion. It has a test-retest value of 0.88 and internal consistency ratings ranging from 0.85 to 0.89 (Gillanders, et al., 2010).
- The Valuing Questionnaire-8 (VQ-8; Davies & Smout, 2011) measures value-consistent behaviour. It has 2 factors: “Progress”; how much people feel they lived by their values in the past week, and “Obstructed”; how much cognitive and emotional barriers restricted the enactment of values in the past week. The VQ-8 consists of 8 items that are rated on a 7-point scale. The internal consistency for the four ‘Progress’ items is 0.86 and for the four ‘Obstructed’ items is 0.83.

The Client Service Receipt Inventory (CSRI) will be used and tailored accordingly. The CSRI is a questionnaire for collecting retrospective information about study participant’s use of health and social care service, accommodation and living situation, income, employment and benefits. The service receipt section is the largest part of the questionnaire. The CSRI was developed by members of the Centre for the Economics of Mental and Physical Health and has been used in numerous mental and physical health care evaluations. It is noted that the questionnaire may

require tailoring for each use to account for variations in study aims and characteristics.

### *Qualitative*

A preconceived framework grounded in this study will be used to form the interview to be conducted with GG&C Trauma Service clinicians. The data obtained will be used support the quantitative information obtained in the assessment measures detailed above.

### *Data Analysis*

Mixed methods of analysis will be used. For quantitative, SPSS statistics programme will be utilised. Data will be checked and both parametric and non-parametric descriptive data will be summarised. Intervention signals will be explored by examining change scores from baseline to follow-up within subjects on the outcome and therapy specific measures using an independent *t*-test or Mann-Whitney test. Effect sizes will be calculated and presented.

The qualitative method of Framework Analysis, using a preconceived framework grounded in this study, will be conducted on the information transcribed from the interviews to establish patterns in the data obtained.

The flow of participants into and out of the study will be described according to CONSORT guidance (Shulz, Altman, Moher, 2010) which will highlight recruitment numbers and recruitment rate.

### *Justification of sample size*

This is a pragmatic study establishing feasibility of ACT for recovery from complex trauma. The resources available in the study allow for the recruitment of up to 32 participants. Effect sizes will be calculated according to Cohen's (1988) conventions. Sensitivity analysis of effectiveness will be calculated on the basis of data collected.

### *Settings and Equipment*

The study will take place in the Trauma Service.

## **Health and Safety Issues**

### *Participant and Researcher Safety Issues*

The study will be conducted in an environment where trained clinicians will be present and protocols will be in place.

## **Ethical Issues**

Ethics approval will be sought from the West of Scotland Research and Ethics Committee. The main researcher will attend NHS GG&C Good Clinical Practice Training on 18<sup>th</sup> September 2013.

Participant data will be stored on a laptop computer encrypted to NHS GG&C specifications. A site file will be set up prior to commencement of

the study and maintained by the researcher and stored at the study setting.

### **Financial Issues**

Finances are required for photocopying materials such as assessment measures that are not copyrighted, and to purchase those that are copyrighted (GHQ-12).

### **Timetable**

- Complete and submit project proposal to the University by March 2013.
- Submit proposal with ethics application to the ethics committee by September/October 2013.

### **Practical Applications**

To establish whether or not the ACT group intervention will be appropriate for a complex trauma population and contribute to the literature on the effectiveness of ACT interventions and interventions for complex trauma.

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