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From trauma to psychosis: developing an interventionist-causal approach for dissociation and voice-hearing in people with complex trauma

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

Institute of Health and Wellbeing
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Le grá agus buíochas,

Moya

Chapter 1: Systematic Review

Integrated approaches to psychological interventions for trauma and psychosis: a systematic review of case studies

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Abstract

Objective: Trauma has been proposed to play a role in the development and maintenance of psychosis. Psychological therapy approaches that integrate both psychosis and traumatic experiences are in their infancy with evidence largely consisting of case reports, case series and single case design studies. This review aimed to synthesise the types of psychological interventions described in case studies, their outcomes and methodological quality.

Method: Systematic database searches were conducted using a pre-determined search strategy and inclusion criteria to identify case studies reporting psychological therapies for psychosis and trauma among adults. Studies that met inclusion criteria underwent a process of calibration, inter-rater reliability and data extraction. The review was pre-registered with PROSPERO (registration number: CRD42020178384).

Results: 17 case studies met inclusion criteria. Psychological interventions included psychotherapy (n=6), integrated CBT for psychosis and trauma (n=2), and trauma-focused approaches (n=9). Methodological quality ranged between poor (n=4), moderate (n=9) and high (n=4). Case studies reported improvements in trauma-related and psychotic symptoms. Case studies also highlighted symptom exacerbation.

Conclusions: This review described a wide range of case studies of psychological interventions, mainly from psychotherapeutic and CBT schools. Methodologically robust research is required and improved adherence to SCRIBE reporting standards.

Keywords: systematic review, psychosis, trauma, therapy, treatment, posttraumatic stress disorder

Clinical or methodological significance of this article: This systematic review contributes to current understandings of trauma-related psychosis by synthesising clinical case studies from a range of therapeutic orientations and designs. This review enhances 'practice-based evidence' within an evolving field of clinical research and practice. We discuss relevant limitations in the literature and pose recommendations for future research and clinical practice.

Introduction

Psychosis is a term that encompasses a spectrum of unusual experiences that can often be a source of distress, disability and can impact upon functioning (American Psychiatric Association, 2013). Despite this, many individuals who experience psychosis lead fulfilling and meaningful lives (Lally et al., 2017). Decades of research have illuminated insights into the possible causal and maintenance factors that underpin the development of psychosis. The link between trauma and psychosis is now well-established (Bendall et al., 2008; Varese et al., 2012), with particular evidence of developmental interpersonal traumatic experiences increasing the likelihood of psychosis (Bebbington et al., 2004; Bebbington et al., 2011). Rates of trauma and especially childhood victimisation, are higher among individuals with psychosis than the general population, although rates vary within studies (Achim et al., 2011; Kessler et al., 2011; Kraan et al., 2015). A recent study found that an estimated that 16% of individuals with schizophrenia-spectrum disorder also met criteria PTSD (de Bont et al., 2015). Having recognised the high rates of trauma among this population group, the National Institute of

Clinical Excellence (2014) has recommended that individuals presenting with a first-episode of psychosis (FEP) be routinely assessed for a history of trauma. This may be an important factor to consider when engaging with individuals to ensure they receive the most appropriate care. Although trauma is now routinely part of FEP assessments, the provision of integrated psychological interventions that consider both trauma and psychosis is in its infancy. Indeed, the term 'trauma-related psychosis' and the three hypothesised pathways linking trauma and psychotic experiences has only recently been proposed (Hardy, 2017).

Individuals have long-presented with trauma-related psychosis, and while psychologists may adopt an integrated approach to therapies in practice, the evidence-base does not reflect this integration. Randomised Control Trials (RCTs) are largely confined to evaluating disorder-specific therapies e.g. trauma-focused CBT (tf-CBT) or CBT for psychosis (CBTp) among samples with co-morbid psychosis and trauma (Sin & Spain., 2016; Brand et al., 2018; Brand et al., 2019). Research suggests feasibility and effectiveness of delivering trauma-focused therapies to individuals with psychosis (de Bont et al., 2013; Brand et al., 2019), however it could be argued that approaches that do not integrate both psychosis and traumatic experiences, may not adequately serve the needs of this population.

The distinct lack of integrated therapeutic approaches available has prompted a recent surge in clinical research (Keen et al., 2017; Mc Cartney et al., 2019; Ward et al., 2020). Despite the renaissance of interest in the field, clinicians have long worked with individuals who present with psychosis in the context of trauma (Calcott et al., 2004). It has been argued that the 'art'

of delivering psychological therapy for complex presentations lies within clinicians' abilities to flexibly draw from multiple evidence-based approaches as well as their own clinical experience to fit individual needs. With this in mind, there is potentially a lot to be learned from published case reports, case series and single case design studies of psychological treatments for trauma-related psychosis and a review in the area is both warranted and timely.

Aims

This review aimed to synthesise current evidence of case reports, case series and single case studies (herein referred to collectively as 'case studies') of psychological interventions for individuals with psychosis and a history of trauma. This review aimed to adopt a trans-diagnostic, cross-cultural approach and included evidence from a wide range of settings.

This review aimed to establish:

1) Methodological quality of current case studies
2) Types of psychological interventions are described within case studies
3) Qualitative and/or quantitative outcomes of these interventions

Method

Protocol and registration

This review was prospectively registered with the International Prospective Register of Systematic Reviews (PROSPERO) in accordance with Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Statement guidelines (Moher et al., 2009). Modifications were made to the original protocol following registration and are detailed on

https://www.crd.york.ac.uk/prospero/ (registration number: CRD42020178384). This modification related to the proportion of studies to be quality assessed by a second reviewer.

Eligibility criteria

The current review adopted broad, inclusive, trans-diagnostic eligibility criteria in order to ensure that all relevant studies were identified and included. We included individual case studies i.e. case reports, case series and single case design studies that outlined clinical cases in which individuals (over 16 years old) with psychosis (diagnosed using any recognised diagnostic criteria or psychotic symptoms as defined by ICD-10 or DSM-5 criteria) and a history of trauma and/or trauma-related symptoms received psychological intervention or therapy. Eligibility was not limited to ICD or DSM diagnostic definitions of psychosis or trauma, which have changed over time and instead considered evidence of trauma and psychosis as identified through structured assessment tools or in the reporting of relevant symptoms as per ICD-10 or DSM-5 criteria. As the focus was on trauma-related psychosis, we did not include case studies relating to traumas that occurred post-onset of psychosis. We included case studies that provided descriptions of clinical work and therapeutic change, as defined by Hilliard's (1993) three basic categories of single case research: case studies, single-case quantitative analyses and single-case experiments. Studies must have been published in English and in peer-reviewed journals. Studies without an active intervention component and studies from non-clinical samples were excluded.

Search strategy

An electronic database search of MEDLINE, EMBASE, PsycINFO and CINAHL was conducted using pre-determined search strategy (Appendix 1.2). Search terms were established following scoping searches, consulting relevant experts in the field and reviewing the literature. Included terms related to population, intervention and design (see below and Appendix 1.2). All searches were limited to English language, human subjects and articles from inception of the databases

until 8th May 2020.

Sample of search terms:

Ovid (MEDLINE (R) 1946 to 2020; Embase 1947 to 2020). Limited to English	
S1 Population / problem (psychosis)	Psychosis [MeSH] OR Psychotic Disorder [MeSH] OR schizophreni* [MeSH] OR psychotic.mp OR hallucinat*.mp OR delusion*.mp OR paranoi*.mp OR voice*.mp OR intrusi*.mp
S2 **Population / problem** (trauma)	psychological trauma [MeSH] OR post-traumatic stress disorder [MeSH] OR psychotrauma [MeSH] OR trauma*.mp OR PTSD.mp OR "post-traumatic stress".mp OR CPTSD.mp OR CPTSD.mp OR "complex trauma".mp OR neglect*.mp OR abus* [MeSH] OR violen* [MeSH] OR assault* [MeSH] OR crime victim* [MeSH] OR survivor* [MeSH]
S3	S1 AND S2
S4 **Intervention**	psychotherapy*[MeSH] OR "Trauma-focused therap*".mp OR "trauma therap*".mp OR therap* [MeSH] OR "Cognitive Behavioural Therapy" [MeSH] OR "Cognitive Behavi?r* Therap*".mp OR CBT.mp OR "Cognitive therap* [MeSH] OR reprocessing.mp

S5 **Design** (case reports/studies)	case reports [MeSH] OR case stud*".mp OR "single case".mp OR SCED.mp OR "single case experimental design".mp OR "N of 1".mp OR "N of one".mp OR "N = 1".mp OR case*.mp OR report*.mp
S6	S3 AND S4 AND S5

Study selection

Articles were exported into Ref Works reference management software and duplicates removed. Articles were screened using a checklist (Appendix 1.3) on the basis of Population/Population/Intervention/Design (PPID) and inclusion and exclusion criteria at 1) title/abstract and 2) full-text level. Primary reasons for exclusion were documented. All papers were screened by the main reviewer (MC) with a second reviewer screening a random sample of 50 papers at title/abstract level and five papers at full text level. Disagreements were resolved by consultation and inconsistencies were documented. To maximize search inclusivity and sensitivity, reference list searches and forward-citation of studies included following full-text screening was completed.

Quality Assessment

Given the inclusion of three study types, three quality assessment tools were used. Descriptive case reports: The Joanna Briggs Institute Checklist for Case Reports (Joanna Briggs Institute, 2017); Case series: Quality Appraisal Tool for Case Series (Moga et al., 2012); Single Case Design Studies*:* Risk of Bias in N of 1 Trials (RoBiNT) Scale (Tate et al., 2013). The main author rated all papers using the relevant tools and a second reviewer rated a random sample

for purposes of calibration and reliability (calibration: n=3, 17.6%; reliability: n=3, 17.6%). The methodology of calibration and reliability rating was established prior to rating (detailed in Appendix 1.4). Inter-rater agreement was calculated using Cohen's kappa. An overall percentage of the total quality scores from each tool were calculated and categorised into poor (0-33%), moderate (34-66%) or high (+67%) quality for the purpose of comparing across the three scales.

Data extraction

The following data were extracted from each study and documented: 1) study design 2) description of intervention 3) participant characteristics and clinical presentation 4) treatment format and characteristics 5) therapist characteristics 6) primary outcomes 7) secondary outcomes 8) treatment retention and 9) main results.

Analysis

Data from studies identified from the search were analysed and presented in a narrative synthesis at three levels of evidence - descriptive case reports, case series and single-case design studies. Treatment descriptions, main outcomes and methodologies were synthesised in the context of current theories and models. Analyses identified and reported on any psychological techniques and interventions being used in clinical practice that may map onto current established approaches or techniques.

Results

17 studies were identified from the search. Figure 1 outlines the search and selection process.

Figure 1: PRISMA Flow Diagram

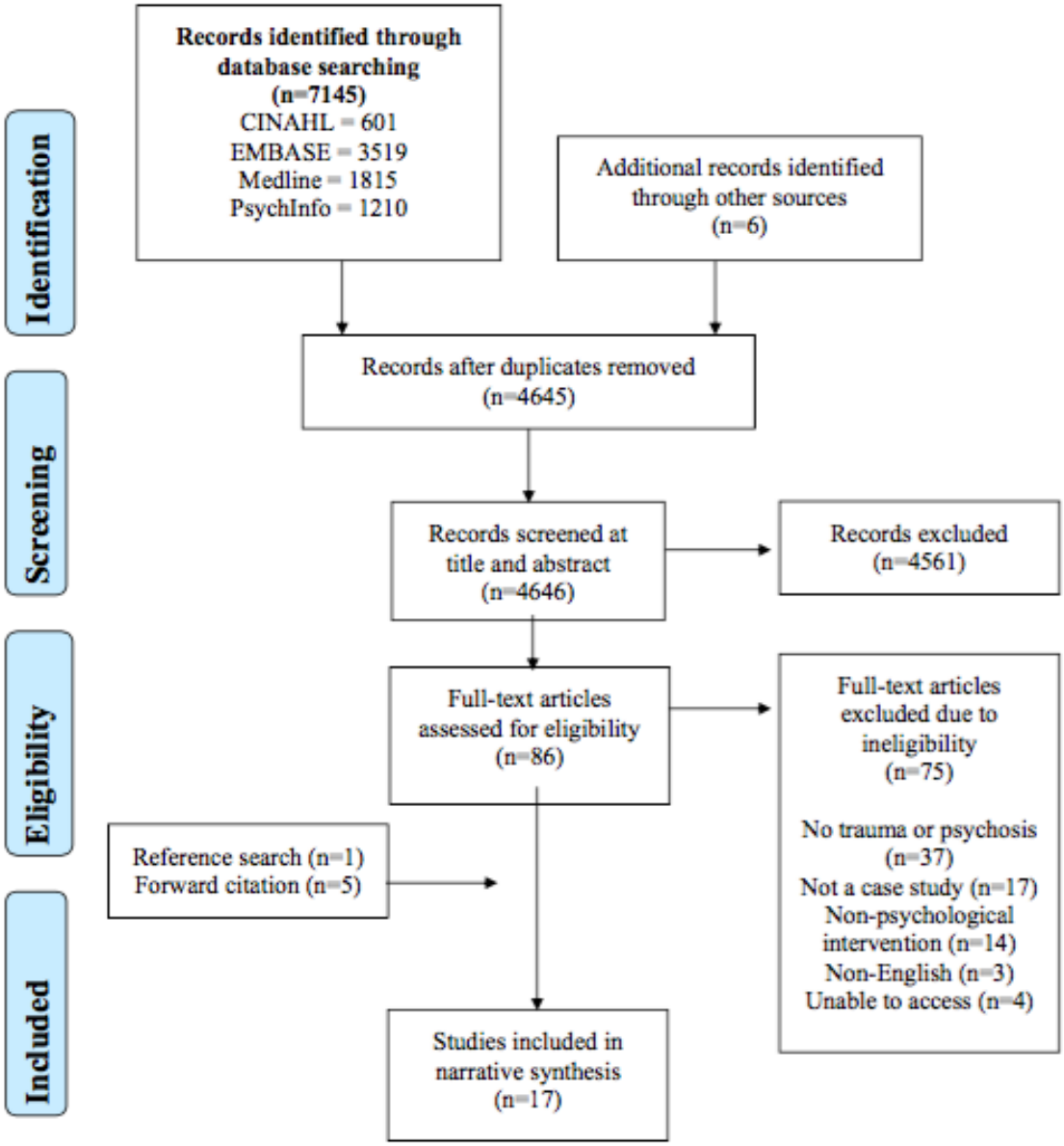

Table 1: Study characteristics

	Study	Setting	Treatment description and duration	Total N (n female)	Clinical Presentation and/or Diagnosis	Mean age (SD)	Primary Outcome measures (trauma)	Primary Outcome measures (psychosis)	Secondary Outcome Measures	Follow-up	Attrition (%)
Descriptive Case Reports											
1	Brent, 2009	Outpatient, USA	Individual Mentalisation-Based Psychodynamic Psychotherapy; weekly, 1 year	1 (0)	Psychotic disorder	20	-	-	-	-	-
2	Frederickson, 1991	Outpatient, USA	Psychotherapy; duration unclear	1 (1)	Psychotic disorder	40	-	-	-	-	-
3	Jackson, 1994	Outpatient, USA	Psychotherapy; 2 years	1 (1)	Grandiosity, ideas of reference, delusions	30	-	-	-	-	-
4	Knafo, 2016	Outpatient, USA	Psychoanalysis; four times weekly for 10 years	1 (0)	Schizoaffective disorder, PTSD	56	-	-	-	-	-
5	Sar & Tutkun, 1997	Inpatient, Turkey	Psychotherapy; 27 months	1 (1)	DID, hysterical psychosis	45	-	-	-	-	-
6	Williams, 1998	UK	Psychoanalysis; 7 years	1 (1)	Psychosis	Not reported	-	-	-	-	-
Case Series											
7	Brand et al., 2019	Specialist Voices Clinic, Australia	IE; 6 sessions	2 (2)	Trauma-related voice hearing	Late 30s; mid 40s	TMQ; PTCI; Session-by-session ratings of voice and memory intrusion frequency and distress.	PSYRATS-AHS	CAPS-5	1-month	0%

8	Brand et al., 2020	Specialist Voices Clinic, Australia	IE; 6 sessions	15 (9)	Trauma-related voice hearing	43.79 (8.64)	TMQ; PTCI; Session-by-session ratings of memory intrusion frequency and distress.	PSYRATS-AHS; PSYRATS-DS; Ecological Momentary Assessment and session ratings of AH intensity and distress.	DASS-21; CAPS-5	1-month	20%
9	Callcott et al., 2004	UK	Integrated tf-CBTp; duration unclear	2 (2)	Trauma-related psychosis	45; 34	IES	SANS-4	CPRS-22	-	-
10	Hamblen et al., 2004	USA	CR; 16 sessions	2 (1)	PTSD & Severe mental illness	43; 56	CAPS		BPRS	3-month	0%
11	Jansen & Morris, 2017	Outpatient Psychotherapy Service, Denmark	ACT; 12 sessions	3 (2)	PTSD & non-affective psychosis	23.66 (2.5)	IES, PCL-C	PANSS	Post-Therapy Questionnaire; BAI; BDI; Acceptance and Action Questionnaire	2-month	0%
12	Keen et al., 2017	Psychological Interventions Clinic for outpatients with Psychosis (PICuP), UK	Integrated tf-CBTp; 9 months although duration varied	9 (4)	PTSD symptoms & persecutory delusions and hallucinations.	37 (11.34)	PDS	PSYRATS-DS and PSYRATS-AHS	BDI, DASS, CORE-10, STQ	9 months (range 5-18 months)	36%
13	Paulik et al., 2019	Perth Voices Clinic, Australia	IR; 8 sessions	12 (9)	Trauma-related voice hearing	41 (13.4)	PSS, Retrospective self-reported	BAVQ	DASS; Rosenberg self-esteem	3-months	25%

							total number of trauma-related intrusions, voice frequency and distress experienced in the past week.		scale; social and occupational functioning assessment scale.		
Single Case Design Studies											
14	Ison et al., 2014	Community Mental Health Teams, UK	IR; 1 session	4 (3)	Trauma-related voice hearing	46.25 (5.2)				1 week; 1 month	
15	Marcello et al., 2009	Outpatient, USA	CR; 16 sessions	1 (0)	Schizoaffective Disorder & PTSD	55	PCL-S	-	BDI-II	-	-
16	McCartney et al., 2019	Early Intervention Psychosis Service, UK	Integrated CBT for trauma, voices and dissociation; 24 sessions	1 (1)	Psychotic disorder with social anxiety	30	IES-R	IVI; PSYRATS-AHS; session-by-session measures	DES-t; DASS-21; QPR; CHOICE	6-months	0%
17	Yaser et al., 2018	Setting unclear, Turkey	EMDR; 2 sessions	1 (1)	Paranoid schizophrenia and PTSD.	43	CAPS, CDSS, IES-R, PDS	PANSS	BAI, BDS, BPRS	6-months	

Note: ACT=Acceptance and Commitment Therapy. BAI=Becks Anxiety Inventory. BAVQ=Beliefs About Voices Questionnaire. BDI=Becks Depression inventory. BPRS=Brief Psychiatric Rating Scale. CAPS-5=Clinician Administered PTSD Scale. CDSS=Calgary Depression Scale for Schizophrenia. CORE-10=Clinical Outcomes in Routine Evaluation. CPRS=Comprehensive Psychopathological Rating Scale. CR=Cognitive Restructuring. DASS-21=Depression, Anxiety and Stress Scale. DES-t=Dissociative Experiences Scale-time bound. DID=Dissociative Identity Disorder. EMDR = Eye-Movement Desensitization and Reprocessing. IE=Imaginal Exposure. IES-R=Impact of Events Scale-Revised. IR = Imagery Rescripting. IVI=Interpretations of Voices Inventory. PANSS=Positive and Negative Syndrome Scale. PCL=PTSD Checklist. PDS=PTSD Diagnostic Scale. PTCI=Post-traumatic

Cognitions Inventory. PTSD = Post-traumatic Stress Disorder. PSS=PTSD Symptom Scale. PSYRATS-AHS & PSYRATS-DS=Psychotic Symptoms Rating Scales-Auditory Hallucinations and Delusions Scale. SANS-4: Scale for Assessment of Negative Symptoms. STQ=Satisfaction with Therapy Questionnaire. tf-CBTp=trauma-focused CBT for psychosis. TMQ=Trauma Memory Questionnaire.

Table 2: Summary of findings

	Study	Treatment description	Treatment duration	Main findings	Quality Rating
Descriptive Case Reports					
1.	Brent, 2009	Individual Mentalisation-Based Psychodynamic Psychotherapy. Use of material from within the therapeutic relationship to practice mentalising skills.	Weekly, 1 year	Improved ability to 'mentalise', tolerate interpersonal discomfort and express emotions and cognitions. Reduced distress.	High
2	Frederickson, 1991	Psychotherapy, relational. Encouraging flexibility in thinking to shift rigid delusional beliefs via humour and modelling. Joint exploration of the person's delusion or 'fantasy' world.	Unclear	Improved ability to challenge distressing delusions, increased flexible thinking.	Poor
3	Jackson, 1994	Psychotherapy, integrated. Trauma-based psychosis formulation and normalising emotional responses e.g. shame, anger in trauma-context.	2 years	Reduced distress reported, improved functioning and wellbeing. Reduced delusional thoughts and paranoia.	Moderate

4	Knafo, 2016	Psychoanalysis, relational. Attachment-focused: soothing the regressed person. Focus on countertransference and re-enactment of roles within therapy based on traumas.	Four times weekly for 10 years	Improved interpersonal relationships, long-term social recovery. Reduced psychotic experiences.	Moderate
5	Sar & Tutkun, 1997	Psychotherapy, DID/alters-focused. Grounding, engaging/dialoguing with alters to re-process trauma memories, and integration of personalities.	27 months	Reduced psychotic and PTSD experiences, integrated personality, reduced inpatient treatment.	Moderate
6	Williams, 1998	Freudian Psychoanalysis. Developed shared trauma-formulation of function of delusion and voice. Dialogued with voice and 'The Director'. Expression of trauma-related emotions (anger, shame, sadness).	7 years	Improved ability to think, reflect, tolerate affect and reduced paranoia.	Moderate
Case Series					
7	Brand et al., 2019	Imaginal Exposure (IE): psychoeducation, trauma-memory reprocessing of memories linked to AHs, expanding trauma-narrative, IE exercises, out-of-session tasks.	6 weekly sessions	Improvements in PTSD and AHs however noted symptom exacerbation.	Moderate
8	Brand et al., 2020	IE as outlined above.	6 weekly sessions	Clinically significant improvements in PTSD, AHs and secondary measures at group level. Variance between-subjects.	High

9	Callcott et al., 2004	Integrated tf-CBTp using both here-and-now and longitudinal formulations	Unclear	Unclear	Poor
10	Hamblen et al., 2004	Breathing Retraining, Psychoeducation and Cognitive Restructuring. PTSD-focused, non-integrative.	16 sessions	Increased control of symptoms, and clinically significant reduction in PTSD.	Moderate
11	Jansen & Morris, 2017	Acceptance and Commitment Therapy (ACT): values-based, exposure, distress tolerance.	12 sessions	Self-reported improvements in PTSD symptoms and emotional distress.	Moderate
12	Keen et al., 2017	Integrated tf-CBTp. 5 phases: assessment, stabilization, coping, tf-CBTp, staying well plan.	9 months of weekly or fortnightly although duration varied.	Session-by-session measures indicated reductions in AH distress and frequency, and trauma-related intrusions. Maintained at 3-month follow-up.	High
13	Paulik et al., 2019	Imagery Rescripting (IR) for trauma memories with direct or indirect links to AHs.	10 sessions total, 8 IR sessions		High
Single Case Design Studies					
14	Ison et al., 2014	Imagery Rescripting (IR)	1 baseline session, 1 IR session	Visual inspection (VI) and reliable change indexes (RCIs) showed clinically significant reductions in distress, negative affect and reduced conviction in beliefs both at 1-week follow-up and 1-month follow-up for three of four participants	Poor

15	Marcello et al., 2009	Cognitive Restructuring (CR). 5 steps of CR, supported by keyworker at end of program. Adaptations made for cognitive difficulties.	16 sessions	Session-by-session reduction of depression and PTSD symptoms and self-reported reduction in distress.	Moderate
16	McCartney et al., 2019	Integrated CBT for trauma, voices and dissociation including a stabilisation phase of grounding and breathing.	24 sessions	RCIs and VI indicated non-significant reductions in frequency and distress of AHs and impact of trauma event. Symptom exacerbation at session 12.	Moderate
17	Yaser et al., 2018	EMDR	2 EMDR sessions and 2 control interviews	Declines observed in all outcome measure scores however no analysis completed.	Poor

Note: AH=Auditory Hallucinations. DID = Dissociative Identity Disorder; EMDR = Eye-Movement Desensitization and Reprocessing. PTSD = Post-traumatic Stress Disorder. tf-CBTp = trauma-focused CBT for psychosis

Study characteristics

Six descriptive case reports (DCR), seven case series (CS) and four single case design studies (SCDS) were identified from the search. Studies were conducted in Turkey, Australia, the UK and the USA, in both inpatient and outpatient contexts, and published between 1991 and 2020 (Table 1). Studies included a total of 58 participants (63% female). Only three studies reported on participant ethnicity. Of these, Brand et al. (2020) reported ethnicity for the full sample (86% 'Caucasian'; 6.67% 'Hispanic' and 6.67% 'Other') and two studies partially reported on ethnicity for the full sample, including 78% 'Black and Minority Ethnic Groups' (Keen et al., 2017) and 50% 'white' (Hamblen et al., 2004).

Quality appraisal

Quality appraisals of included studies are detailed in Table 2 and Appendix 1.4. Study quality was rated poor (n=4), moderate (n=9) and high (n=4). Inter-rater reliability was established for a proportion of studies (n=3, 17.6%) using established criteria and pre-determined method (McHugh, 2012; Appendix 1.3). Inter-rater reliability was deemed moderate for descriptive case reports (Cohen's k=0.5), almost perfect for case series (Cohen's k=0.87) and 'substantial' range for single case designs (0.73). Combined inter-rater reliability score was within substantial range (Cohen's k=0.75).

Descriptive case reports

Six Descriptive Case Reports (DCRs) published between 1991 and 2016 were identified. All were psychoanalytic or psychotherapeutic in orientation with quality appraisal ratings of poor (n=1), moderate (n=4) and high (n=1) (Tables 1&2).

Mentalisation Based Therapy (MBT)

Brent (2009) presented a DCR of Mentalisation-Based Psychodynamic Psychotherapy for Psychosis with a man in his 20s in an outpatient setting in USA. True to Mentalisation-Based Therapy (Fonagy et al., 2002), treatment emphasized "identifying and labelling the patient's emotional states and cognitions and using the attachment relationship to consider alternative perspectives" and provided examples in the form of three treatment vignettes (p.805). Re-enactment of previous traumatic relationships within the therapeutic dyad, projections and countertransference were noted as material for MBT.

Psychotherapy

Frederickson (1991) described a DCR of a woman in her 40s experiencing delusions. Frederickson adopted a playful stance in their psychotherapy exploring the division between fantasy and reality and encouraging flexibility and movement between these stances using humour, openness and curiosity. He formulated delusions or the 'fantasy' as serving a protective defensive function against painful realities of traumatic memories, noting that delusions often surfaced when trauma was touched upon in therapy. Defensiveness and rigidity

within the therapist and their own attachment to reality and unwillingness to venture outside of this were seen as barriers to therapy. Challenges such as re-enactment of trauma within the therapeutic relationship were also highlighted.

Sar and Tutkun (1997) reported a DCR from inpatient setting in Turkey and described a phased-based integrated psychotherapy treatment for dissociation, trauma and psychotic experiences for a 45-year-old woman. This included phases of stabilisation, re-processing and integration, mainly working with dissociated personalities (or 'alters'). While all other DCRs alluded to elements of dissociation in presentation, this was the only DCR to explicitly work with alters to re-process traumas and to integrate into an over-arching personality. The authors highlighted the protective function of the alters as a defence from painful past traumatic memories.

Despite spanning over twenty years, case reports echoed themes of trauma re-enactment within the therapeutic relationship and formulate psychotic experiences as functional defences that are a protective response to interpersonal trauma. For example, paranoia was argued to maintain interpersonal distance and mistrust of others, which emerged in a response to developmental interpersonal traumas within caregiver relationships. Jackson (1994) described two DCRs within a series of psychotherapy for individuals with severe mental illness in an outpatient setting. The treatment involved formulating psychosis from a trauma-lens and interpreting "these same symptoms as originating in… response to her childhood trauma" this then "removed some of the guilt and stigma associated with them" (p. 395).

The closeness and care experienced within the therapeutic relationships are hypothesised to be perceived as both threatening and comforting and as such, the therapeutic dyad is a potential vehicle for treatment (Brent, 2009; Knafo, 2016). Counter-transference, projection, re-enactments and regressions are noted to be challenges that require careful consideration from therapists. Establishing and maintaining trust and navigating ruptures were core components of therapeutic change (Brent, 2009; Frederickson, 1991; Jackson, 1994; Knafo, 2016; Williams, 1998). This is perhaps unsurprising considering the interpersonal nature of traumatic experiences among the sample.

The role of dissociation was commented on within all DCRs and grounding techniques were integrated into treatment e.g. grounding alters using client's body (Jackson, 1994), and reminding the client that they are an adult now and that trauma is in past (Knafo, 2016; Williams, 1998). Dissociation was not only incorporated into therapy but also integrated into the trauma-related formulation and/or psychoanalysis, including relational aspects within the presentation and the therapeutic dyad.

Case series

We identified seven case series (CS) that described the psychological treatment of psychosis and trauma published between 2004 and 2020 (Table 1). Treatment approaches included trauma-focused CBT (tf-CBT), Acceptance and Commitment Therapy (ACT), Cognitive

Restructuring, Imagery Rescripting and Imaginal Exposure. Methodological quality of CS varied from poor (n=1), moderate (n=3) and high (n=3) (Tables 1&2).

Acceptance and Commitment Therapy (ACT)

Jansen and Morris (2017) presented a case series of Acceptance and Commitment Therapy (ACT) for posttraumatic stress disorder in early psychosis in Denmark. Three participants received 12 sessions of integrated ACT for psychosis and PTSD. In keeping with the ACT stance, therapy consisted of values-based, experiential components. Reliable changes were reported in outcomes of psychosis symptoms, post-traumatic stress symptoms, anxiety, depression and acceptance and action (a measure of ACT process targets). Limitations included lack of detailed case description, results and methods sections e.g. unclear what sample norms the statistical analysis was based on.

CBT approaches

Two CS utilised a CBT approach. Callcott and colleagues (2004) illustrated the use of integrated formulation and treatment for PTSD and psychosis among two individuals using a problem-specific and longitudinal CBT approach. Measures were taken at baseline and mid-intervention, however no formal analysis was conducted and reporting of measures was inconsistent and not declared a-priori. This CS was short and lacked in detail, with focus on presenting the CBT model rather than the cases. Keen and colleagues (2017) conducted a CS of integrated trauma-focused CBT for post-traumatic stress (PTS) and psychotic symptoms

with nine participants in the Psychological Interventions Clinic for outpatients with Psychosis (PICuP). Therapy consisted of five broad phases integrating PTS and psychotic symptoms in a formulation-based, individualized protocol including 1) assessment, engagement and goal-setting 2) stabilization and coping strategy enhancement 3) tf-CBT-p formulation 4) integrated psychosis and trauma-focused interventions and 5) relapse prevention and staying well plan. Clients were assessed at five time points including baseline, pre-therapy, mid-therapy, post-therapy and 6-month follow-up. Duration of therapy and follow-up varied (8-35 months and 5-18 months respectively) and the sample consisted of individuals with a broad range of PTS and psychotic experiences, ages and ethnicities. Phase 4 of the protocol varied and included schema work, cognitive restructuring and imagery re-scripting. Qualitative feedback indicated that the stabilisation phase increased perceived control, trust and therapeutic alliance and that this was deemed beneficial to later therapeutic work.

Cognitive restructuring

A case series by Hamblen et al. (2004) presented two cases of individuals with PTSD and schizoaffective disorder, who completed breathing retraining, psychoeducation and cognitive restructuring. Increases in control of symptoms, and clinically significant reduction in CAPS and BPRS scores were observed. Traumatic experiences ranged from childhood physical and sexual abuse to war experiences and the role of cognitive impairment and symptom exacerbation were reflected upon. One of the cases reported an exacerbation of distress at the beginning of treatment.

Imagery rescripting

Paulik and colleagues (2019) conducted a case series of eight sessions of imagery rescripting (IR) with 12 voice-hearers, whose voices were directly or indirectly linked to their past traumas in their thematic or emotional content (Hardy, 2017). IR involved the therapist entering the trauma memory to address unmet needs of the adult clients' younger-self and subsequently, the adult client entering the memory and rescripting the memory. Results indicated improvements in voice distress, frequency and trauma intrusions from session-by-session measures, and at pre, mid and post-treatment. A further significant reduction in intrusion frequency was observed at 3-month follow-up, as well as a non-significant decrease of voice frequency. However, voice distress increased at a non-significant level at 3-month follow-up, highlighting initial symptom exacerbation.

Imaginal exposure

Brand and colleagues reported a case series of six sessions of Imaginal Exposure (IE) for auditory hallucinations (Brand et al., 2019; Brand et al., 2020). Although separate studies, Brand2020 illustrates two cases from the larger case series (Brand et al., 2019) with differing outcomes of symptom exacerbation and remission. Intervention was based on Foa's IE manual (Foa et al., 2007) and included psychoeducation, imaginal exposure using narratives of 'hot spots', and out-of-session tasks. Brand et al. (2019) found a large reduction in AH severity and large reductions in PTSD symptoms and trauma-related intrusions that was maintained at follow-up. However individual responses were highly variable and temporary distress and symptom exacerbation were common.

Single case design studies

We identified four Single Case Design Studies (SCDS) published between 2007 and 2019. Treatment approaches included Eye-Movement Desensitization and Reprocessing (EMDR) and CBT with methodological quality ranging from poor to moderate (Tables 1&2).

Integrated CBT approaches

McCartney and colleagues (2019) presented a SCDS of 24-sessions of integrated CBT for voices and dissociation formulated in the context of interpersonal trauma. Treatment consisted of 1) targeting dissociation and 2) trauma re-processing. Results from a combination of session-by-session measures and assessment points at pre, mid, post and 6-month follow-up, indicated significant improvements in frequency and distress of dissociation, and voice-hearing. However, it was noted that despite reductions in dissociation and voice distress post-therapy, initial reductions in dissociation led to worsening of symptoms of voice severity, frequency and post-traumatic intrusions. Authors attributed this to life circumstances rather than therapy.

Cognitive restructuring

Marcello and colleagues (2009) reported a SCDS of Cognitive Restructuring (CR) with a 55-year-old male with PTSD and psychosis. CR led to reductions in PTSD and depressive symptoms over the course of the 16-week program, with measures taken every third session. Considerable limitations were noted including lack of a baseline or follow-up period, as well as no formal visual or statistical analysis. The role of cognitive impairment was highlighted as

having impacted on treatment however was not elaborated upon or formally assessed. Despite this, the intervention was well described and would be easily replicated by clinicians reading the report.

Imagery rescripting

Ison and colleagues (2014) reported a single case series of imagery rescripting (IR) among four participants, comparing pre-and post-scores of one individual baseline and one intervention session. The IR session followed a three-stage rescripting protocol (Arntz & Weertman, 1999) and participants were followed-up at one-week and one-month post-intervention. The baseline session consisted of memory elaboration without therapeutic attempts to modify. Visual inspection and reliable change indices found clinically significant reductions in distress, negative affect and reduced conviction in beliefs both at one-week and 1-month follow-up for three of four participants.

Eye-Movement Desensitization and Reprocessing (EMDR)

Yaser and colleagues (2018) presented a SCDS of two sessions of EMDR with a 43-year-old woman in Turkey. Measures of post-traumatic stress, psychosis, depression and anxiety were administered at baseline, between sessions and at 6-month follow-up. While improvements occurred across all outcomes, missing data was not accounted for and the authors noted that "drug compliance was seemingly increased" during the period of improvement (pg.4). It is also unclear if the study utilised adapted versions of the measures to account for effects of re-

administering measures eight days after baseline assessment as many of the measures are concerned with experiences within the past month only. It was also unclear who had administered the measures.

Discussion

This review synthesised current and historic evidence from case studies of psychological therapies for trauma-related psychosis. We included 17 case studies from a broad range of approaches and sources, including CBT, dynamic psychotherapies, and EMDR published in the last 29 years. Studies were from differing historical, epistemological and discursive contexts, and used various designs. There appeared to be differences in the detail of information provided between DCRs, CS and SCDS, with DCRs providing richer descriptions of interventions. These notable differences in discourse meant that it was challenging to integrate and synthesise findings across methodologies given substantial differences in underlying epistemologies.

Potential sources of bias

There were a number of potential sources of reporting biases identified in the literature. Structural factors such as the publishing journal's philosophy, the political context and guild bias may have biased reporting. Guild bias, or the extent to which clinicians are married to their therapeutic orientation, may have led to selective and biased reporting. Studies may have presented information in a manner that favoured authors' or journals' therapeutic stances and

may not have been representative of the full therapeutic experience. Indeed, the issue of publication bias within the scientific community and a movement towards open science has been raised in recent years (Joober et al., 2012).

Methodological quality of case studies

Methodological quality of case studies was highly variable. There were notable limitations in the design of CS and SCDS and in the reporting quality of DCRs (Appendix 1.5). While DCRs may be considered the lowest level of evidence, three studies provided an account of interventions that would arguably be replicable (Brent, 2009; Frederickson, 1991; Sar & Tutkun, 1997). These contained vignettes to demonstrate core therapeutic components that clearly linked to relevant models or were presented as distinct detailed phases. Other DCRs lacked clarity in describing interventions which is problematic for clinical and research replication. Four studies did not detail incidents of symptom exacerbation that occurred (Brent, 2009; Frederickson, 1991; Knafo, 2016; Williams,1998).

With regard to the quantitative case studies, we did not identify any SCDS with an experimental design. This would have added to the methodological quality of studies. Four studies had poor quality (Frederiskon, 1991; Calcottt et al., 2004; Ison et al., 2014: Yaser et al., 2018), due to unclear reporting, inadequate design and no analysis. Despite 11 studies utilising a quantitative element, methods of data analysis were poor. No studies conducted visual analysis (Lane & Gast, 2014), and opted instead for visual inspection which was more likely to lead to biased

interpretations. Some studies provided descriptive scores only (Calcott et al., 2004; Hamblen et al., 2004; Yaser et al., 2018). Quantitative case studies showed some methodological strength in design by utilising a combination of ideographic and standardised assessment measures and administering these at multiple time-points e.g. daily, session-by-session, and at key time points (Brand et al., 2019; Brand et al., 2020; Keen et al., 2017; Paulik et al., 2019; McCartney et al., 2019). CS also analysed outcomes at both a group and individual level (Brand et al., 2019; Brand et al., 2020; Keen et al., 2017; Paulik et al., 2019). This multi-level approach to designs gave studies strength in their interpretations of findings.

Psychological interventions described within case studies

Regardless of the design of case studies, therapeutic similarities emerged across all psychological interventions described. Activities including psychoeducation, trauma-based formulations of psychotic experiences, shifts in meaning and interpretations, and dialoguing with voices or dissociative alters were components across all psychological therapies. Psychological intervention frequency ranged from one isolated session (Ison et al., 2014) to four sessions per week for 10 years (Knafo, 2016). Interventions also varied from more structured, time-limited, manualised protocols aimed at altering specific, isolated 'hot' intrusive trauma-memories, to more unstructured, longer-term psychotherapeutic approaches that targeted long-standing relational difficulties originating from developmental trauma.

This review also highlighted an on-going debate about whether a stabilisation phase is necessary or leads to an unhelpful delay (McFetridge et al., 2017). While Herman's model of trauma highlights the importance of safety and stabilisation (Herman, 1992), evidence suggested that re-processing can be delivered effectively without a stabilization phase (deBont et al., 2013). Only three studies incorporated a stabilisation phase prior to trauma-focused interventions (Hamblen et al., 2004, Keen et al., 2017; McCartney et al., 2019), and despite longer intervention durations, similar outcomes of initial symptom exacerbation and comparable treatment drop-out rates were observed. However, it may be the case that studies without a formal stabilisation phase did establish and maintain a sense of relational safety which may have enhanced individuals' engagement with trauma-focused work.

In keeping with this finding, recent developments in novel psychological therapies for auditory hallucinations (AHs) including Avatar Therapy and Compassion-Focused Therapy for psychosis, have highlighted that social safety, compassion, trust and control are core therapeutic components for working with distressing voices (Heriot-Maitland, in preparation; Ward et al., 2020). Qualitative feedback from studies indicated that stabilization enhanced participants' perceived sense of control and trust prior to engaging with trauma-work (Hamblen et al., 2004; Keen et al., 2017). Given the high sense of interpersonal threat and mistrust experienced following interpersonal traumas, future clinical research should account for and measure factors such as trust, control and perceived social safety within the therapeutic relationship.

This review highlighted a variety of approaches from time-limited, protocol-driven psychological interventions such as Imaginal Exposure (Foa et al., 2007), to approaches that were longer in duration such as Psychotherapy. Psychotherapeutic approaches often reflected on therapeutic ruptures, relapses or regressions that occurred over longer periods of time. However, Paulik et al. (2019) and Keen et al. (2017) noted that a degree of flexibility was possible within CBT approaches and that this was beneficial for providing therapy to this population.

Qualitative and/or quantitative outcomes of interventions

While all studies reported improvements in both trauma-related symptoms and psychotic experiences, there appeared to be notable individual variation in responsiveness to psychological treatments with symptom exacerbation and increased distress reported in most studies. Few studies included statistical or visual analysis, so it was difficult to establish how reliable and clinically significant the observed changes were.

Individuals in DCRs were often re-admitted to hospital over the course of years of treatment, whereas participants in CS tended to either disengage or persevere following initial increases in distressing symptoms and intense emotions. Symptom exacerbation often coincided with beginning trauma-focused interventions, ruptures in the therapeutic relationships, or external stressors and life circumstances. Symptom exacerbation is not an unexpected, abnormal or adverse event and while some participants found this intolerable and subsequently disengaged,

others tolerated this and later saw improvements in their symptoms. Normalising this process and expectation may serve to increase treatment adherence, minimize drop-outs, foster hope and facilitate long-term recovery.

Studies highlighted other factors that impacted on therapy such as dissociation and cognitive impairment, and what adaptations and considerations were made as a result. While only one study directly targeted dissociation as an a-priori primary outcome (McCartney et al., 2019), it is perhaps unsurprising that other authors hypothesised about its clinical and therapeutic importance, given both recent and historic claims that dissociation plays a key role in the development and maintenance of psychosis following trauma (Ferenczi, 1933; Varese et al., 2012; Pilton et al, 2015).

Strengths

A notable strength of this review is the inclusion of rich evidence from case reports, case series and single case design studies. Case studies are often excluded from systematic reviews despite containing valuable, person-specific and rich contextual information. This level of detail is often lacking in the reporting of results from studies with larger sample sizes e.g. RCTs (deBont et al., 2013). While case studies may be less generalisable, they may also lend themselves well to delivering psychological interventions that are more appropriate for specific complex presentations. Considering clinical researchers are currently in the midst of establishing and untangling complex causal and maintenance mechanisms within trauma-related psychosis,

case studies are a valuable resource of practice-based evidence that can inform future research as well as ongoing clinical practice.

This review used a broad search strategy, with search terms and inclusion criteria that were unrestricted by diagnostic criteria or terminology that may have evolved over time. This resulted in identifying current and historic case studies that spanned a range of clinical presentations, settings, and cultures. Given recent quantitative evidence that dissociation plays a role in the pathway between trauma and psychosis (Pilton et al., 2015), this review provides evidence that these links have long been recognised within clinical practice and can be successfully integrated into psychological interventions for trauma and psychosis.

Limitations

While the inclusion of quality appraisal tools specific for each study type enhanced our review, the use of three different tools (one of which was not a validated appraisal tool), may have impacted the validity of our appraisal ratings. We used cut-off scores (low, moderate, high) for the purposes of comparing methodological quality across the three differing designs based on total scores from each tool (see Appendix 1.5). However, quality ratings may not be directly comparable due to differences in the items and operational definitions used. For example, ROBIN-T scale (used for single case design studies) focused on methodological rigour and items were well operationalised. Whereas, items for the descriptive case report tool focused on take home messages and key learnings and were therefore, more subjective. While these foci

were arguably appropriate for their respective designs, differences in how rating scales defined quality may have impacted total scores (see Appendix 1.5). The sample of papers that underwent calibration and reliability rating by a second reviewer for reliability was also small (calibration: n=3, 17.6%; reliability: n=3, 17.6%), which may have resulted in problems generalising reliability ratings to the total sample. The current review also excluded grey literature and non-English studies. This favoured case studies published in English-speaking countries and thus richer psychotherapy traditions from outside of western cultures may have been excluded. The lack of reporting on ethnicity among included studies is a key limitation, especially considering the high rates of trauma among refugees and asylum seekers (Fazel et al., 2005) and higher prevalence of psychosis within black and ethnic minority populations (Fearon et al., 2006). Participants therefore may not be representative of the wider population and results may be limited in their generalisability. Finally, our review did not include literature involving accounts of people with lived experience of psychological therapies and thus relied only on subjective reports of psychotherapists descriptions of process and meaning. The subjective experiences of the individuals who received therapy may not have been adequately represented in this review. In addition to the therapist description, future case studies ought to report from the participant's perspective to facilitate a richer understanding of therapy experiences from multiple viewpoints.

Research and clinical recommendations

This review highlighted the complexity of presentations within this population, the diversity of approaches that exist, and the flexibility of clinicians, researchers and clients alike to actively

consider developmental and systemic factors in research and therapy. While this is an evolving field, this review highlights the need for more methodologically robust research to inform clinical care for trauma-related psychosis. Future research and case studies should emphasise co-production with individuals with lived experience to facilitate the individual's perspective in the discourse as well following established single case reporting guidelines to reduce bias (SCRIBE; Tate et al., 2016). Future case studies would benefit from being translated into other languages to facilitate learnings from other non-English speaking countries, leading to more culturally diverse understandings and applications. Future case studies also ought to firstly report on ethnicity and secondly, aim to include a more diverse and representative range of ethnic groups. This review suggested that initial symptom exacerbation is common however this is not incorporated into the reporting of larger trials (deBont et al., 2013; Sin & Spain, 2016) which warrants consideration in future research. In terms of clinical practice, establishing relational safety, sharing trauma-informed psychosis formulations and normalising initial symptom exacerbation may be beneficial. A flexible approach to delivering care with particular focus on interpersonal and relational processes rather than strictly adhering to specific time-limited protocols is also recommended. Finally, consideration ought to be given to factors such as cognitive impairment, dissociation and temporary symptom exacerbation.

Conclusions

This review described a wide range of case studies of psychological interventions, mainly from psychotherapeutic and CBT schools of thought. Case studies reported improvements in trauma-

related and psychotic symptoms however, many case studies were of poor quality and symptom exacerbation (particularly distressing voices) was quite common. This may lead to early disengagement from treatment or research trials.

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Chapter 2: Major Research Project

Connection to the Environment with Cognitive Therapy (CONNECT): Exploring trauma, dissociation and voices through targeted psychological intervention using a single-case experimental design.

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Plain English Summary

Title

Connection to Environment with Cognitive Therapy (CONNECT): Exploring Trauma, Dissociation and Voices through Targeted Psychological Therapy

Background

It is estimated that 5-15% of adults will experience voices or auditory hallucinations (AH) at some point in their lives (Maijer et al., 2018). For some, this can be distressing, particularly when their content holds negative associations or meanings for individuals (Morrison, 2001). We know that many people who hear voices have often experienced trauma and feel disconnected (or 'dissociated') from themselves, other people and the world around them. Dissociation is quite common. Examples include:

- Feeling "spaced out" or detached from situations
- Feeling like things, people and the world around you aren't real
- Feeling as if your body doesn't belong to you.

There is evidence that dissociation plays a role in the development and maintenance of distressing AH (Pilton et al., 2015; Pearce et al., 2017) however limited studies have tested this by means of targeted psychological interventions.

Aims

This study aimed to investigate whether reducing dissociation through targeted psychological intervention (Connection to Environment with Cognitive Therapy [CONNECT]) led to improvements in distressing voices among people with a history of trauma. It was hypothesised that, following CONNECT:

1. Dissociation will significantly reduce.

2. Auditory hallucination frequency (AH-F) will significantly reduce.
3. Auditory hallucination distress (AH-D) will significantly reduce.
4. Reductions in dissociation will precede reductions in AH-F and AH-D.
5. Perceived movement towards goals will significantly increase.

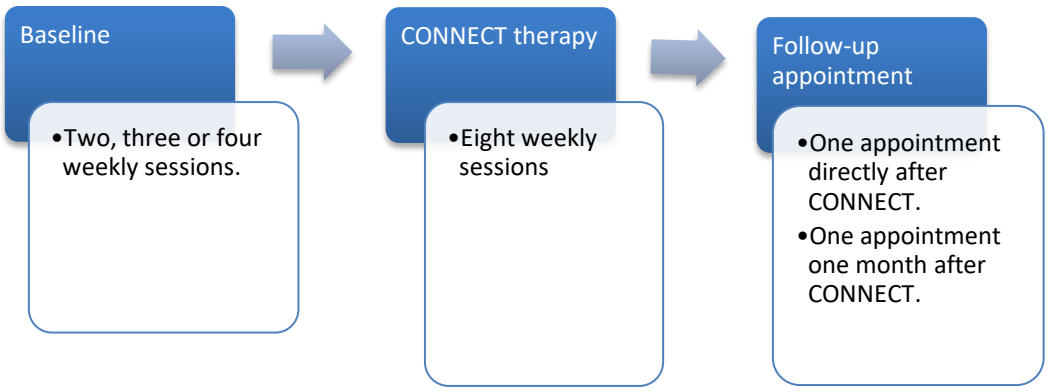
What the study involved

We recruited four individuals from the Glasgow Psychological Trauma Service experiencing distressing AH and dissociation. After gaining informed consent and completing screening questionnaires to establish eligibility, participants were randomly allocated to baseline periods of two, three or four sessions. These sessions did not involve any therapy. The purpose of these sessions was to complete questionnaires to establish individual baseline rates of dissociation and voices to later compare with the intervention period.

What is CONNECT?

All participants received eight sessions of a targeted dissociation therapy called CONNECT (see below). CONNECT involved learning new strategies to help reduce distressing dissociative experiences. This involved becoming aware of the environment using the senses e.g. grounding objects and therapy oils, noticing things in the surroundings.

CONNECT overview



Dissociation and auditory hallucinations were assessed at four main time points: baseline, pre-intervention, post-intervention and one-month post-intervention. During baseline and CONNECT therapy participants completed:

- Questionnaires after the first and last sessions.
- A short questionnaire at weekly sessions.
- A daily questionnaire between sessions.

Data were analysed using specific methods of statistical analysis for single case data which aimed to detect clinically significant and reliable changes.

Results

Results yielded a clinically significant reduction in dissociation following CONNECT. Targeting dissociation did not lead to improvements in the frequency or distress of auditory hallucinations at a group level however AH-F significantly decreased for one participant. Results suggested that temporary increases in AH-F and AH-D may be common, particularly in the initial stages

of therapy. Additional factors such as external stressors, therapeutic alliance and psychological distress may have also contributed to findings.

Conclusions

While CONNECT shows promise as a targeted psychological therapy to reduce dissociation among people with AH and trauma histories, this study did not suggest that reducing dissociation led to improvements in AH. Further research is warranted to aid our understanding of distressing AH in the context of dissociation and trauma.

References

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Word count: 546

Highlights

- Results yielded a clinically significant reduction in dissociation following targeted dissociation intervention.
- Targeting dissociation did not lead to improvements in the frequency or distress of auditory hallucinations.
- Between-participant variation was observed.
- Temporary increases in distress and frequency of auditory hallucinations were common in initial stages of therapy.

Abbreviations

Auditory Hallucinations (AH). Auditory Hallucination Frequency (AH-F). Auditory Hallucination Distress (AH-D). Connection to Environment with Cognitive Therapy (CONNECT). Post-Traumatic Stress Disorder (PTSD). Complex Post-Traumatic Stress Disorder (CPTSD). Single-Case Experimental Design (SCED). Reliable Change Indices (RCI). Visual Analysis (VA).

Abstract

Background: When considering pathways from trauma to psychosis, evidence suggests that dissociation plays a pivotal role. Adopting an interventionist-causal stance, the current study investigated whether targeting dissociation through psychological intervention (Connection to Environment with Cognitive Therapy [CONNECT]) lead to improvements in dissociation, Auditory Hallucination Frequency (AH-F) and Distress (AH-D) for people who have experienced trauma.

Methods: This study utilised a randomised multiple baseline single-case experimental design. Four participants with dissociation, AH and trauma were randomised to baselines of two, three of four weeks and received eight sessions of CONNECT. Dissociation, AH-F and AH-D were assessed at baseline, pre-intervention, post-intervention and 1-month follow-up, session-by-session, and daily self-report. Data were analysed using visual analysis, Tau-U analysis and Reliable Change Indices.

Results: CONNECT led to a significant improvement in dissociation at combined level and non-significant improvements at the individual level. CONNECT did not lead to significant improvements in AH-D or AH-F at the combined or individual level, with the exception of one participant among whom AH-F significantly decreased.

Conclusions: Contrary to evidence that dissociation maintains AH, reducing dissociation through targeted psychological intervention did not lead to improvements in AH. Further

research is warranted with particular emphasis on interventionist-causal approaches, digital technology and network analysis.

Keywords: psychosis, trauma, dissociation, auditory hallucinations, , trauma-focused, single-case experimental design

Introduction

Intrusions can be defined as any thoughts, images or memories that are involuntary and spontaneous (Berntsen, 2009). Involuntary and highly intrusive traumatic memories are considered to be a hallmark symptom of both Post-Traumatic Stress Disorder (PTSD) (American Psychiatric Association, 2013) and Complex PTSD (CPTSD) (Cloitre et al., 2013) and can occur in the form of 'flashbacks' from moments of intense distress experienced during trauma. Whilst intrusions are a common feature of PTSD and CPTSD, they are also commonly reported among individuals with psychosis. Research in cognitive psychology and neuroscience has highlighted similarities in the phenomenology of traumatic intrusions in both PTSD and psychotic disorders, particularly among people experiencing auditory hallucinations (AH) (Brewin et al., 2010; Steel et al., 2005; Morrison, 2001). It has been posited that traumatic events serve as a trigger for the development of intrusions in both PTSD and psychosis (Bebbington et al., 2004; Janssen et al., 2004). Therefore, the underlying mechanisms that maintain trauma-related intrusions may play a vital role in the development and testing of novel treatments to target these symptoms.

Intrusions

Information-processing theories have attempted to explain traumatic memory intrusions that are interpreted as AH (Brewin et al., 2010; Steel et al., 2005). Dual Representation Theory posits that intrusions occur when information from two different memory systems interact (Brewin et al., 2001; Brewin et al., 2010). The first of these systems, the S-Memory, encodes information simultaneously from all sensory fields, creating relatively inflexible sensory and emotive memories. The second system, C-memory, encodes information into a form where it can interact with other relevant autobiographical memories. This system allows for *allocentric processing* – a flexible and integrated representation of information. Intrusions therefore occur when memories from the S-system are retrieved involuntarily in response to related cues where little to no encoded information from the C-memory exists for the same event. This results in sensory memories or 'flashbacks' which occur spontaneously, are vivid and without autobiographical context. Steel and colleagues (2005) have drawn from previous information-processing models of PTSD (Ehlers & Clark, 2000; Brewin, 2001) and psychosis (Morrison, 2001) to develop a cognitive understanding of how intrusions are developed and maintained. They argue that the ability to integrate information into a spatial and temporal context (i.e. allocentric processing) exists on a continuum and that individuals more prone to psychotic experiences are vulnerable to experiencing decontextualized trauma-related memory intrusions due to a reduced ability to contextually integrate information during the traumatic events.

Dissociation

When considering the pathways from trauma to psychosis, evidence suggests that dissociation plays a pivotal role in the emergence and maintenance of AH (Varese et al., 2011; Varese et

al., 2012; Perona-Garcelan et al., 2012; Pilton et al., 2015; Pearce et al, 2017). The DSM-5 describes dissociation as a disruption in the usually integrated functions of consciousness, memory, identity or perception of the environment (American Psychiatric Association, 2013). Indeed, some longitudinal evidence suggests that dissociation predicts the onset and maintenance of distressing voices (Geddes et al., 2016; Escher et al., 2002) and predicts daily voice-hearing experiences (Varese et al., 2011). This link appears to be trans-diagnostic, with significant associations also seen among individuals with psychosis, PTSD, Dissociative Identity Disorder (DID) and non-clinical samples (Pilton et al., 2015).

Dissociation and information-processing accounts of PTSD and psychosis suggest that AH can be understood as de-contextualised trauma-related intrusions. In the case of prolonged and sustained traumatic incidents, the likes of which are highly prevalent within psychosis populations (Bebbington et al, 2004), enduring trait dissociation and poorer contextual integration abilities may contribute to more frequent de-contextualised trauma-related AH. Recent reviews have highlighted the need to develop and test phenomena in a more targeted way, adopting an interventionist-causal stance (Thomas et al., 2014, Hardy, 2017). Indeed, the interventionist-causal approach (Kendler & Campbell, 2009) has been successfully adopted for therapies that target specific maintaining factors in psychotic phenomena such as sleep and worry (Freeman et al., 2015a; 2015b). This approach not only examines effectiveness and causality but also crucially bridges the gap between clinical research and practice, ensuring that subsequent interventions developed are a product of more robust and transparent tests of proposed mechanisms.

This study aimed to investigate whether targeting dissociation through a novel psychological intervention (Connection to Environment Cognitive Therapy [CONNECT]) was associated with improvements in distressing AH for people with a history of trauma. It was hypothesised that, following CONNECT:

1. Dissociation will significantly reduce.
2. AH-F will significantly reduce.
3. AH-D will significantly reduce.
4. Reductions in dissociation will precede reductions in AH-F and AH-D.
5. Perceived movement towards goals will significantly increase.

Method

Design

This study used a randomised multiple baseline Single-Case Experimental Design (SCED) with two phases: baseline and intervention. Participants were also followed-up one month after the intervention. The baseline phase consisted of either two, three or four weekly sessions with the main researcher and therapist (MC). The intervention phase consisted of eight weekly sessions of CONNECT. Outcome measures (see below) were administered at four time points (beginning of baseline [T1], beginning of intervention [T2], end of intervention [T3] and one-month follow-up [T4]). Session-by-session and daily self-report outcome data was also gathered during baseline and intervention phases. Study design and procedures are detailed in Appendix 2.2. As per SCED methodology, participants served as their own baseline (Evans et al., 2014) with outcome measures for daily, session-by-session and assessment time-points being analysed within and between individual baseline and intervention phases. The multiple

baseline lengths of two, three and four weeks were chosen in order to balance both retention and the ethics of withholding access to an active treatment. As per SCED methodology guidelines, observations are recommended to occur across at least three participants, with a minimum of three time points per participant per phase in order to account for between-participant variance and chance (Tate et al., 2013). Therefore this study aimed to recruit a minimum of three participants and thus gained ethical approval to recruit six in order to account for attrition.

Participants

Participants attending the Glasgow Psychological Trauma Service were invited to take part. Clinicians identified and discussed the study with potential participants. If interested in taking part, the main researcher met participants to share study information and gain informed consent (Appendix 2.3 & Appendix 2.4,). Following this, participants completed screening measures and their clinical notes reviewed to establish eligibility.

Inclusion/exclusion

Participants were required to 1) be ≥16 years old; 2) have capacity to consent; 3) have sufficient English to engage in therapy or have access to interpreters and translation services; 4) have a history of trauma and/or CPTSD with a score of ≥ 1 on any of the items of the Brief Betrayal Trauma Survey-14 (BBTS-14) assessing lifetime exposure to interpersonal trauma; 5) be actively experiencing AH of significant frequency and distress for +6 months as indicated by scores ≥ 2 on frequency (e.g. “Voices occurring at least once a day”) and scores ≥ 3 on distress

intensity (e.g. “Voices are very distressing, although subject could feel worse”) items of the Psychotic Symptom Rating Scale (PSYRATS); 6) be experiencing dissociation at a clinical level, as indicated by a score > 20 on the Dissociative Experiences Scale Taxon (DES-T); 7) report AHs and dissociation as their main difficulties, and that they would like to receive a psychological intervention to address these. Participants were excluded if they were concurrently receiving another form of psychological intervention or had an established cognitive impairment that impacted their ability to consent and/or engage.

Procedure

Eligible participants were randomised to baseline periods of two, three or four weeks using a pre-determined randomisation method completed by an independent individual out-with the research team using a computer-generated sequence. The main researcher and therapist (MC) and participants were blinded to baseline allocation until after individual screening. Following screening, participants attended baseline sessions for the purposes of completing in-session measures, socialising to the use of daily measures and establishing personalised goals for use in the daily measure (Appendix 2.2). Baseline sessions did not consist of any intervention components and were focused on the above tasks. Participants then received eight sessions of CONNECT, review, and follow-up at one month. See Appendix 2.1 for detailed procedural information. Baseline and intervention sessions were audio recorded using an encrypted digital audio recorder. Recordings were used for supervision and reflective purposes. MC had access to weekly supervision from a qualified Clinical Psychologist and additional research supervision throughout. In order to minimize response bias in completing the Working Alliance Inventory with MC, participants completed this independently before sessions. Any deviations

from the protocol were documented.

Intervention

CONNection to Environment with Cognitive Therapy (CONNECT) consisted of eight 60-minute sessions delivered weekly (Figure 1). CONNECT was developed by incorporating interventions from current literature including a case-series of cognitive therapy in clients with trauma, dissociative experiences and distressing voices (McCartney et al. 2019) as well as feedback from a survey in managing dissociation among clinicians from the Glasgow Psychological Trauma Service.

Figure 1: CONNECT Intervention

Sessions 1-3	*Assessment and Formulation* Psycho-education and normalisation of voice-hearing and dissociative phenomena. Trauma-informed formulation sharing and building rationale. Introduction to intervention strategies and brainstorming of 'what works' with focus on sensory grounding strategies.
Sessions 4-7	*Exploring strategies to manage dissociation* Training and practicing of skills to manage dissociative responses and increase perceived controllability. Adopting a sensory-based, person-centered 'toolbox' approach. Incorporating any individual sensory preferences and what works. Encouraging personal and meaningful aspect to grounding (e.g. art, music, teddy bears, favourite smells) and involving loved ones where appropriate.
Session 8	*Consolidation* Consolidating the above learnings and skills, relapse prevention

Context

All participants engaged in the procedure in therapy rooms within the Glasgow Psychological Trauma Service.

Screening measures

Trauma: Trauma history was measured using the BBTS-14 (Goldberg & Freyd, 2006). The BBTS-14 is a 14-item self-report measure of frequency of traumatic experiences with responses ranging from 'never', 'one or two times' or 'more than that'.

Dissociation: Dissociation was measured using the DES-T (Waller & Ross, 1997). The DES-T is an eight- item subscale of the full-scale DES-II (Carlson & Putnam, 1993). Each item is scored on a scale from 0-100% with the mean of the eight items being the total score.

Auditory hallucinations: To minimise burden at the point of screening, only the frequency and distress items of the auditory hallucination subscale of the PSYRATS (Haddock et al., 1999) were administered. Item responses range from 0 (absent) to 4 (severe).

Primary outcome measures

Dissociation: The DES-II Carlson & Putnam, 1993) is a 28-item self-report measure of dissociative experiences with answers ranging from 0-100%. The DES-II has good internal consistency (Cronbach's alpha = 92.31) and test-retest reliability (.93) (Dubester & Braun, 1995). Dissociation was also measured using a session-by-session measure and a daily self-report measure as used in previous study (McCartney et al., 2019).

Auditory hallucinations: The PSYRATS-AH (Haddock et al, 1999) was used to measure AH symptom severity at the main study time points. This consists of 12-items with responses ranging from 0 (absent) to 4 (severe). AHs were also measured using a session-by-session measures and a daily self-report measure as used in previous studies (McCartney et al., 2019).

Perceived movement towards goal: A daily self-report visual analogue rating scale was used for the purpose of the current study (Appendix 2.5). At baseline participants defined their goal for this question. Responses ranged for 0-100% to the question "*To what extent do you feel that you have moved towards your goal of X today?"*

Secondary outcome measures

Psychological distress: The Clinical Outcomes in Routine Evaluation-10 (CORE-10; Barkham et al, 2013) was used to measure psychological distress. The CORE-10 is a 10-item scale routinely used in the NHS. Responses are on a four-point likert scale from 0 to 4.

Therapeutic alliance: The Working Alliance Inventory - Short Revised (WAI-SR; Hatcher & Gillaspy, 2006) is a 12-item self-report scale with responses on a five-point likert scale. It has good reliability and validity with moderate correlation to clinical outcomes (r=0.24; Martin et al., 2000).

Participant experience: The Satisfaction with Therapy Questionnaire (STQ; Lawlor et al., 2017) is a 22-item self-report measure to assess satisfaction with CBT-psychosis which was adapted for the purpose of CONNECT. Items are scored on a scale ranging from 1 to 5, with

higher scores corresponding to higher satisfaction

Reflective journal: The researcher kept a reflective journal to qualitatively aid implementation of the study and identify any processes issues or research biases that emerged.

Materials

Materials included participant information sheets, consent forms, outcome measures and daily measures. The therapist also used items for sensory grounding e.g. aroma oils, images of local scenery and stones. A digital audio recorder was used to record sessions (SONY ICD-PX470).

Procedural changes

Weekly sessions were not possible for part of the procedure due to service closure in December and during COVID-19 (March 2020 onwards) which impacted sessions 7 and 8 of CONNECT as well as review and follow-up sessions. The study procedure for these sessions were therefore adapted to be completed remotely by telephone. The WAI-SR and STQ were posted to participants in order to minimize response bias of completing this by telephone. Participants returned the WAI-SR and STQ along with remaining daily measures by post with no identifying information. Due to significant postal delays and lack of access to NHS buildings, additional WAIs were not posted as planned at 1-month follow-up for three remaining participants (75%) resulting in no follow-up analysis for WAI-SR.

Analysis

Primary hypotheses relating to changes in dissociation and AH were tested at the following

levels:

Session-by-session: Combined and single-case Tau-U analysis of session-by-session measures of dissociation and AH were conducted to establish the significant degree of non-overlap between baseline and intervention phases. Tau-U is a non-parametric rank order correlation statistic with promising application for SCED research (Brossart et al., 2018). The session measures of dissociation and AH were also analysed by Visual Analysis (VA) (Lane & Gast, 2013)

Phase level: Individual DES-II and PSYRATS-AH scores were compared against a Reliable Change Indices (RCIs) (Jacobson & Truax, 1992) to determine which phase changes were greater than would be expected from the standard measurement error. Reliability coefficients for the measures and current sample means were used for RCI analysis. RCIs were calculated by dividing the change scores by the standard error of change between the scores. RCIs greater than 1.96 is considered a reliable change (Jacobson & Truax, 1991).

Secondary measures of psychological distress (CORE-10) and working alliance (WAI-SR) were also analysed using RCIs in order to consider contextual observations related to the main hypotheses.

Approvals

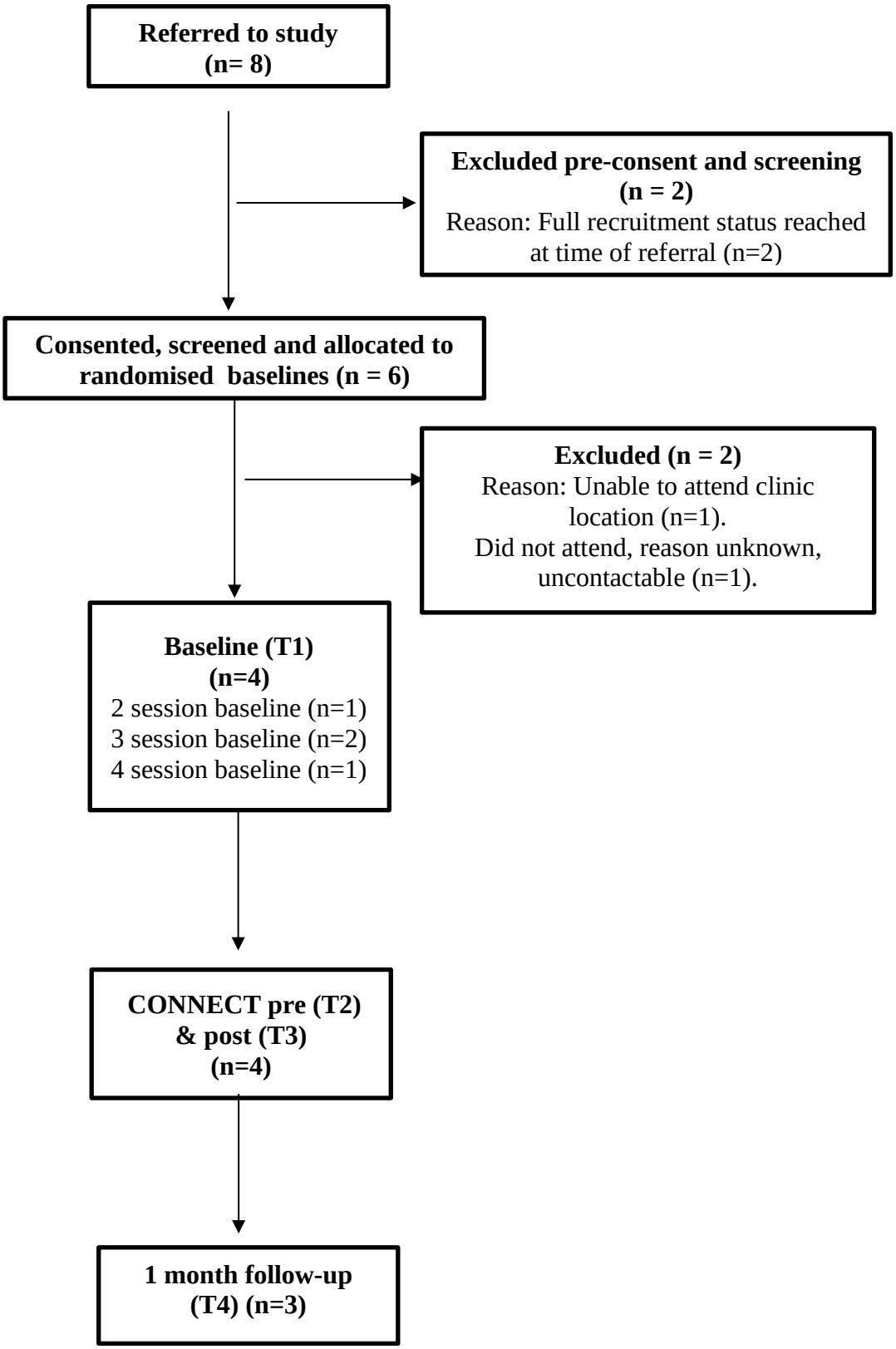
The study was pre-registered on clinicaltrials.gov (reference: NCT04127526) and approved by NHS Research Ethics Committee 5 and NHS Greater Glasgow & Clyde Research & Development (Appendix 2.6 and Appendix 2.7). Following COVID-19 restrictions in March 2020, the study gained approval to continue the study in an adapted remote format.

Results

Recruitment, retention and attrition

Participant flow is outlined in the CONSORT diagram below (Figure 2). Eight participants were consecutively referred for CONNECT therapy between September and December 2019. Six individuals were deemed eligible following screening. Two participants subsequently withdrew prior to baseline because one was unable to travel to the service and the other was not contactable.

Figure 2: CONSORT flow diagram of participant recruitment



Participant characteristics

A total of four participants completed CONNECT therapy and were included in the final analyses. Three identified as 'White British' and one as 'Black African'. Ages ranged from 23-37 years old (mean=32, SD=3.43). Clinical characteristics are highlighted in Table 1, with pseudonyms for anonymity. An overview of relative time sequencing of study procedures is provided in Appendix 2.8.

Table 1: Participant clinical characteristics (n=4)

	P1 "Kim"	**P2 "Eve"**	**P3 "Maria"**	**P4 "Beth"**
Screening Measures (ranges)				
DES-T (0-100)	56.3	53.8	33.8	61.3
PSYRATS-AH Frequency (0- 4)	4	3	2	2
PSYRATS-AH Distress (0-4)	3	3	3	3
BBTS-14 (0-56)	24	15	33	27
Baseline Measures (ranges)				
CORE-10 (0-40)	19	29	21	29
WAI-SR (0-60)	57	51	55	43
DES-II (0-100)	67.9	53.9	38.6	55.1
PSYRATS-AH (0-44)	35	26	31	18
Other within-sample differences				
Baseline length (sessions)	2	3	3	4
Total procedure length (days)	112	162	109	133

Note: BBTS-14 = Brief Betrayal Trauma Survey-14 (range = 0-56); CORE-10 = Clinical Outcomes in Routine Evaluation (range = 0-40); DES-T = Dissociative Experiences Scale-Taxon (range = 0-100); DES-II = Dissociative Experiences Scale - II Revised (range = 0-100); PSYRATS-AH =Psychotic Symptom Rating Scale – Auditory Hallucination Subscale (range = 0-44); PSYRATS-AH = Psychotic Symptom Rating Scales – Auditory Hallucination Scale. Frequency question (range = 0-4) and Distress question (range = 0-4); WAI-SR = Working Alliance Inventory Short Revision (range = 0-60)

Feasibility, acceptability and missing data

All participants provided full primary outcome measures at three of the four assessment time points. One participant was uncontactable at follow-up (T4) and her GP was informed. All participants consented to sessions being audio recorded. Completion of daily outcome measures was variable, with large amounts of missing data (Appendix 2.9) and thus inadequate for VA. All session-by-session measures were administered on all occasions except two (4.5% of total sessions) for two participants (P2 and P4). Both were in the first CONNECT session where P2 expressed thoughts of suicide which took clinical priority and P4 reported finding administration too burdensome therefore it was agreed to discontinue completing measure.

Hypothesis 1: dissociation will significantly reduce following CONNECT

Results from combined Tau-U analysis supported the hypothesis that dissociation significantly reduced following CONNECT (Table 2). Tau-U analysis at the combined level showed a significant reduction in dissociation (Tau U= -.48, p=0.014, 90% CI: -0.81, -0.16). However, this hypothesis was not supported at the individual level: baseline Tau-Us indicated negative baseline trends for P1 and P2 and positive trends for P3 and P4 with high levels of variation across observations (Table 2). Standard deviations for dissociation scores were also larger than in the change phase, indicating greater variance during intervention phase when compared to baseline phase.

Table 2: Tau-U analysis for session-by-session measures of dissociation

	Participant	**Tau-U**	**SD**	**p-value**	**90% CI**
Baseline (baseline trend)	P1 Kim	-.33	1.91	.602	-1.00, .59
	P2 Eve	-.33	1.91	.601	-1.00, .59
	P3 Maria	.33	2.94	.497	-.37, 1.00
	P4 Beth	.33	2.94	.497	-.37, 1.00
Intervention (phase change)	P1 Kim	-.14	8.78	.732	-0.83, 0.55
	P2 Eve	-.57	8.78	.171	-1.00, .12
	P3 Maria	-.57	10.58	.131	-1.00, .05
	P4 Beth	-.60	10.58	.108	-1.00, .02
Combined (combined phase change)		-.48		.014*	-.81, -.15

* = *significance at p>0.05*

VA of session-by-session dissociation scores are summarized in Tables 3 and 4 (detailed analysis in Appendix 2.10). Within-condition VA indicated deceleration in dissociation trends for P1, P2 and P4 and acceleration for P3 during baseline (Table 3). During intervention phase, deceleration trends were observed for all participants (Table 3). Between-condition VA indicated decreases in dissociation for all participants except for P1 (Table 4).

Table 3: Summary of within-condition visual analysis for session-by-session dissociation

Participant		**Baseline**	**CONNECT**
P1 Kim	Direction	↓	↓
	Stable or variable?	Stable	Variable
	Multiple paths within trend? (n)	Yes (2)	Yes (4)
P2 Eve	Direction	↓	↓
	Stable or variable?	Stable	Variable
	Multiple paths within trend? (n)	No	Yes (4)
P3 Maria	Direction	↑	↓
	Stable or variable?	Variable	Variable
	Multiple paths within trend? (n)	Yes (2)	No
P4 Beth	Direction	↓	↓
	Stable or variable?	Stable	Stable
	Multiple paths within trend? (n)	Yes (2)	Yes (4)

↑ = accelerating; ↓ = decelerating

Table 4: Summary of between-condition visual analysis for session-by-session dissociation measure (range 0-100)

Participant	Median 2nd half of baseline	Median 1st half of intervention	Relative level change in scores
P1 Kim	60	72.6	+12.5
P2 Eve	40.8	35.8	-5
P3 Maria	17.5	10	-7.5
P4 Beth	69.5	61.3	-8.3

At the phase level, RCI analyses indicated clinically significant reductions in dissociation during CONNECT therapy (T2->T3) for P1 and P2 and non-clinically significant reductions for P3 and P4 (Table 5). At follow-up, clinically significant changes in dissociation scores were observed in P1 (10.1 increase) and P4 (19.29 decrease).

Table 5: Dissociation score differences and direction of changes between time-points.

	Participant	T1 -> T2 (Baseline)	T2 -> T3 (CONNECT)	T3->T4 (C->1MFU)
DES-II score differences	P1 Kim	4.29 ↑	**27.85 ↓***	**10.1 ↑***
	P2 Eve	7.15 ↑	**28.93 ↓***	7.14 ↑
	P3 Maria	5.36 ↓	5.00 ↓	-
	P4 Beth	**11.77 ↑***	6.52 ↓	**19.29↓***

Note: DES-II=Dissociative Experiences Scale - II Revised (range = 0-100). T1=Pre-baseline; T2=Pre-CONNECT; T3=Post-CONNECT; T4=1-month follow-up. 1MFU=1 month follow-up.). Changes in scores higher than the RCI of 1.96 are highlighted in bold and '*'

Hypothesis 2: AH-F will significantly reduce following CONNECT

Results from combined Tau-U analysis did not support the hypothesis that frequency of AH-F significantly reduced following CONNECT (Table 6). Combined Tau-U analysis suggested a non-significant reduction in AH-F (Tau-U= -.18, p=0.368). At an individual level, the hypothesis was supported for P2 only while baseline Tau-U values suggested negative baseline trends for P1, P3 and P4. (Table 6). Baseline trends were non-significant and there were high levels of variance within observations. Following CONNECT, individual Tau-U analysis indicated a significant reduction in AH-F for P2 (Tau-U=-0.85, p=0.040) while P1, P2 and P4 showed non-significant changes and high variation (Table 6).

Table 6: Tau-U analysis for session measures of auditory hallucination frequency

	Participant	**Tau-U**	**SD**	**p-value**	**90% CI**
Baseline (baseline trend)	P1 Kim	-.33	1.91	.602	-1.00, 0.72
	P2 Eve	.33	1.91	.602	-0.72, 1.00
	P3 Maria	-.50	2.94	.308	-1.00, 0.31
	P4 Beth	-.33	2.94	.497	-1.00, 0.47
Intervention (phase change)	P1 Kim	.24	8.78	.569	-0.449, 0.925
	P2 Eve	-.85	8.78	**.040***	-1.00, -0.17

	P3 Maria	-.60	10.58	.108	-1.00, 0.015
	P4 Beth	.46	10.58	.219	-0.16, 1.00
Combined (combined phase change)		-0.18		.368	-0.51, 0.14

* = *significance at p>0.05*

VA of session-by-session AH-F scores are summarised in Table 7 and 8 (detailed analysis in Appendix 2.11). Within-condition VA indicated deceleration in AH-F trends for P1, P3 and P4 and acceleration for P2 during baseline (Table 7). Intervention phase data indicated acceleration trends in P1 and P2, a deceleration trend in P3, and no change in P4 (Table 7). Relative level changes from between-condition VA indicated relative increases in AH-F for all participants except for P2 (Table 8).

Table 7: Summary of within-condition visual analysis for session-by-session auditory hallucination frequency

Participant		**Baseline**	**CONNECT**
P1 Kim	Direction	↓	↑
	Stable or variable?	Variable	Stable
	Multiple paths within trend? (n)	Yes (2)	Yes (3)

P2 Eve	Direction	↑	↑
	Stable or variable?	Stable	Stable
	Multiple paths within trend? (n)	Yes (2)	Yes (4)
P3 Maria	Direction	↓	↓
	Stable or variable?	Variable	Stable
	Multiple paths within trend? (n)	Yes (2)	Yes (3)
P4 Beth	Direction	↓	→
	Stable or variable?	Variable	Variable
	Multiple paths within trend? (n)	Yes (2)	Yes (4)

↑ = accelerating; ↓ = decelerating; → no change

Table 8: Summary of between-condition visual analysis for session-by-session auditory hallucination frequency (range 0-100)

Participant	**Median 2nd half of baseline**	**Median 1st half of intervention**	**Relative level change in scores**
P1 Kim	80	85	+5
P2 Eve	70	50	-20
P3 Maria	40	50	+10
P4 Beth	35	55	+20

Hypothesis 3: AH-D will significantly reduce following CONNECT

Results from the Tau-U analysis did not support the hypothesis relating to AH-D (Table 9). Combined Tau-U analysis indicated a non-significant increase in AH-D at phase change (Tau-U = -.13, p=0.608). Individual baseline Tau-Us showed negative baseline trends for all participants except for P1 and baseline trends did not reach significance (Table 9). Individual Tau-U for phase change following intervention were positive except for that of P3 and all were non-significant (Table 9). There was high variation in participant scores in CONNECT compared to baseline (Table 9).

Table 9: Tau-U analysis for session measures of auditory hallucination distress.

	Participant	**Tau-U**	**SD**	**p-value**	**90% CI**
Baseline (baseline trend)	P1 Kim	.33	1.91	.602	-.70, 1.00
	P2 Eve	-1.00	1.91	.117	-1.00, .05
	P3 Maria	-.67	2.94	.174	-1.00, .14
	P4 Beth	-.50	2.94	.308	-1.00, .31
Intervention (phase change)	P1 Kim	.29	8.78	.494	-.40, .97
	P2 Eve	.43	8.78	.305	-.26, 1.00
	P3 Maria	-.36	10.58	.345	-.98, .27
	P4 Beth	.14	10.58	.705	-.48, .77
Combined (combined phase change)		.13		.608	-.22, .43

* *= significance at p>0.05*

VA of session-by-session AH-D scores are summarised in Table 10 and 11 (detailed analysis in Appendix 2.12). Within-condition VA indicated deceleration in AH-D trends for P2, P3 and P4 and acceleration for P1 during baseline (Table 10). Intervention phase data indicated acceleration trends in P1, P2 and P4 and a deceleration trend in P3 (Table 10). Relative level changes from between-condition VA indicated relative increases in AH-D for all participants except for P1 (Table 11).

Table 10: Summary of within-condition visual analysis for session-by-session auditory hallucination distress

Participant		**Baseline**	**CONNECT**
P1 Kim	Direction	↑	↑
	Stable or variable?	Variable	Variable
	Multiple paths within trend? (n)	Yes (2)	Yes (5)
P2 Eve	Direction	↓	↑
	Stable or variable?	Variable	Variable
	Multiple paths within trend? (n)	No	Yes (5)
P3 Maria	Direction	↓	↓
	Stable or variable?	Variable	Stable
	Multiple paths within trend? (n)	Yes (2)	Yes (4)
P4 Beth	Direction	↓	↑

	Stable or variable?	Variable	Variable
	Multiple paths within trend? (n)	Yes (2)	Yes (5)

↑ = accelerating; ↓ = decelerating; → no change

Table 11: Summary of between-condition visual analysis for session-by-session auditory hallucination distress (range 0-100)

Participant	**Median 2nd half of baseline**	**Median 1st half of intervention**	**Relative level change**
P1 Kim	85	75	-10
P2 Eve	25	40	+15
P3 Maria	40	50	+10
P4 Beth	35	55	+20

At the phase level, RCI analyses did not support Hypotheses 2 or 3 that CONNECT therapy led to significant reduction in frequency or distress of AH. Directions of changes observed in T2->T3 were mixed, with none reaching clinical significance (Table 12). Notably, both P1 and P2 experienced a reduction of AH symptom reduction during the baseline period (T1-> T2) and experienced a subsequent increase in AH scores during CONNECT, however at a non-significant level.

Table 12: Auditory hallucination score differences and direction of changes between time-points.

	Participant	**T1 -> T2 (Baseline)**	**T2 -> T3 (CONNECT)**	**T3->T4 (1MFU)**
PSYRATS-AH score differences	P1 Kim	10 ↓	7 ↑	9↑
	P2 Eve	2 ↓	1↑	5↓
	P3 Maria	0 →	5↓	-
	P4 Beth	10 ↑	6 ↓	4↑

Note: PSYRATS-AH = Psychotic Symptom Rating Scale – Auditory Hallucination Subscale (range = 0-44). T1=Pre-baseline; T2=Pre-CONNECT; T3=Post-CONNECT; T4=1-month follow-up. 1MFU=1 month follow-up.). Changes in scores higher than the RCI of 1.96 are highlighted in bold and '*'

Hypothesis 4: Reductions in dissociation will precede reductions in AH-F and AH-D

Tau-U and RCI analyses did not support Hypotheses 1-3 (Tables 2-12 above); by extension, the above hypothesis was not supported.

Hypothesis 5: CONNECT will lead to perceived movement towards goals

Planned VA to explore the above hypothesis was not possible due to missing daily self-report data (Appendix 2.9).

Secondary analysis

In addition to analysis of the primary hypotheses, supplementary analyses were conducted for the secondary outcome measures administered. RCIs were calculated for psychological distress and therapeutic alliance based on current sample means. Missing item responses for 3 of the 12 WAI-SR were imputed using median scores of completed responses within each subscale. Results of RCI analyses indicated that psychological distress significantly decreased for P1, P2 and P3 and decreased at a non-significant level for P4 (Table 13). Alliance significantly increased for P2 and P4 during CONNECT (Table 13). CORE-10 and WAI-SR scores are detailed in Appendix 2.13.

Table 13 Score changes and direction changes in CORE-10 and WAI scores between phases

	Participant	**T1 -> T2 (Baseline)**	**T2 -> T3 (CONNECT)**	**T3->T4 (1MFU)**
Outcome measure				
CORE-10	P1 Kim	**8 ↑***	**7 ↓***	**12 ↑***
	P2 Eve	6 ↑	**20 ↓***	1 ↑
	P3 Maria	6 ↓	**8 ↓***	-
	P4 Beth	4 ↓	3 ↓	0
WAI-SR	P1 Kim	5 ↓	4 ↑	5 ↓
	P2 Eve	**11↓***	**15 ↑***	-
	P3 Maria	1 ↓	-	-
	P4 Beth	1 ↓	**15 ↑***	-

Note: CORE-10=Clinical Outcomes in Routine Evaluation (range = 0-40); WAI-SR=Working Alliance Inventory Short Form (range=0 -60). T1=Pre-baseline; T2=Pre-CONNECT; T3=Post-CONNECT; T4=1-month follow-up. Changes in scores higher than the Reliable Change Index (RCI) are significant and highlighted in bold and *

Three participants completed the STQ one month post-intervention. All participants reported having expected to make "no progress" or "little progress" prior to CONNECT, however reported having made "a lot of progress" and that they would make "a lot of progress" in future. All participants reported being "very satisfied" with CONNECT overall and found the between-session tasks "very helpful".

Adverse events

No adverse events related to the study procedure were reported.

Discussion

This was, to our knowledge, the first single-case experimental design study exploring the effects of a targeted dissociation intervention among individuals with trauma histories and AH. We triangulated findings from a trilogy of analytic methodologies (VA, Tau-U, RCIs) to evaluate the impact of CONNECT on dissociation, AH-F and AH-D. This was done at both an individual and combined level, and within- and between-phases. The variety of analytic approaches, frequency and depth of measurement, and the inclusion of multiple baselines, enabled us to interpret results with greater context, adding richness and strength to our observations.

Dissociation

In triangulating findings from across the three analyses, CONNECT appeared to reduce levels of dissociation. However this was only of clinical significance at the combined level. Interestingly, RCIs indicated clinically significant reductions for two participants following CONNECT; however, this was not reflected in individual Tau-U analyses or VAs, where reductions were non-significant and variable. Moreover, score differences observed for those participants at phase change suggested that dissociation was increasing over baseline, making the subsequent significant reductions in RCIs following CONNECT even more striking. Inspection of graphic displays (see Appendix 2.10-2.12) as well as wide confidence intervals and large standard deviations in Tau-Us raise the issue of high variance and multiple paths observed, particularly within the CONNECT phase. Improvements in dissociation were also only maintained at a clinically significant level for one participant one month after CONNECT. These observed improvements in dissociation are in line with a recent single-case study by McCartney and colleagues (2019), which found improvements in dissociation following a 24-sessions dissociation intervention for individuals with AHs and trauma.

Auditory hallucinations

Adopting an interventionist-causal perspective (Kendler & Campbell, 2009), we hypothesised that targeting dissociation would result in clinically significant reductions in AH-F and AH-D. However, findings did not support this and were highly variable. An exception to this was found at the individual level, whereby one participant saw a clinically significant reduction in AH-F following CONNECT. VA indicated reductions in AH-F for three participants over

baseline, with relative increases observed following the subsequent introduction of CONNECT. This is in stark contrast to accounts that consider AH to be trauma-related intrusive phenomena with dissociation proposed to lead to poorer contextual integration and more frequent AH (Steel et al., 2005). Targeting dissociation did not lead to fewer AH and in some individual cases, led to more AH, especially in the initial stages. Similarly for AH-D, data suggested that CONNECT did not lead to clinically significant improvements. While results from Tau-U analyses for AH-D were non-significant, the direction of phase changes was consistent at all levels of analyses with decreasing trends observed over baseline followed by increasing trends following the introduction of CONNECT. The observed decrease in AH-D during the baseline phase and subsequent increase following CONNECT poses interesting questions. It may be that CONNECT's initial focus on psychoeducation and developing a trauma-informed understanding of AH, led to AH being interpreted in the context of distressing trauma-memories. Thus, increasing contextual integration (Steel et al., 2005) may increase AH-D. Dissociation may play a protective role in avoiding engagement with distressing trauma-related AH. Indeed, recent evidence suggests that individuals who experience 'trauma-related dissociation' and AH are often ambivalent about whether AH are related to their traumatic experiences despite links in AH content (Luhrman et al., 2019). Individuals in this sample had not yet completed trauma-focused therapy and therefore associations between AH and unprocessed trauma-memories may have led to high levels of distress. However, initial increases in distress would be expected in the early stages of trauma-focused psychological therapy and we would caution against pathologising such a response.

While dissociation may play a key role in the development of AH (Pilton et al., 2015; Hardy, 2017), high levels of individual variation suggest that dissociation may hold different maintenance roles for AH for different participants. This raises the question of whether AH are primarily dissociative or intrusive phenomena, or both, and whether differential AH phenomenology may have existed among the current sample. If so, a simplistic interventionist-causal pathway approach may not have adequately captured the complexity and variation of mechanisms between dissociation, trauma and AH (Pearce et al., 2017; Perona- Garcelán et al., 2012; Hardy, 2017).

Uncertainty of outcomes and individual differences

Factors such as time, external life events and individual differences may have contributed to the variable responses observed, and hence uncertainty of causality of outcomes. Three participants experienced significant distressing life events including bereavements, romantic relationship breakdown, financial stressors and fear of re-victimisation. Furthermore, both the VA and RCI analyses of CORE-10 and WAI-SR scores hint at the complexity and potential interplay between dissociation, AH and other factors such as stress, sleep and the therapeutic relationship. At an individual level, daily self-report measures often provided additional evidence that day-to-day stressors impacted on experiences of dissociation, voice hearing and associated distress. Individual external stressors may be particularly important confounding factors to consider, as both trauma and psychosis are widely understood within a stress-vulnerability model (Zubin & Spring, 1977). Daily fluctuations in distress have also been suggested to be associated with AH intrusions and dissociation (Varese et al., 2011; Steel et al., 2005). Individual differences in observations also echo recent findings from network

analyses which suggest that negative affect and fear of relapse (Allen et al., in prep) and trauma-related beliefs and responses (Hardy et al., 2020) are associated with psychotic phenomena.

Qualitative feedback from participants and therapist observations mirror recent research that identified trust and power as core therapeutic processes in psychological approaches for trauma-related AH (Ward et al., 2020). Given the interpersonal nature of traumatic events in CPTSD, providing a safe relationship and establishing a trusting working alliance was an important aspect of the intervention. Furthermore, the significant increases observed in the WAI scores following CONNECT may have aided tolerance of increases in AH-F and AH-D. Although not formally measured, all participants had high levels of internal motivation, resilience and strength as evidenced by the historic and ongoing experiences reported during therapy. Therefore, internal traits such as resilience, empowerment and motivation may also impact outcomes and would be an important area for future research.

Strengths

CONNECT is a targeted, person-centred, adaptable therapy that is concept-driven, using sensory grounding to target dissociation. CONNECT is flexible with the strategies and techniques tailored to individual participants . For example, P2 (Eve) preferred grounding strategies that were visual, while P3 (Maria) preferred grounding strategies that incorporated family and spirituality. This study also used a single-case experimental design, which enabled individual observations to be interpreted in a rich, person-specific context and reduced the risk of overinterpreting changes in outcomes as being related to CONNECT. The utilisation of a

multiple-baseline design enhanced our ability to interpret changes in outcomes following CONNECT with greater confidence.

Limitations

This study also had limitations. The instability of the dependent variables seen within the baseline phase may have impacted on our ability to detect a treatment effect following phase change. Future studies could account for this by introducing treatment at the point of stability of variables being established. While we incorporated clinicians feedback into the development of CONNECT, no individuals with prior experience of similar interventions were consulted in the process. We also did not establish fidelity to CONNECT i.e. if sessions within baseline and intervention phases were fundamentally different in their content. This would have been achieved by an independent assessor blindly assessing a random sample of audio recordings from baseline and intervention phases for the presence of CONNECT intervention components. We had planned to do this however were unable to proceed due to local restrictions to non-essential research following COVID-19. Future research and developments should incorporate feedback from the Satisfaction with Therapy Questionnaires, seek public and patient involvement (PPI), and assess fidelity to CONNECT.

The current sample was small and consisted of females under the age of 37 with CPTSD diagnoses. Findings therefore may not be generalisable to other clinical populations. Most participants identified as 'White British', a key limitation given the high rates of trauma among refugees and asylum seekers (Fazel et al., 2005) and higher prevalence of psychosis within black and ethnic minority populations (Fearon et al., 2006). The inclusion of non-English

speakers and individuals with poor literacy may be an avenue for future exploration to enhance CONNECT's applicability and inclusiveness. Our study found interesting variation in AH responses to a targeted dissociation intervention, suggesting that AH phenomenology may have fundamentally differed within the sample. The current study did not explore or measure differences in the causal or maintenance mechanisms of dissociation in relation to AH. However individual psychological formulations suggested that individual differences may have contributed to the variance in AH responses observed following dissociation reductions. The interventionist-causal approach may have thus led to varied responses and uncertainty in outcomes.

The outbreak of COVID-19 in March 2020 resulted in the latter part of CONNECT being completed remotely for three participants. Outcomes may therefore be fundamentally different due to factors unrelated to CONNECT. Necessary changes to the administration as well as the known impact of COVID-19 on mental health (Holmes et al., 2020) may have impacted participant experiences and responses. Finally, there were missing data for the daily self-report measures, leading to inability to complete the planned analysis. Future research should consider using digital technology to monitor symptoms, such as a mobile phone application which is immediate, less labour-intensive, and shows promise for individualised formulation and therapy decision-making (Allen et al., 2019; Bell et al., 2020).

Application

CONNECT was originally developed from a variety of sources including interventions from similar case series (Keen et al., 2017; McCartney et al., 2019), pilot work completed with the

Glasgow Psychological Trauma Service and an evolving knowledge of the field of psychological therapies for trauma-related AH and dissociation. At face-value, CONNECT consists of strategies routinely used across a variety of clinical settings for complex psychological presentations. Given recent evidence for the efficacy and feasibility of trauma therapies for people with psychosis (Keen et al., 2017; Paulik et al., 2019; Brand et al., 2020), CONNECT may have a role as a pre-cursor to trauma-reprocessing within this population.

Conclusions

CONNECT shows promise as a therapy to reduce dissociation for people with AH and a history of trauma, although further development and research is needed. Contrary to previous findings, results indicate that targeting dissociation did not lead to reductions in AH-F or AH-D. Dissociation may not play as central a role in the maintenance of trauma-related AH as theories propose and may serve as a protective function against distressing AH for some. However our sample size was small with variability in responses and the length of intervention was brief.

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CRediT authorship contribution statement

Moya Clancy: Conceptualisation, data curation, analysis, writing - original draft. Kirsten

Atherton: Conceptualisation, supervision, writing - review & editing. Filippo Varese: Conceptualisation. Andrew Gumley: Conceptualisation, supervision, writing - review & editing.

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Appendix 1.1: Author guidelines for submission to Psychotherapy Research

2 Instructions for authors

Please note that this journal only publishes manuscripts in English.

2.1.1 Preparing your paper

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

2.1.1.1 Structure

Authors will need to include a separate 2-3 sentence summary labelled "Clinical or Methodological Significance of this Article" and should also include a word count with their article.

2.1.1.2 Word limits

Manuscripts reporting results of quantitative or qualitative research generally should not exceed 35 double-spaced pages (including cover page, abstract, text, references, tables, and figures), with margins of at least 1 inch on all sides and a 12-point font. Concise manuscripts are favored over lengthier manuscripts, as long as quality is not compromised in abbreviating a paper. For manuscripts that exceed these page guidelines, authors must provide a rationale in their cover letter to justify the length of their paper. Papers that do not conform to these guidelines will be returned to authors without a peer review.

2.1.1.3 Style guidelines

Please use APA (American Psychological Association) style guidelines when preparing your paper, rather than any published articles or a sample copy.

Please use American, British-ize spelling style consistently throughout your manuscript.

Please use double quotation marks, except where "a quotation is 'within' a quotation". Note that long quotations should be indented without quotation marks.

References

All submitted manuscripts should conform to the current APA (American Psychological Association) style. Please use this reference style guide when preparing your paper. An EndNote output style is also available to assist you.

Appendix 1.2: Search Strategy (available on PROSPERO, CRD: 42020178384)

An electronic database search was conducted using MEDLINE, EMBASE, PsycINFO and CINAHL. The search strategy and terms were agreed following examination of previous reviews in the area, scoping searches, consulting relevant experts in the field and discussions within the review team. Searches were limited to English language articles and humans. In order to maximize our search inclusivity, references of review articles that fit our criteria were reviewed to identify any that may have not been identified in the search. Forward citation of review articles were conducted using Google Scholar.

Ovid (MEDLINE (R) 1946 to 2020; Embase 1947 to 2020). Limited to English	
S1 Population / problem (psychosis)	Psychosis [MeSH] OR Psychotic Disorder [MeSH] OR schizophreni* [MeSH] OR psychotic.mp OR hallucinat*.mp OR delusion*.mp OR paranoi*.mp OR voice*.mp OR intrusi*.mp
S2 **Population / problem** (trauma)	psychological trauma [MeSH] OR post-traumatic stress disorder [MeSH] OR psychotrauma [MeSH] OR trauma*.mp OR PTSD.mp OR "post-traumatic stress".mp OR CPTSD.mp OR CPTSD.mp OR "complex trauma".mp OR neglect*.mp OR abus* [MeSH] OR violen* [MeSH] OR assault* [MeSH] OR crime victim* [MeSH] OR survivor* [MeSH]
S3	S1 AND S2
S4 **Intervention**	psychotherapy*[MeSH] OR "Trauma-focused therap*".mp OR "trauma therap*".mp OR therap* [MeSH] OR "Cognitive Behavioural Therapy" [MeSH] OR "Cognitive Behavi?r* Therap*".mp OR CBT.mp OR "Cognitive therap* [MeSH] OR reprocessing.mp
S5 **Design** (case reports/studies)	case reports [MeSH] OR case stud*".mp OR "single case".mp OR SCED.mp OR "single case experimental design".mp OR "N of 1".mp OR "N of one".mp OR "N = 1".mp OR case*.mp OR report*.mp
S6	S3 AND S4 AND S5

EBSCO (PsycInfo). Limited to English	
S1 Population / problem (psychosis)	MM schizophreni* OR KW schizophreni* OR MM psychosis OR KW psychosis OR MM psychotic disorder OR KW psychotic disorder OR MM hallucinati* OR KW hallucinati* OR KW delusion* OR KW delusion* OR DE "Hallucinations" OR DE "Auditory Hallucinations" OR DE "Visual Hallucinations" OR DE "Delusions" OR DE "Paranoia" OR DE "Paranoia (Psychosis)" OR DE "Paranoid Schizophrenia"
S2 **Population / problem** (trauma)	MA trauma OR KW trauma OR MA post-traumatic stress OR KW post-traumatic stress OR MA post-traumatic stress disorder OR KW post-traumatic stress disorder OR KW complex ptsd OR KW stress and trauma-related disorders OR KW combat experience OR KW abus* OR KW violen* OR KW assault* OR KW survivor* OR KW victim* MM "Complex PTSD" OR MM "Posttraumatic Stress Disorder" OR MM "Crime Victims" OR MM "DESNOS" OR MM "Domestic Violence" OR MM "Emotional Trauma" OR MM "Survivors" OR MM "Trauma" OR MM "Victimization"
S3	S1 AND S2
S4 **Intervention**	MM psychotherapy OR MA psychotherap* OR KW psychotherap* OR MM cognitive therapy OR MM cognitive behavior therapy OR KW prolonged exposure therapy OR KW cognitive processing therapy OR MM intervention OR KW intervention KW treatment OR KW therapy
S5 **Design** (case reports/studies)	MM case study OR KW case srudy OR KW case report OR KW single case OR KW n of 1 or MM single case experimental design OR KW single case experimental design OR KW single case design
S6	S3 AND S4 AND S5

EBSCO (CINAHL) limited to English	
S1 Population / problem (psychosis)	MM schizophreni* OR MM psychotic disorders OR MM hallucinations OR TI psychosis OR AB psychosis OR MM delusions OR MM paranoid disorders
S2 **Population / problem** (trauma)	MA trauma OR MM psychological trauma OR MM "Stress Disorders, Post-Traumatic" OR TI ptsd OR AB ptsd (MM "Child Abuse") OR (MM "Human Trafficking") OR (MM "Sexual Abuse") OR (MM "Assault and Battery") OR (MM "Violence") OR (MM "Patient Abuse") OR (MM "Adverse Childhood Experiences") OR (MM "Elder Abuse") (MM "Domestic Violence") OR (MM "Gender-Based Violence") OR (MM "Exposure to Violence") "victim" OR (MM "Victims") OR (MM "Survivors") OR “assault”
S3	S1 AND S2
S4 **Intervention**	(MM "Psychotherapy+") OR "psychotherapy" OR (MM "Cognitive Therapy+") OR “trauma therapy” TI (therapy or treatment or intervention) OR AB (therapy or treatment or intervention) OR MM intervention trials
S5 **Design** (case reports/studies)	(MM "Case Studies") OR "case study" OR TI "case report" OR AB "case report" OR TI "single case" OR AB "single case"
S6	S3 AND S4 AND S5

Appendix 1.3: Screening checklists

Title/Abstract screening checklist items:

Responses: 0=no 1=yes ?=unclear

1. Psychosis diagnosis or experiences?
2. Psychological trauma/post-traumatic stress?
3. Psychological intervention/therapy (non-pharm)?
4. Case study/case series/rich single case data (not large trials or RCTs)? i.e. every participant receives intervention.
5. Peer-reviewed article/research study?

Comments:

Outcome (inclusion or exclusion?):

Full-text screening checklist items:

0=no 1=yes ?=unclear

1. Psychosis diagnosis or experiences? E.g. hallucinations, delusions, paranoia… schizophrenia, schizoaffective disorder etc.
2. Psychological trauma symptoms or experiences? E.g. flashbacks, nightmares, intrusions, avoidance, hyperarousal...PTSD or CPTSD. Note: exposure to traumatic events not enough to include, must have evidence of impact of trauma on person.
3. Main target of treatment is psychosis and/or trauma? Are both or one an adequate focus of the study as set out from the beginning of article i.e. not emergent in the discussion or not a secondary outcome? Does the study measure or comment on both aspects adequately in the description of the case and intervention? Exclude if at least one is not the main focus and the second is not commented on well.
4. Psychological intervention/therapy (non-pharmaceutical)? Include psychoanalysis and other less recognized evidence-based approaches that are psychological in basis.
5. Case study/case series/rich single case data? Note: Do not include case control trials or RCTs. Every participant gets intervention. May get baseline period but must all receive intervention. Is there enough detail of each case, the intervention and outcomes to include in review?
6. Is this a peer reviewed journal article or original research study? No general commentary on multiple clinical experiences and reflections that do not provide case descriptions. No books. No conference papers. No theses or any other unpublished and non-peer-reviewed material.

Comments:

Outcome (inclusion or exclusion?):

Appendix 1.4: Protocol for method of calibration and reliability co-rating

Following identification of articles from the search strategy outlined in the registered protocol (prospero:CRD42020178384) the following steps will be taken:

1) **Calibration phase**

The purpose of calibration is to co-rate a sample of the total articles using the appropriate tools and to discuss any differences that emerge between independent quality ratings completed by review team members.

Sample:

A sample of the three articles from the total articles meeting inclusion for the review will be manually selected for calibration. One study from each design-type will be selected i.e. one single-case experimental design (SCED), one case series and one case report. Articles will be randomly selected by the lead author (MC) using a random number-generated sequence on excel and allocating this to the alphabetical reference number (where reference authors are alphabetized and rank ordered such that A=1, B=2, etc.). Randomisation process will be documented and can be requested from MC.

Tools:

The three selected studies will be quality assessed using the relevant quality/bias tools. These include: the Risk of Bias in N-of-1 Trials (RoBiN-T) Scale (Tate et al., 2015) for SCEDs; The Quality Appraisal Tool for Case Series Studies (Moga et al., 2012) for case series; The Joanna Briggs Institute Critical Appraisal Checklist for Case Reports (2017) for case reports.

Procedure:

The following procedure will consist of 2 meetings that will take place over zoom.

1) *Meeting 1*: Following selection of articles, MC and NZ will discuss the tools with the aim to clarify any item descriptions or other issues that may exist before beginning rating independently. After this meeting, MC and NZ will work independently out-with zoom and provide responses (numeric and qualitative responses with rationale for scores given) into a similar blank excel spreadsheet template. The template will include relevant item questions, response options and supplementary prompts from the relevant manuals. Where possible, both raters should provide as much information regarding rationale for item responses as this will aid the discussion and highlight any differences. Where possible, this should reference the studies.
2) *Meeting 2:* Once both MC and NZ have rated all 3 papers they will arrange a 'calibration' meeting to discuss responses. Any discrepancies will be resolved by discussion. MC will note both the final decision regarding rating of items as well as qualitative discussion points that emerge from the process. After the meeting, NZ will send MC the excel complete with initial independent responses with his supplementary comments on rationale. MC will also keep a copy of her original rating excel as well as notes on discussion and final rating agreed for these 3 papers.

2) **Establishing reliability phase**

Taking the above factors into consideration, MC and NZ will repeat the above procedure up to and including 'meeting 1' for a further 3 papers using the same method as above (randomization, spreadsheet, meetings). Once NZ has completed independent rating, he will send this to MC. MC will then assess this sample of 3 for inter-rater reliability. MC will determine combined reliability ratings for the total sample of all quality tools and designs (n=3) as well as individual design/studies (i.e. three ratings). Inter-rater agreements of much lower than 80% will be initially discussed with the extended review team (AG and KA). If time allows, 'meeting 2' may be repeated for these 3 studies to allow for calibration of these 3 studies. The previous process of documentation will be repeated.

Step 1 (calibration) and step 2 (reliability) may be repeated until an acceptable reliability rating has been reached. It has been agreed that lower than 50% is not acceptable and while +80% is ideal for purposes of the DClinPsy submission, given the time and resource burden of the above process, flexibility will be applied.

Once an acceptable reliability has been reached, MC will then proceed to rate the remaining articles.

References:

Moga, C., Guo, B., Schopflocher, D., & Harstall, C. (2012). Development of a quality appraisal tool for case series studies using a modified Delphi technique. *Edmonton AB: Institute of Health Economics*.

Moola S, Munn Z, Tufanaru C, Aromataris E, Sears K, Sfetcu R, Currie M, Qureshi R, Mattis P, Lisy K, Mu P-F. https://wiki.joannabriggs.org/display/MANUAL/Appendix+7.4+Critical+appraisal+checklist+for+case+reports

Tate, R., Rosenkoetter, U., Wakim, D., Sigmundsdottir, L., Doubleday, J., Togher, L., & Perdices, M. (2015). The Risk of Bias in N-of-1 Trials (RoBiNT) Scale: An expanded manual for the critical appraisal of single-case reports.

Appendix 1.5 : Quality Appraisal

Table 3: Descriptive Case Reports: *JBI Critical Appraisal Checklist for Case Reports Items*

Author/Year	*Demographics*	*History*	*Clinical condition*	*Assessment methods*	*Treatment procedure*	*Post-condition*	*Adverse events*	*Takeaway lessons*	Total Score *Total items yes (%)*	Descriptive
1. Brent(2009)	Yes	Yes	No	N/A	Yes	Yes	Yes	Yes	6(75%)	High
2. Frederickson(1991)	No	No	No	No	Yes	No	No	Yes	2(25%)	Poor
3. Jackson(1994)	No	No	Yes	No	No	Yes	No	Yes	3(38%)	Moderate
4. Knafo(2016)	Yes	No	Yes	No	No	Yes	No	Yes	4(50%)	Moderate
5. Sar & Tutkun(1994)	Yes	No	Yes	No	Yes	Yes	No	No	4(50%)	Moderate
6. Williams(1998)	Yes	Yes	No	No	Unclear	No	Yes	Yes	4(50%)	Moderate

Table 4: Case Series: *IEHE Scale*

Author/Year	*Aims*	*Characteristics*	*Multicentre*	*Criteria*	*Recruitment*	*Entry point*	*Intervention*	*Additional Intervention*	*Outcome measures*	*Tool quality*	*Measurement*	*Statistics*	*Follow-up*	*Loss to follow-up*	*Variability*	*Adverse events reported*	*Conclusions*	*Competing sources declared*	*Prospectively*	*Blinding*	*Total items yes (%)*	*Descriptive*
7. Brand et al.(2019)	Yes	Yes	U	No	U	No	Yes	U	Yes	Yes	Yes	N/A	Yes	Yes	No	Yes	Yes	Yes	No	No	11 (55%)	Mod.
8. Brand et al.(2020)	Yes	Yes	U	Yes	U	U	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	16 (80%)	High

9. Callcott & Standart(2004)	No	Yes	U	No	U	No	No	Yes	No	No	Yes	No	N/A	N/A	No	No	No	No	U	No	3 (15%)	Poor
10. Hamblen et al.(2004)	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	Yes	No	Yes	N/A	No	No	Yes	No	U	No	10 (50%)	Mod.
11. Jansen & Morris(2017)	Yes	Yes	No	Yes	Yes	No	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	No	U	13 (65%)	Mod.
12. Keen et al.(2017)	Yes	Yes	No	PR	Yes	U	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	U	No	14 (70%)	High
13. Paulik et al.(2019)	Yes	Yes	No	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	17 (85%)	High

Note: Responses: Yes, No, U (unclear), N/A (not applicable).

Table 5: Single Case Design Studies: *Risk of Bias in N-of-1 Trials (ROBiN-T) scale*

Author/Year	*Design*	*Randomisation*	*Sampling*	*Blinding 1*	*Blinding 2*	*Interrater agreement*	*Adherence*	*Baseline characteristics*	*Setting*	*Dependent variable*	*Independent Variable*	*Raw data record*	*Data analysis*	*Replication*	*Generalisation*	*Total Score (/19) (%)*	*Descriptive*
14. Ison et al.(2014)	0	0	0	0	0	0	0	0	1	1	2	2	0	0	0	6 (32%)	Poor
15. Marcello et al.(2009)	0	0	2	0	1	1	1	0	1	2	2	2	0	0	0	12 (63%)	Moderate

16. McCartney et al.(2019)	0	0	0	0	1	0	2	0	0	2	2	2	1	0	0	10 (53%)	Moderate
17. Yaser(2018)	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	2 (11%)	Poor

Appendix 2

Appendix 2.1: Author Guidelines for submission to Behavior Therapy

ELSEVIER

BEHAVIOR THERAPY

Published on behalf of Association for Behavioral and Cognitive Therapies (ABCT)

AUTHOR INFORMATION PACK

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DESCRIPTION

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GUIDE FOR AUTHORS

Introduction

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Questions about a possible manuscript for *Behavior Therapy* may be discussed with the editor-elect:

Denise M. Sloan, Ph.D.
Associate Director, Behavioral Science Division, National Center for PTSD
Professor of Psychiatry, Boston University School of Medicine

Phone: +1 857 364 6333
Email: Denise.Sloan@va.gov

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Follow internationally accepted rules and conventions: use the international system of units (SI). If other units are mentioned, please give their equivalent in SI.

Math formulae
Please submit math equations as editable text and not as images. Present simple formulae in line with normal text where possible and use the solidus (/) instead of a horizontal line for small fractional terms, e.g., X/Y. In principle, variables are to be presented in italics. Powers of e are often more conveniently denoted by exp. Number consecutively any equations that have to be displayed separately from the text (if referred to explicitly in the text).

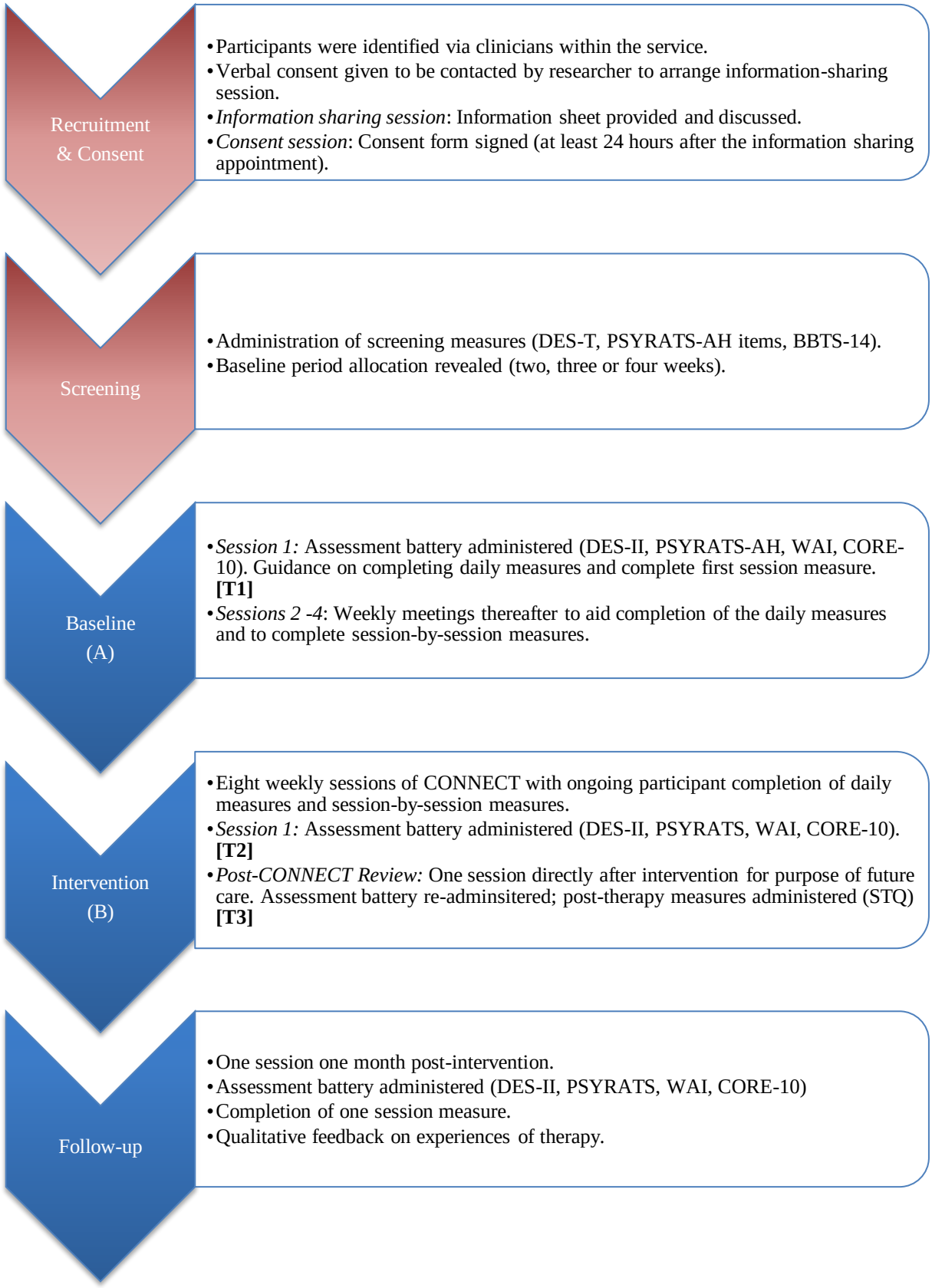
Footnotes
Footnotes should be used sparingly. Number them consecutively throughout the article. Many word processors can build footnotes into the text, and this feature may be used. Otherwise, please indicate the position of footnotes in the text and list the footnotes themselves separately at the end of the article. Do not include footnotes in the Reference list.

Artwork

Color artwork
Please make sure that artwork files are in an acceptable format (TIFF (or JPEG), EPS (or PDF), or MS Office files) and with the correct resolution. If, together with your accepted article, you submit usable color figures then Elsevier will ensure, at no additional charge, that these figures will appear in color online (e.g., ScienceDirect and other sites) regardless of whether or not these illustrations are reproduced in color in the printed version. **For color reproduction in print, you will receive**

Appendix 2.2: Summary of study design and procedure.

All contacts with main researcher (MC) unless specified otherwise.



Appendix 2.3: Participant Information Sheet

University of Glasgow
Institute of Health & Wellbeing

NHS Greater Glasgow and Clyde

Connection to Environment with Cognitive Therapy (CONNECT): Exploring Dissociative Experiences and Voices

Main Researcher:
Moya Clancy
Trainee Clinical Psychologist
m.clancy.1@research.gla.ac.uk

Address:
Institute of Health and Wellbeing
University of Glasgow
Administration Building, 1st floor
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow G12 0XH
Tel: 0141 211 0690/3927

This information sheet is designed to give information about this research study. It is important that anyone who might wish to take part is completely aware of what the study is about, what it involves, and the potential benefits and risks of taking part. It is yours to keep and you can show it to other people and talk about it with them if you wish. You can then decide if you would like to take part and if you do, you will be asked to sign a consent form.

This sheet goes into detail about all aspects of the study. *Please feel free to take breaks as needed and ask me if you have any questions.*

1. What is the purpose of the project?

We know that many people who have experienced trauma can often hear voices and feel disconnected (or 'dissociated') from themselves, other people and the world around them. Examples include:

- Feeling "spaced out" or detached from situations
- Feeling like things, people and the world around you aren't real
- Feeling as if your body doesn't belong to you.

These experiences can be distressing and can get in the way of living a full and meaningful life. We are examining the effects of a psychological therapy called **CONN**ection to **E**nvironment with **C**ognitive **T**herapy (**CONNECT**).

2. Why have I been asked to participate?

You have been asked to participate because you receive services from The Glasgow Psychological Trauma Service (the Anchor) within NHS Greater Glasgow and Clyde. Someone who works with you thinks that you may have the types of experiences described above and may benefit by receiving this additional psychological treatment.

3. Do I have to take part?

No. It is up to you to decide if you want to take part or not. If you decide "yes" you want to take part, you will be given this information sheet to keep and will be asked to sign a consent form. If you decide you don't want to take part that is absolutely fine and you don't need to tell us why. Your decision about whether or not to participate will have **no effect** on the care you receive from the NHS.

4. What if I decide to withdraw from the study?

You can withdraw from the study at any time. You do not have to provide a reason and if you withdraw it will not affect the care you receive. If you do withdraw, any personally identifiable information about you (e.g. your name, date of birth) will be destroyed. However, anonymised data already collected will be retained to ensure that the results of the research project can be measured properly. You should be aware that data collected up to the time that you withdraw will form part of the research project results.

5. Am I eligible for the study?

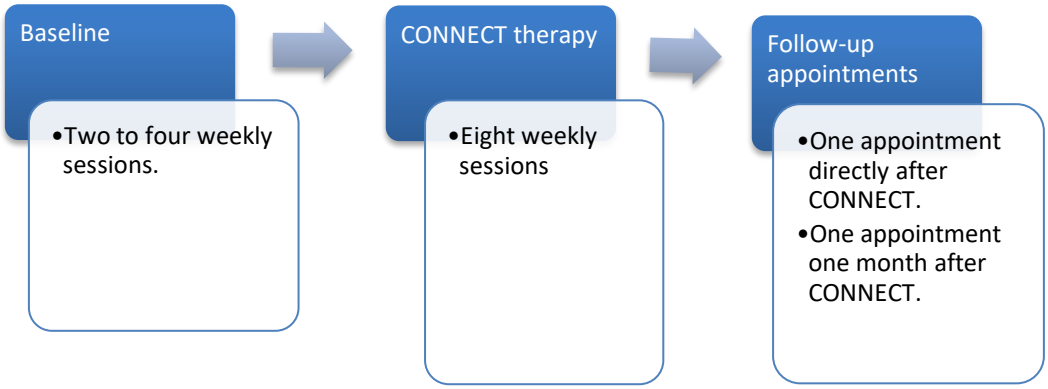
To take part in this study, you must currently be a service user within the Anchor. You also must be over 16 years old. If English is not your first language then we will need to ensure that we have access to an appropriate interpreter for you. In order to make sure that this research is suitable for you, I will ask you to fill out some questionnaires about dissociative experiences and the voices that you are currently hearing as well as some more general information. I will also seek your consent to look at your mental health records in order to get information, such as the date when you were referred to the Anchor Service, what medication (if any) you are receiving and any other psychological treatments you have received in the past. I will not look at the content of any past treatment you have received and will only look at the information we need to for the purposes of the study.

6. What will happen if I am eligible?

If you are eligible for the study, we will offer you the option of receiving CONNECT therapy. We will not offer the therapy to anyone whose dissociation or voices are not suitable for this extra treatment.

7. What does the study involve?

The study involves the following stages which will take place at the Anchor Centre:



7.1 Baseline:

If you are eligible and wish to take part in the study then you will complete a baseline monitoring period before therapy beings. This will last between two to four weeks. I will meet you once weekly for around 45 minutes. In the first baseline meeting, we will complete some questionnaires to help understand your experiences. In each baseline session, we will complete a short questionnaire. You will also complete a brief daily questionnaire between sessions at home. In the first baseline meeting, I will show you how to fill these out and will answer any questions you may have.

7.2 CONNECT therapy:

You will then be offered eight sessions of CONNECT therapy. Firstly, we will talk about your experiences and identify goals. Then we will learn new strategies to help reduce distressing dissociative experiences. We will work together to build a 'toolbox' of skills and techniques to help you do this. This may include using grounding objects and therapy oils. I will need your help to be creative and to find things that are meaningful and work best for you.

During CONNECT therapy you will:

- Complete four questionnaires after the first and last sessions.
- Complete a short questionnaire in our weekly sessions.
- Complete a daily questionnaire between sessions.

All therapy sessions will be recorded. This is to ensure that the therapy is being delivered as it should, and will help my supervisors, Professor Andrew Gumley and Dr Kirsten Atherton, to support me with this.

7.3 Follow-up sessions

After CONNECT therapy, we will discuss your experiences of therapy and to think about what happens next in your care. This will be an open and honest conversation, with your

needs being at the centre. It may be appropriate to continue working with the Anchor, with another service, or you may be discharged to your GP if you are doing well. This will depend on how things are at that time and what's best for you. Dr Kirsten Atherton (field supervisor) will also be involved in this decision-making process and may also attend the appointment.

I will also meet you one month after CONNECT therapy to ask about your experiences of the therapy and to fill out questionnaires.

8 What are the benefits and harms of taking part?

8.1 Potential Benefits:

If you are eligible, you will be offered up to eight sessions of CONNECT therapy. This means you will have access to a therapy aimed at improving experiences of dissociation. If dissociation is a problem for you then this type of therapy may have positive effects.

8.2 Potential Harms:

We are hopeful that the people invited to participate are eligible for this study. However, it is possible we might ask people to participate who turn out not to be eligible. I understand that this might result in disappointment.

An important part of therapy is learning about why people dissociate, particularly in response to trauma. I understand that discussing this may be distressing. While we do not anticipate that this research will have unexpected adverse effects, in the unlikely event that you experience any negative side-effects, I will encourage you to describe these, I will ensure that this is documented in the scientific report from this research and in the event of this, you and I together can decide what to do about this. I will also have the support of my supervisors to help.

9 How will my data be kept confidential?

If you choose to take part, relevant members of your care team will be informed. This is to ensure you are supported if you have any difficulties during or after the study. Only if you disclose information that indicates that you or others are at risk of serious harm would I disclose relevant information about you, and only to a relevant person.

As part of this study, Moya Clancy will receive supervision to ensure that the research is of high quality. This means that there may be discussions between Moya Clancy and academic and clinical supervisors, which will be done in a confidential manner and no personal data relating to participants will be disclosed. All supervisors are NHS staff and are bound by confidentiality through General Data Protection Regulations.

10 What will happen to my data?

Why we keep data*:* The University of Glasgow uses personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research.

When we keep data:
If you do not wish to take part in the study after meeting with Moya Clancy or if you are found not to be eligible, then your data will be securely destroyed in line with University of Glasgow guidelines. If you are eligible and agree to take part in the study, we will use your data in the ways needed to support the analysis and obtain the findings for the research study. When the study is complete, we will delete any personal data which identifies you, including audio recordings. All other data will be retained in an anonymised format.

Managing data: NHS GG&C is the sponsor for this study based in the United Kingdom. We will be using information from you and/or your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. NHSGG&C will keep identifiable information about you for 10 years after the study has finished.

Your data rights*:* Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already collected. If you were to lose the capacity to consent to the study while it is still going on, you will be withdrawn from the study but we will keep non-personal information about you collected before that point. To safeguard your rights, we will use the minimum personally-identifiable information possible.

How we store the data: All information collected for the purposes of the study will be stored in locked cabinets or on password-protected computers in rooms with restricted access within study settings in [NHS GG&C] and the University of Glasgow. This information, including any information stored on university computers, will be anonymized – which means no one would be able to tell the information came from you. The code which links you to the information will be held separately. All anonymised study data will be held in accordance with The General Data Protection Regulation (2018). The anonymised data will be stored in archiving facilities for 10 years as per University of Glasgow recommendations. After this period, further retention may be agreed or your data will be securely destroyed in accordance with the relevant standard procedures.

Data sharing: Your information might be shared with the study sponsor (NHS GG&C) who check that the study is done properly and to carry out research supervision. Individuals from NHS GG&C and regulatory organisations may look at your medical and research records to check the accuracy of the research study.

The Anchor will use your name, CHI number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. The Anchor will pass these details to NHSGG&C along with the information collected from you and/or your medical records. The only people who will have access to information that identifies you will be people who need to contact you to follow-up about the study or to audit the data collection process. The

people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

11. Who has reviewed the study?

The study has been reviewed by NHS West of Scotland Research Ethics Committee, the University of Glasgow, and NHS Greater Glasgow and Clyde Research and Development Departments.

12. What will happen if there is a problem or if I want to make a complaint?

If you have any concerns about the study, please contact the researcher in the first instance. If you wish to make a complaint, please contact Professor Andrew Gumley, Mental Health and Wellbeing, Gartnavel Royal Hospital, 1st Floor, Admin Building, University of Glasgow, Glasgow, G12 0HX or the Research and Development Department, NHS Greater Glasgow and Clyde on 0141 211 6208. Normal NHS complaint mechanisms will also be available to you at 0141 287 0130 or https://www.nhsggc.org.uk/get-in-touch-get-involved/complaints/.

13. What will happen to the results of the research project?

The results of this project will form the basis of the thesis (a large scientific report) that Moya Clancy will write as part of the Doctorate in Clinical Psychology at the University of Glasgow. This work will be published in an academic journal, presented at conferences, and other clinical forums. As CONNECT is a new therapy, an individual case report may also be written and published in an academic journal to look at the feasibility and applicability of this therapy in more depth. Any personally identifiable information that you provide will not be included in any reports arising from this study (e.g. places, names). When the project is completed you will be provided with a summary of the results.

14. Will taking part in the study cost me anything?

This study should not cost you anything additional out-with routine clinical care at the Anchor. Travel expenses will not be provided.

15. Who is organising and funding the study?

This study is part of my Doctorate in Clinical Psychology training and is not externally funded.

16. How to contact us

If you require any further information about the study please contact us.

Main Researcher:
Moya Clancy
Trainee Clinical Psychologist
m.clancy.1@research.gla.ac.uk
0141 211 0690/3927

Chief Investigator:
Professor Andrew Gumley
Professor of Psychological Therapy
andrew.gumley@glasgow.ac.uk
Tel: 0141 211 3939

Field Supervisor:
Dr Kirsten Atherton
Clinical Psychologist
The Anchor Centre
kirsten.atherton@ggc.scot.nhs.uk
0141 303 8968

External contact option:
Professor Hamish McLeod
Professor of Clinical Psychology
hamish.mcleod@glasgow.ac.uk
0141 211 3922

Thank you for reading this information sheet

Appendix 2.4: Consent Form

University of Glasgow
Institute of Health & Wellbeing

NHS Greater Glasgow and Clyde

Connection to Environment with Cognitive Therapy (CONNECT): Exploring Dissociative Experiences and Voices

Name of Researcher(s): Moya Clancy; Professor Andrew Gumley; Dr Kirsten Atherton

CONSENT FORM

	Please initial box if you consent or 'X' if not
1. I confirm that I have read and understand the Participant Information Sheet version 4 (29.08.2019).	☐
2. I have had the opportunity to consider the information sheet, ask questions, and understand the answers that I have been given.	☐
3. I understand that my participation in this study is voluntary and that I am free to withdraw at any time, without giving any reason, without my legal rights or services I receive being affected.	☐
4. I confirm that I allow members of my clinical team, including my GP, to be informed that I am taking part in this study.	☐
5. I agree that my name, contact details and data described in the information sheet will be kept for the purposes of this research study.	☐
6. I allow the researcher to have proportionate access to my medical records to record information about me as described in the information sheet.	☐

7. I confirm that I agree to the way my data will be collected and processed and that data will be stored for up to 10 years in University archiving facilities in accordance with relevant Data Protection policies and regulations. ☐
8. I understand that if I share information that causes concern for my safety or the safety of others, that the research team have a duty of care to tell other people involved in my care. ☐
9. I agree to the use of audio-recordings as described in the Participant Information Sheet and I understand that I can withdraw my consent for this data to be recorded at any time during the study. ☐
10. I understand that if I am not eligible to participate, my data will be destroyed as outlined in the Participant Information Sheet version 4 (29.08.2019). ☐
11. If I withdraw from the study, or lose capacity to participate during the research, that my data collected up to that point will be retained and used for the remainder of the study. ☐
12. I agree to be contacted in future regarding this research. ☐
13. I agree for my data to be used for the purpose of research related to this study including case reports. ☐
14. I agree to take part in the above study. ☐

_____	_____	_____
2.1.1.4 Name of Participant	**Date**	**Signature**
_____	_____	_____
2.1.1.5 Name of Person Taking Consent	**Date**	**Signature**

Appendix 2.5: Participant daily self-report measure of voices, dissociation, goal movement and use of techniques.

Please answer the following questions about your experiences for <u>today only.</u>
Date: Time filled out:

<u>How much have the voices been a problem today?</u>

0%	10	20	30	40	50	60	70	80	90	100%
Never					About half of the time					Always

<u>How much has dissociation been a problem today?</u>

0%	10	20	30	40	50	60	70	80	90	100%
Never					About half of the time					Always

<u>How often were you able to use the techniques learned in therapy?</u>

0%	10	20	30	40	50	60	70	80	90	100%
Never										Always

<u>To what extent do you feel that you have moved towards your goal of .....</u>

<u>..... today?</u>

0%	10	20	30	40	50	60	70	80	90	100%
Not at all					Moderately					Extremely

Appendix 2.6: NHS Ethical Approval

WoSRES
West of Scotland Research Ethics Service

NHS
Greater Glasgow and Clyde

Professor Andrew Gumley
Professor of Psychological Therapy Honorary
Consultant Clinical Psychologist
Institute of Health and Wellbeing
Administration Building, 1st floor
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
G12 0XH

West of Scotland REC 5
West of Scotland Research Ethics Service
Ward 11, Dykebar Hospital
Grahamston Road
PAISLEY
PA2 7DE

Date 28 August 2019

Direct line 0141 314 0213
E-mail WoSREC5@ggc.scot.nhs.uk

Dear Professor Gumley

Study title: **Connection to Environment with Cognitive Therapy (CONNECT): A Single-Case Experimental Design**
REC reference: **19/WS/0125**
Protocol number: **3**
IRAS project ID: **264875**

The Research Ethics Committee reviewed the above application at the meeting held on 21 August 2019. Thank you to Ms Clancy for attending to discuss the application.

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. .

Conditions of the favourable opinion

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

Number	Condition
1	An updated version of the Participant Information Sheet should be submitted which includes the following changes: a) In section 6 of the Participant Information Sheet, the second sentence should remove the phrase "not severe enough" and be changed to a more neutral explanation such as " whose voices *are not suitable for* this extra treatment." or " whose voices are *not of the required type for* this extra treatment." b) In section 7.2, please add "*therapy oils*" as an example of the "toolbox" of skills. c) The number of questionnaires to be completed in total should be added to section 7 of the document. d) Also in section 7.2, it should be clear that the therapy sessions will be audio recorded.

	e) In the same section, the Committee asked that the exclamation mark at the end of the first paragraph as this is not needed. f) Furthermore, it was suggested that the daily diary is renamed as it implies that free text entries are required and could be onerous to some patients. g) In section 9, the first sentence implies that the GP is involved in this study. It is also not necessary for them to know about this study. The words "eg your GP" should be removed. h) In section 10, the researchers should ensure that the Main Researcher Name is inserted before giving the document to potential participants.

Recommendations:

Number	Recommendation
1	The Committee wished to remind the applicants that if they wish to recruit new participants after someone has dropped out, an amendment should be submitted to the REC to request this.
2	Since the submitted insurance certificate has now expired (31 July 2019), the researchers should ensure that a current certificate is in place before the study starts. However, a copy of this document is not required to be submitted for our records.

You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which you can make 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.

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

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

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

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

Registration of Clinical Trials

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

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

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

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

Publication of Your Research Summary

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

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

After ethical review: Reporting requirements

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

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report

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

Ethical review of research sites

NHS/HSC Sites

The favourable opinion applies to all NHS/HSC sites taking part in the study taking part in the study, subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland)being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Confirmation of any other Regulatory Approvals (e.g. CAG) and all		23 July 2019

correspondence		
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Clinical Trials Revised TWIMC Letter]		06 August 2018
GP/consultant information sheets or letters [MRP GP letter Version 2 12.07.2019]	2	12 July 2019
IRAS Application Form [IRAS_Form_29072019]		29 July 2019
Non-validated questionnaire [Daily Measure version 3 12.07.2019]	3	12 July 2019
Non-validated questionnaire [Reduced Therapy session measures, version 1.0, 30-10-2014]	1.0	30 October 2014
Participant consent form [Consent Form Version 3 (12.07.2019)]	3	12 July 2019
Participant information sheet (PIS) [Participant Information Sheet Version 3 (12.07.2019)]	3	12 July 2019
Research protocol or project proposal [Major Research Project Proposal Version 3 (12.07.2019)]	3	12 July 2019
Summary CV for Chief Investigator (CI) [Andrew Gumley CV]		
Summary CV for student [Moya Clancy CV]		20 June 2019
Summary CV for supervisor (student research) [Kirsten Atherton CV]		
Validated questionnaire [WAI-SR Version 3 (12.07.2019)]	3	12 July 2019
Validated questionnaire [BBTS-14 items]		
Validated questionnaire [CORE-10]		
Validated questionnaire [PSYRATS Version 2 20.06.2019]	2	20 June 2019
Validated questionnaire [Satisfaction with Therapy version 2 12.07.2019]	2	12 July 2019
Validated questionnaire [DES + DES-T]		

Membership of the Committee

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

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

User Feedback

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

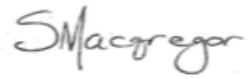
HRA Learning

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

19/WS/0125	Please quote this number on all correspondence

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

Yours sincerely



for
Dr Stewart Campbell
Chair

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

"After ethical review – guidance for researchers"

Copy to: Ms Emma-Jane Gault, University of Glasgow

Lead Nation - Scotland: nhsg.NRSPCC@nhs.net

West of Scotland REC 5

Attendance at Committee meeting on 21 August 2019

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mrs Linda Boyle	Retired Company Secretary	Yes	
Dr Stewart Campbell	Consultant Physician & Gastroenterologist (CHAIR)	Yes	
Dr James Curran	GP	Yes	
Dr James Dale	Consultant Rheumatologist	Yes	
Dr Kirsteen Goodman	Trial Manager/Research Fellow	Yes	
Dr Palghat Gopalakrishnan	Consultant Neonatologist	No	
Mrs Naomi Hickey	Research Nurse (Alternate Vice-Chair)	Yes	
Professor Eddie McKenzie	Statistician	Yes	
Canon Matt McManus	Retired Parish Priest (Vice-Chair)	Yes	
Dr Audrey Morrison	Research Practitioner	Yes	
Mrs Karen Mowbray	Health Records Manager	No	
Ms Janis Munro	Key Account Manager	Yes	
Mr Charles Sargent	Retired	No	
Mr James Timmons	Retired IT Manager	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Mrs Sharon Macgregor	REC Manager

Appendix 2.7: NHS R&D Approval

Co-ordinator/Administrator: Emma McDonough/ Erin Brodie
Telephone Number: 0141 314 4000
E-Mail: Emma.McDonough@ggc.scot.nhs.uk
Website: https://www.nhsggc.org.uk/about-us/professional-support-sites/research-development/

Clinical Research & Development
Dykebar Hospital, Ward 11
Grahamston Road
Paisley, PA2 7DE
Scotland, UK

10 September 2019

Dr Kirsten Atherton
NHS Greater Glasgow and Clyde
The Anchor, Glasgow Psychological Trauma Service
Festival Business Centre
150 Brand Street
Glasgow G51 1DH

NHS GG&C Board Approval

Dear Dr K Atherton,

Study Title:	Connection to Environment with Cognitive Therapy (CONNECT): Exploring Dissociative Experiences and Voices
Principal Investigator:	Dr Kirsten Atherton
GG&C HB site	Community Mental Health
Sponsor	NHS Greater Glasgow and Clyde
R&D reference:	GN19MH346
REC reference:	19/WM/0254
Protocol no: (including version and date)	V3; 12/07/19

I am pleased to confirm that Greater Glasgow & Clyde Health Board is now able to grant **Approval** for the above study.

Conditions of Approval

1. **For Clinical Trials** as defined by the Medicines for Human Use Clinical Trial Regulations, 2004

    a. During the life span of the study GGHB requires the following information relating to this site
        i. Notification of any potential serious breaches.
        ii. Notification of any regulatory inspections.

It is your responsibility to ensure that all staff involved in the study at this site have the appropriate GCP training according to the GGHB GCP policy (www.nhsggc.org.uk/content/default.asp?page=s1411), evidence of such training to be filed in the site file.

NHS
Greater Glasgow and Clyde

2. **For all studies** the following information is required during their lifespan.
   a. First study participant should be recruited within 30 days of approval date.
   b. Recruitment Numbers on a monthly basis
   c. Any change to local research team staff should be notified to R&D team
   d. Any amendments – Substantial or Non Substantial
   e. Notification of Trial/study end including final recruitment figures
   f. Final Report & Copies of Publications/Abstracts

Please add this approval to your study file as this letter may be subject to audit and monitoring.

Your personal information will be held on a secure national web-based NHS database.

I wish you every success with this research study.

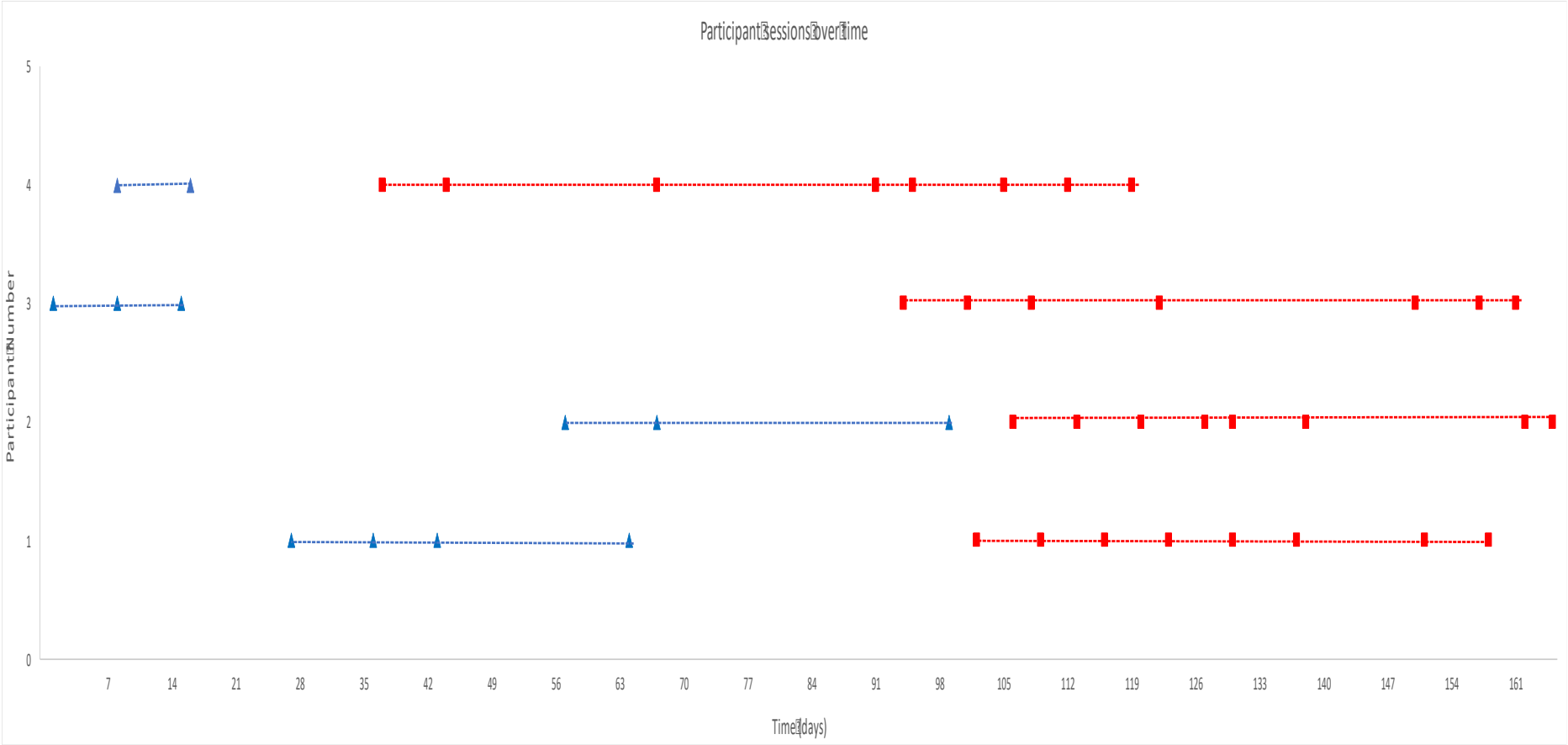
Yours sincerely,

E. McDonough.

Mrs Emma McDonough
Research Co-ordinator

CC: Emma Jane Gault (Glasgow University)
Moya Clancy (Glasgow University)
Andrew Gumley (Glasgow University)

Appendix 2.8: Relative participant time sequencing of CONNECT procedures (P1-P4). Baseline lengths 2,3,3 and 4.



= baseline session

NOTE: Participant number on legend: 4= P1 (Kim); 3= P2 (Eve); 2= P3 (Maria); 1=P4 (Beth)

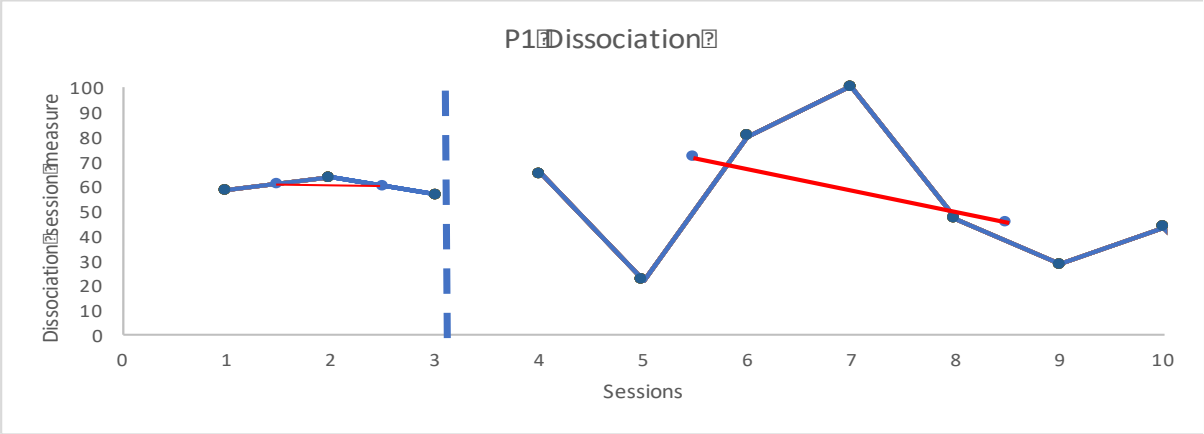
= intervention session

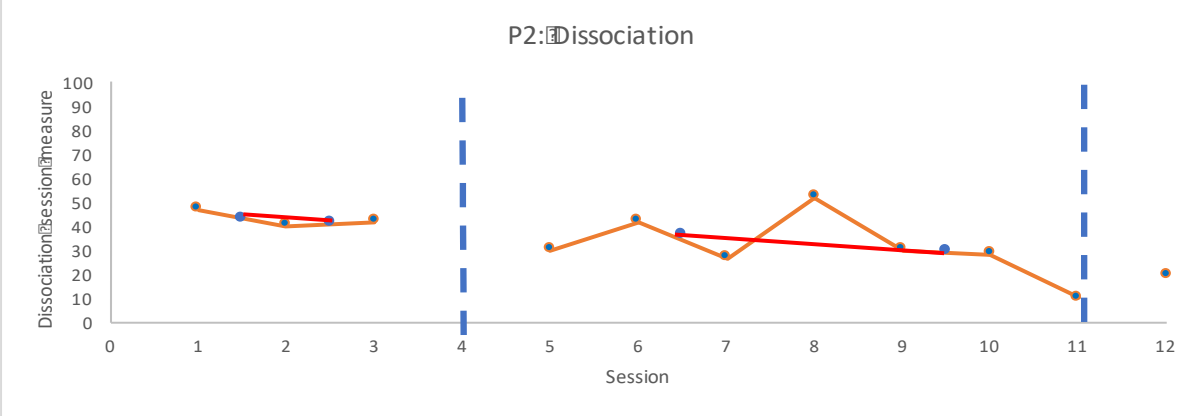
Appendix 2.9: Missing Data for Daily Measures

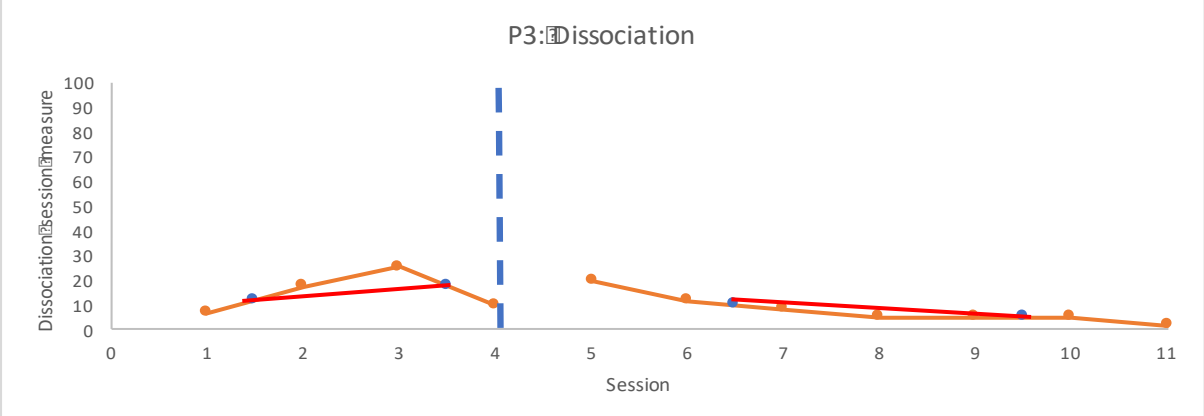
	Total days of daily data collection (baseline & CONNECT)	**Total daily measures completed (%)**	**Total daily measures completed (%)**	**Total daily measures completed (%)**
		Q1: Voices	**Q2: Dissociation**	**Q4: Goals**
P1 (Kim)	112	85 (76%)	85 (76%)	85 (76%)
P2 (Eve)	162	62 (38%)	62 (38%)	62 (38%)
P3 (Maria)	109	64 (59%)	64 (59%)	62 (71%)
P4 (Beth)	133	59 (44%)	62 (46%)	49 (37%)
	Total days of daily data collection (CONNECT)	**Total daily measures completed (%)**		
		Q3: Techniques		
P1 (Kim)	82	26 (32%)		
P2 (Eve)	68	48 (71%)		
P3 (Maria)	59	29 (49%)		
P4 (Beth)	57	31 (54%)		

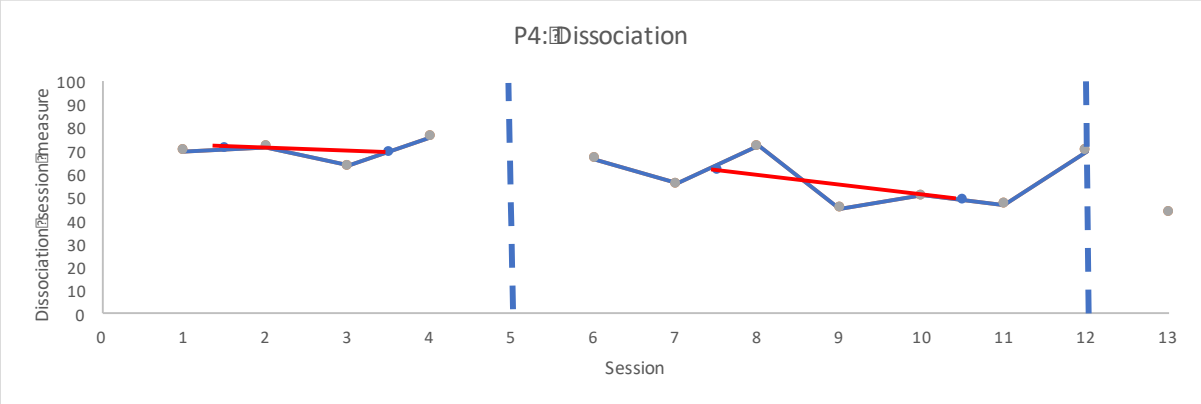
Appendix 2.10: Visual analysis of dissociation.

Baseline lengths 2,3,3,4.









Visual analysis (Dissociation) using Lane & Gast (2013) method of visual analysis.

Step 1: Assign letter to each condition

Step 2: Counting number of sessions for each condition

	Participant 1	**Participant 2**	**Participant 3**	**Participant 4**
Number of data points in baseline (A)	3	3	4	4
Number of data points at/after intervention (B)	7	7	7	7

Step 3: Summary of data.

Participant 1	**Condition A**	**Condition B**
Median	58.33	46.66
Mean	59.44	55.05
Range	56.66 – 63.33	22 – 100
Percent on or within the stability envelope (80+/-20)	+/- 14.58 of median (43.75-72.91) = 3/3 = 100%	+/- 11.66 (35–58.32) = 1/7 = 14%
Participant 2	**Condition A**	**Condition B**

Median	41.66666667	29.16666667
Mean	42.77777778	29.79166667
Range	40 – 46.66	10 – 51.66
Percent on or within the stability envelope	+/- 10.41 (31.25 - 52.075) = 100%	+/- 7.29 (21.87 – 36.456) = 4/7 = 57.14%
Participant 3	**Condition A**	**Condition B**
Median	13.75	5
Mean	14.79166667	8.095238095
Range	6.66 - 25	1.667 - 20
Percent on or within the stability envelope	+/- 3.44 (10.31–17.18) = 2/4 = 50%	+/-1.25 (3.75-6.25) = 3/7 = 42.85%
Participant 4	**Condition A**	**Condition B**
Median	70.83333333	56
Mean	70.20833333	58.16666667
Range	63 – 75.83	45 – 72
Percent on or within the stability envelope	+/- 17.70 (52.3-88.53) = 100%	+/- 14 (42-70) = 85.7%

Step 4a. Relative level change

Participant 1	**Condition A**	**Condition B**
Median of 1st half	60.83333333	72.5
Median of 2nd half	60	45
Relative change	-0.833	-27.5

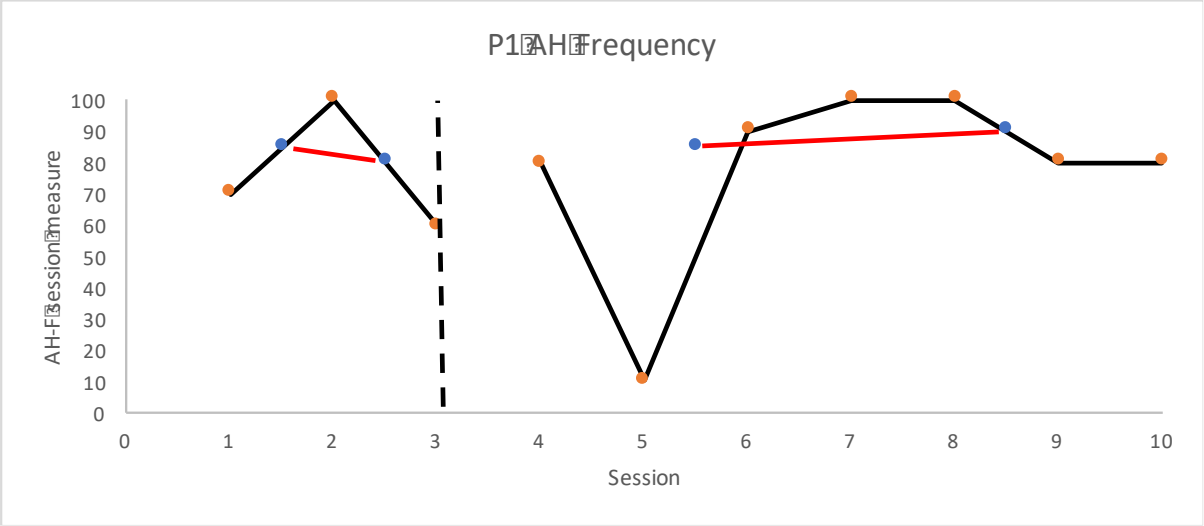
	Decrease	Decrease
Participant 2	**Condition A**	**Condition B**
Median of 1st half	43.33333333	35.83333333
Median of 2nd half	40.83333333	29.16666667
Relative change	-2.5 Decrease	-6.67 Decrease
Participant 3	**Condition A**	**Condition B**
Median of 1st half	12.08333333	10
Median of 2nd half	17.5	5
Relative change	+5.5 Increase	-5 Decrease
Participant 4	**Condition A**	**Condition B**
Median of 1st half	70.83333333	61.33333333
Median of 2nd half	69.58333333	48.75
Relative change	-1.25 Decrease	-12.58 Decrease

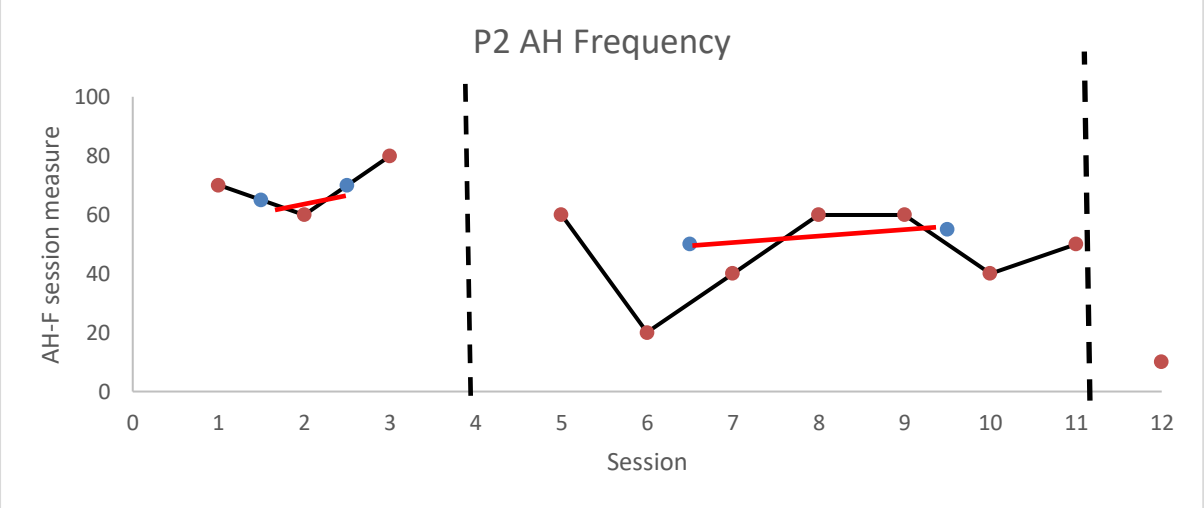
Participant 1	**Condition A**	**Condition B**
First value	58.33	65
Last value	56.33	43.33
Absolute Level Change	-2 Decrease	-21.67 Decrease
Participant 2	**Condition A**	**Condition B**
First value	46.67	30
Last value	41.67	10
Absolute Level Change	-5 Decrease	-20 Decrease
Participant 3	**Condition A**	**Condition B**
First Value	6.67	20
Last Value	10	1.67
Absolute Level Change	+3.33 Increase	-18.33 Decrease

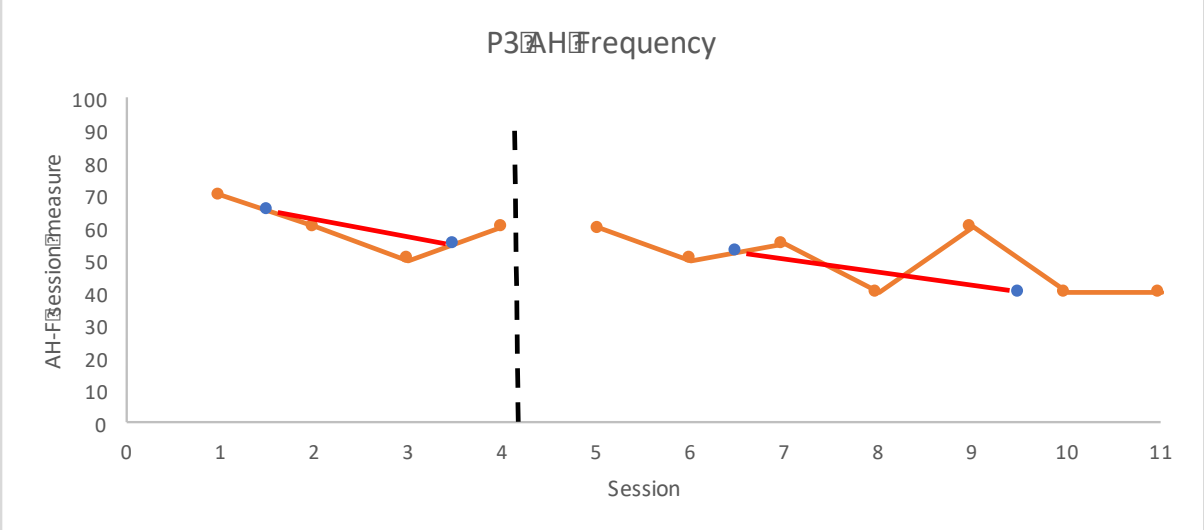
Participant 4	**Condition A**	**Condition B**
First Value	70	66.67
Last Value	75.83	70
Absolute Level Change	+5.83 Increase	+3.33 Increase

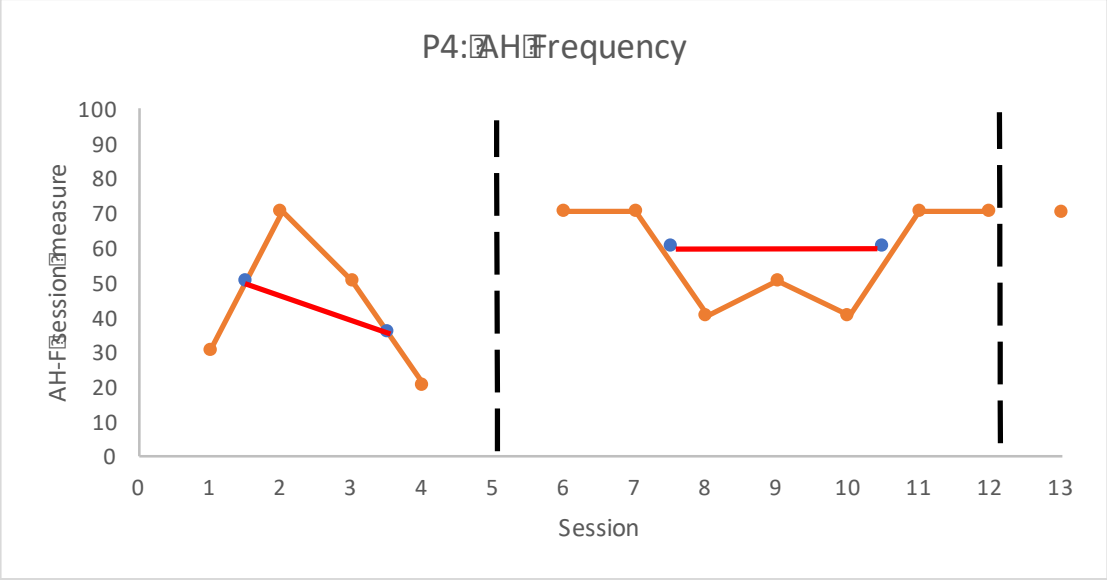
Appendix 2.11: Visual analysis of auditory hallucination frequency.

Baseline lengths 2,3,3,4.









Auditory Hallucinations Frequency visual analysis

Step 1: Assign letter to each condition
Step 2: Counting number of sessions for each condition

	Participant 1	**Participant 2**	**Participant 3**	**Participant 4**
Number of data points in baseline (A)	**3**	**3**	**4**	**4**
Number of data points at/after intervention (B)	**7**	**7**	**7**	**7**

Step 3.

Participant 1	**Condition A**	**Condition B**
Median	70	80
Mean	76.66	77.14285714
Range	60-100	10-100
Percent on or within the stability envelope (80+/-20)	+/-17.5 (52.5-87.5) = 2/3 = 66.6%	+/-20 (60-100)= 6/7 = 85.7%
Participant 2	**Condition A**	**Condition B**
Median	70	50
Mean	70	47.14285714
Range	60-80	20-60

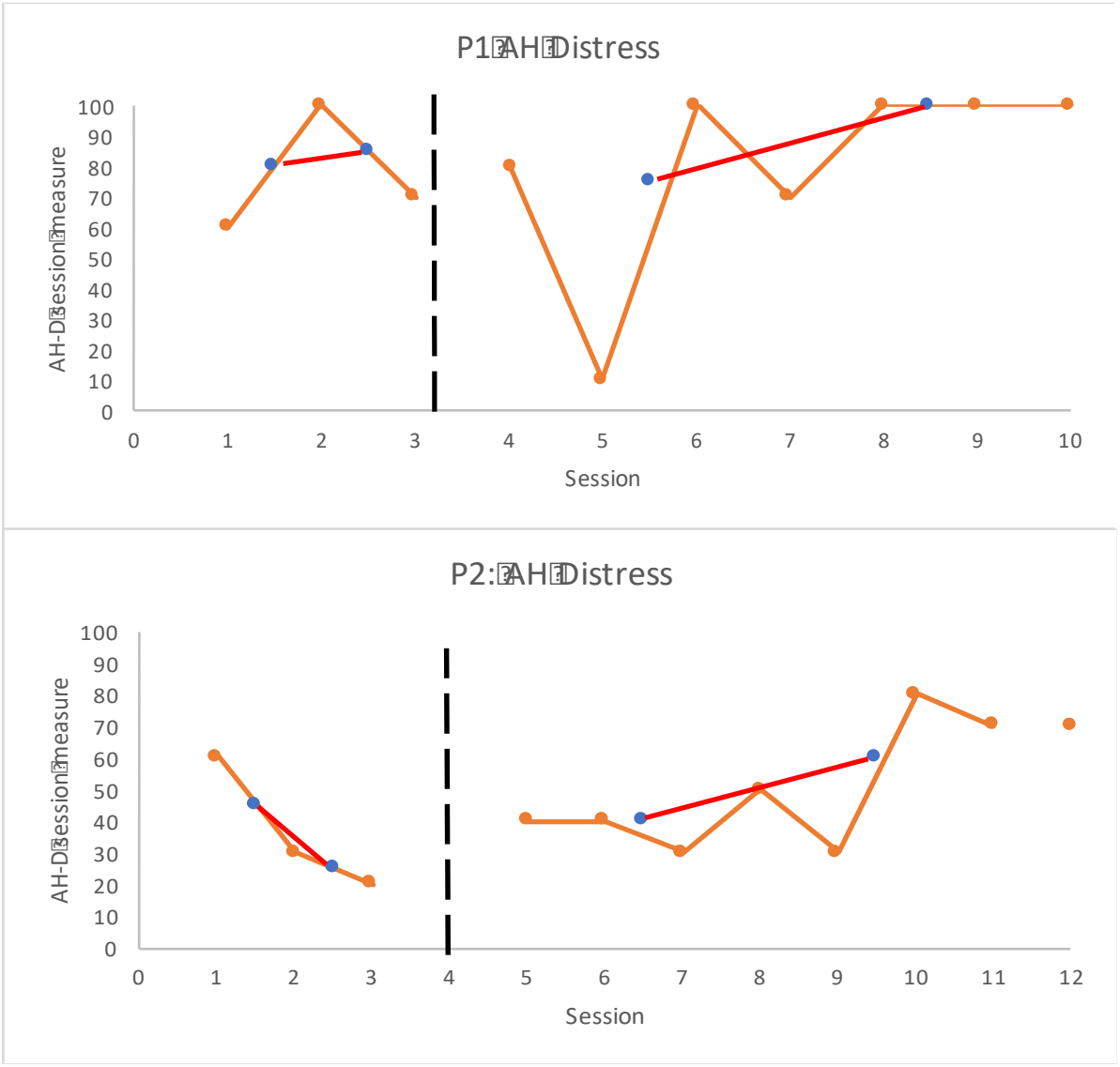
Percent on or within the stability envelope	+/-17.5 (52.5-87.5)= 100%	12.5 (37.5-82.5)= 85.7%
Participant 3	**Condition A**	**Condition B**
Median	60	50
Mean	60	60
Range	50-70	40-60
Percent on or within the stability envelope	+/-15 (45-65)= ¾ =75%	12.5 (37.5-82.5) = 100%
Participant 4	**Condition A**	**Condition B**
Median	40	70
Mean	42.5	58.57142857
Range	20-70	40-70
Percent on or within the stability envelope	+/-10 (30-50) = ¾ = 75%	+/-17.5 (52.5-87.5) = 5/7 =71.4%

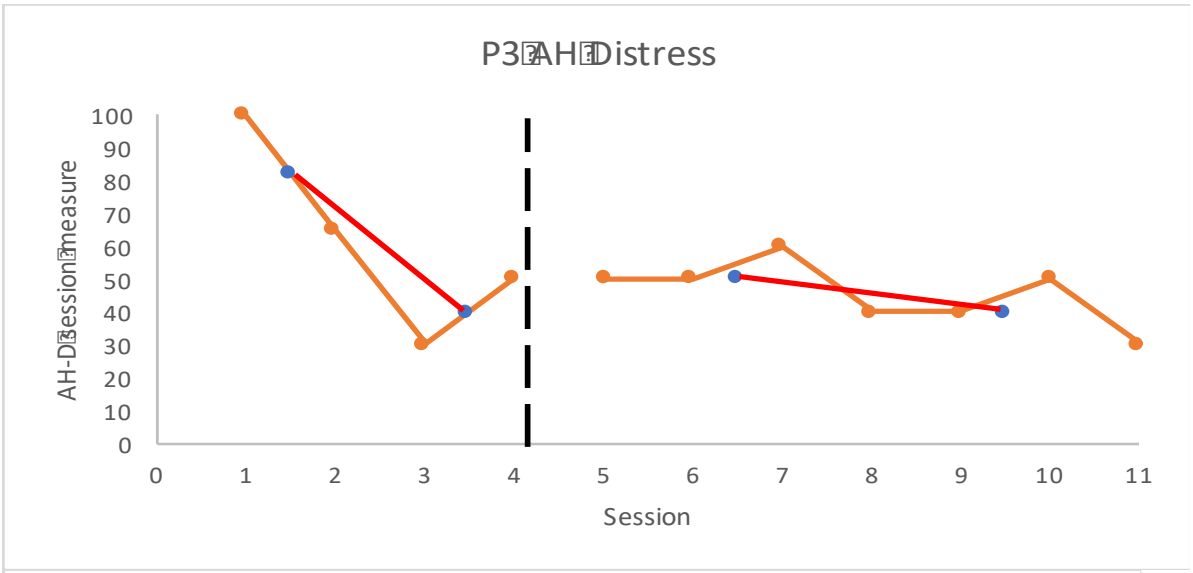
Step 4a: Relative change (in text)
Step 4b: Absolute level of change:

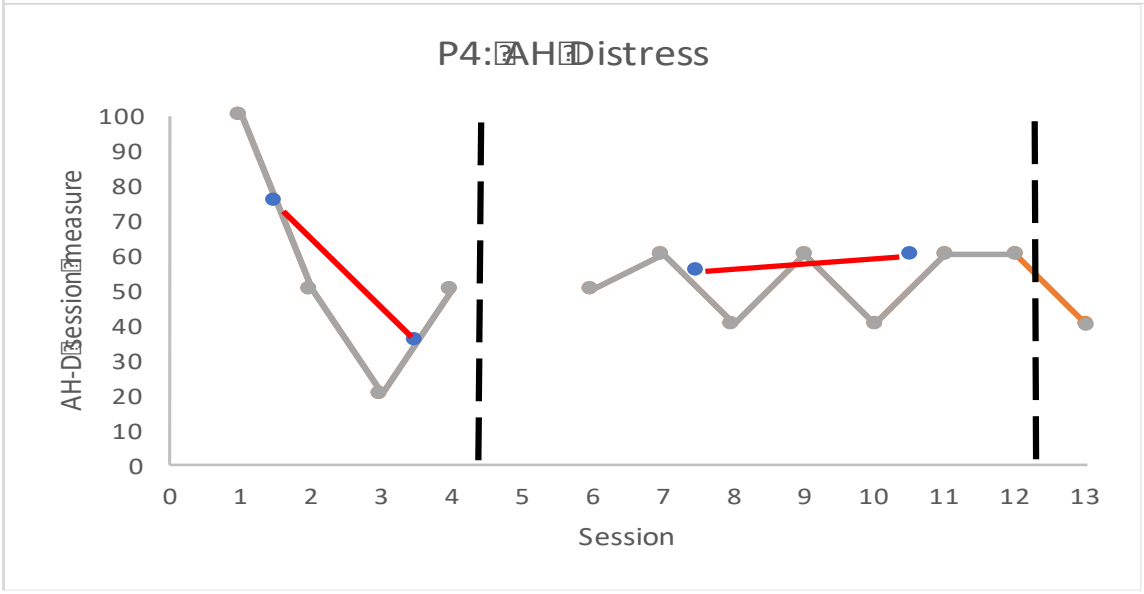
Participant 1	Condition A	Condition B
First value	70	80
Last value	60	80
Absolute Level Change	-10 decreasing frequency	0 No change
Participant 2	Condition A	Condition B
First value	70	60
Last value	80	50
Absolute Level Change	+10 Increasing frequency	-10 Decreasing frequency
Participant 3	Condition A	Condition B
First Value	70	60
Last Value	60	40
Absolute Level Change	-10 Decreasing frequency	-20 decreasing frequency
Participant 4	Condition A	Condition B
First Value	30	70
Last Value	20	70
Absolute Level Change	- 10 Decreasing frequency	+0 No change

Appendix 2.12: Visual analysis of auditory hallucination distress.

Baseline lengths 2,3,3,4.




P3 AH Distress
AH-Distress measure
100
90
80
70
60
50
40
30
20
10
0
0 1 2 3 4 5 6 7 8 9 10 11
Session


P4: AH Distress
AH-Distress measure
100
90
80
70
60
50
40
30
20
10
0
0 1 2 3 4 5 6 7 8 9 10 11 12 13
Session

Auditory Hallucinations Distress visual analysis
Step 1: Assign letter to each condition
Step 2: Counting number of sessions for each condition

	Participant 1	**Participant 2**	**Participant 3**	**Participant 4**
Number of data points in baseline	**3**	**3**	**4**	**4**
Number of data points at/after intervention	**7**	**7**	**7**	**7**

Step 3.

Participant 1	**Condition A**	**Condition B**
Median	70	100
Mean	76.66	80
Range	60-100	10-100
Percent on or within the stability envelope +/- 25% of median	25%=17.5 52.5-87.5 2/3 within =66%	25%=25. 75-125 5/7 within =71.4%
Participant 2	**Condition A**	**Condition B**
Median	30	40
Mean	36.66666667	48.57142857
Range	20-60	30-80
Percent on or within the stability envelope	25%=7.5 22.5-37.5 1/3 within=33%	25%=10 30-50 5/7=71.4%
Participant 3	**Condition A**	**Condition B**
Median	57.5	50
Mean	61.25	45.71
Range	50-70	40-60
Percent on or within the stability envelope	25%=14.38 43.12-71.88 2/4 within=50%	25%=12.5 37.5-62.5 7/7 within=100%
Participant 4	**Condition A**	**Condition B**
Median	50	60
Mean	55	52.86
Range	20-100	40-60
Percent on or within the stability envelope	25%=12.5 37.5-62.5	25%=15 45-75

	3/4 within=75%	5/7 within=71.4%

Step 4a. Relative level change (in text)

Step 4b: Absolute level of change in voice distress

Participant 1	Condition A	Condition B
First value	60	80
Last value	70	100
Absolute Level Change	+10 Increasing	+20 Increasing
Participant 2	Condition A	Condition B
First value	30	40
Last value	20	70
Absolute Level Change	-10 Decreasing	+30 Increasing
Participant 3	Condition A	Condition B
First Value	100	50
Last Value	50	30
Absolute Level Change	-50 Decreasing	-20 decreasing
Participant 4	Condition A	Condition B
First Value	100	50
Last Value	50	60
Absolute Level Change	-50 Decreasing	+10 Increasing

Appendix 2.13: Summary of secondary measure scores

		T1 (pre-baseline)	**T2 (Pre-CONNECT)**	**T3 (Post-CONNECT)**	**T4 (1 month follow-up)**
Outcome measure	Participant				
CORE-10	P1 Kim	19	27	20	32
	P2 Eve	29	35	15	16
	P3 Maria	21	15	7	-
	P4 Beth	29	25	22	22
WAI	P1 Kim	57	52	56	49
	P2 Eve	51	40*	55	-
	P3 Maria	43	42*	-	-
	P4 Beth	55	56	53*	44

T1=Pre-baseline. T2=Pre-CONNECT. T3-Post-CONNECT. T4=1 month follow-up.
CORE-10=Clinical Outcomes in Routine Evaluation (range=0-50)
WAI=Working Alliance Inventory (range=0-60)
*Imputed scores were used to generate responses for final 3 questions. Missing due to independent administration (COVID-19).

Appendix 3 : Major Research Project Proposal

Major Research Project Proposal

Title: Connection to Environment with Cognitive Therapy (CONNECT): A Single-Case Experimental Design

Student: Moya Clancy

Matriculation Number: 2356257C

Date of submission: 28th May 2019

Version number: 1

Word count: 3, 320

Abstract:

Background: Emerging empirical evidence has suggested that dissociation is a robust determinant of voice-hearing in psychosis, and that dissociation mediates the link between trauma and voices (Pilton et al., 2015; Pearse et al, 2017). Despite the emerging evidence-base, targeted therapeutic interventions focusing on dissociation remain largely untested.

Aims: The aim of the current study is to investigate whether targeting dissociation is associated with improvements in distressing voices in people with a history of trauma. It is hypothesised that reduced levels of dissociation will lead to improvements in the frequency and distress associated with hearing voices.

Method: Six participants will be recruited from the Glasgow Psychological Trauma Service (GPTS). This study utilizes a randomized multiple baseline single-case experimental design with assessment at four time points (baseline, pre-intervention, post-intervention and follow-up) with daily diary measures during baseline (A) and intervention (B) phases. Data will be analysed using visual analysis and Tau-U.

Applications:

This study will contribute to the evidence-based for dissociation interventions targeting distressing voices among this population. It will especially inform clinicians of the effectiveness and feasibility of using such strategies in clinical practice.

Introduction

Recent research in cognitive psychology and neuroscience has highlighted the similarities in phenomenology of traumatic intrusions in both Post-Traumatic Stress Disorder (PTSD) and psychotic disorders, particularly among people experiencing auditory and visual hallucinations (Brewin et al., 2010; Steel et al., 2005; Morrison, 2001). While traumatic events have been suggested to serve as a trigger for the development of intrusions in both PTSD and psychosis (Bebbington et al., 2004; Janssen et al., 2004), our understanding of how trauma-related information is encoded, stored and retrieved is vital in developing and testing treatments for trauma-related psychosis.

The theoretical rationale for developing therapies to treat comorbid symptoms of trauma among people with psychosis is supported by evidence that PTSD symptoms mediate the association between trauma and psychosis (Hardy et al., 2017). Furthermore, the presence of PTSD symptoms has been linked to more distressing psychotic symptoms and poorer response to treatment (Hasan & De Luca, 2015). While a relatively small proportion of people with psychosis also meet criteria for PTSD, trauma may still contribute to many individuals' experiences. Psychological responses to traumatic life events such as cognitive/behavioural avoidance, hyperarousal and intrusions/re-experiencing may influence vulnerability to and maintenance of psychosis and therefore are important factors to consider.

One common response to traumatic events is dissociation (Kennerley, 2009). Dissociation can be described as a 'disruption in the usually integrated functions of consciousness, memory, identity or perception of the environment' and may present as an altered sense of

perception in terms of time, environment and self (Schauer and Elbert, 2010). When considering the link between trauma and psychosis, recent empirical evidence has suggested that dissociation and attachment styles mediate links between trauma and positive symptoms of psychosis, with dissociation being a robust determinant of voice hearing (Varese et al., 2011; Varese et al., 2012; Perona-Garcelan et al., 2012; Pilton et al., 2015; Pearse et al, 2017). Indeed, some longitudinal evidence suggests that dissociation predicts the onset and maintenance of distressing voices (Geddes et al., 2016; Escher et al., 2002) and a recent study has also suggested that dissociation predicts voice-hearing episodes on a daily basis (Varese et al., 2011). This link appears to be trans-diagnostic, with significant associations seen across different diagnostic groups including Psychosis, PTSD, Dissociative Identity Disorder (DID) and non-clinical samples (Pilton et al., 2015).

Despite the emerging evidence-base, targeted therapeutic interventions focusing on dissociation remain largely untested. Recent reviews have highlighted the need to develop and test psychological interventions in a more targeted way, adopting a causal-interventionist approaches (Pilton et al., 2015; Thomas et al., 2014, Hardy et al., 2017). Indeed, the causal-interventionist approach has previously been successfully adopted to develop and test specified mechanisms underpinning psychotic phenomena e.g. poor sleep and worry to paranoia (Freeman et al., 2015a; 2015b). This approach not only tests the efficacy and applicability of interventions in clinical practice but also serves to bridge the gap between research and clinical practice. As such, it is imperative that interventions combine the best available evidence with current clinical practice to ensure that interventions are grounded in both research and clinical practice.

5. Aims and Hypotheses

The aim of the current study is to investigate whether targeting dissociation through Connection to Environment Cognitive Therapy (CONNECT) is associated with improvements in distressing voices in people with a history of trauma. It is hypothesised that reductions in dissociation will lead to improvements in the frequency and distress associated with hearing voices.

5.2 Hypotheses

Primary Hypotheses:

6. Dissociation will significantly reduce following CONNECT therapy.
7. Voice frequency and distress will significantly reduce following CONNECT therapy.
8. Reductions in dissociation will precede reductions in voice frequency and distress

Secondary Hypothesis:

1. CONNECT therapy will lead to increased perceived movement towards goals.

6. Plan of Investigation

This study aims to investigate the above hypotheses by delivering a dissociation intervention to individuals who hear voices and have experienced trauma. The variables of interest will be monitored and compared within-participants between and within baseline and intervention phases. Follow-up data will be gathered two months after therapy. The intervention (**CONN**ection to **E**nvironment with **C**ognitive **T**herapy:'CONNECT') was developed incorporating: a) interventions from current literature including previous work from a case-series of cognitive therapy in clients with trauma, dissociative experiences and distressing voices delivered in Manchester and b) interventions used in clinical practice in the GPTS.

This information was gathered by means of a survey which was circulated to the Glasgow Psychological Trauma Service (GPTS) staff in February 2019.

6.1 Participants

Six service users of the GPTS will partake in this study (see Appendix I for GPTS referral criteria). Participants will be screened according to the following criteria:

Inclusion:

1. Voices:
    a. Hearing a voice/voices for a minimum of six months.
    b. Score ≥ 2 (i.e. “Voices occurring at least once a day”) on the frequency item of the Psychotic Symptom Rating Scale (PSYRATS).
    c. Score ≥ 3 (i.e. “Voices are very distressing, although subject could feel worse”) on the distress intensity rating of the PSYRATS.
2. Trauma:
    a. Score ≥ 1 on any of the items of the Brief Betrayal Trauma Survey-14 (BBTS-14) assessing lifetime exposure to interpersonal trauma.
3. Dissociation:
    a. Dissociative Experiences Scale Taxon (DES-T) score suggestive of clinical levels of dissociative symptoms, as indicated by a score > 20.
4. Treatment motivation:
    a. Indicated that they consider voices and dissociation as a presenting difficulty, and that they would like to receive a psychological intervention specifically designed to address these difficulties. This will be assessed using four items integrated in the

PSYRATS interview and the self-reported therapy goals generated through the initial assessment in the GPTS.

5. Over 16 years old.
6. Capacity to provide informed consent.
7. Deemed to have sufficient English to engage in therapy or have access to an appropriate interpreter and translation service.

Exclusion:

1. Concurrently receiving another form of psychological intervention.
2. Cognitive impairment that may impact ability to consent and/or engage.

6.3 Recruitment Procedure

Identifying participants: Potential participants will be recruited via their routine assessment within the GPTS. CONNECT would be regarded as a phase 1 trauma intervention and those with voices and dissociation who would be suitable for phase 1 work will be offered the opportunity to participate in the study. If interested in taking part, the clinician will (with the individual's consent) pass on contact information to the researcher, who will contact participants to arrange an information sharing appointment.

Information sharing and gaining consent: The researcher will meet with potential participants for an information sharing appointment. The participant information sheet (PIS) will be provided and the study will be discussed with any questions answered. In order to ensure that participants have at least 24 hours to decide to take part, a further appointment will be arranged to take informed consent. In the interim, participants will be encouraged to read the PIS at home, and to consider what the study will involve before agreeing to take part. Following this, participants will undergo screening for the study and study procedure will

begin.

6.4 Settings and Equipment

This study will be carried out during working hours in clinical rooms within the GPTS. Equipment will include participant information sheets, consent forms, paper copies of measures, paper, pens and a 'toolkit' consisting of various grounding objects e.g. aroma oils. A digital voice recorder and laptop belonging to the University of Glasgow will be used, both of which are encrypted and password protected.

6.5 Measures

6.51 Baseline/Inclusion Measures:

Trauma History: Brief Betrayal Trauma Survey (BBTS; Goldberg & Freyd, 2006) is a 14-item self-report measure of frequency of traumatic experiences with responses ranging from 'never', 'one or two times' or 'more than that'.

Dissociation: Dissociative Experiences Scale Taxon (DES-T; Waller & Ross, 1997) is an eight- item subscale of the full-scale DES (outlined below). The format is the same as the full-scale DES, with each item scored on a scale from 1 to 100 and the overall score being the mean of the eight items.

Voices: The Auditory Hallucinations subscale of the Psychotic Symptom Rating Scale (PSYRATS; Haddock et al, 1999) will be used. This comprises of 11-items with responses ranging from 0 (absent) to 4 (severe).

6.52 Mechanism Measure

Dissociation: The Revised Dissociative Experiences Scale (DES-II, Carlson & Putnam, 1993). A 28-item, self-report measure of dissociative experiences in daily life with answers ranging from 0-100%. Dissociation will also be measured using a session measure and a daily self-report diary technique as used in previous studies (Varese et al., 2012).

6.53 Primary Outcome Measures:

Voices: The Psychotic Symptom Rating Scale (PSYRATS) (Haddock et al, 1999). As described above. Voices will also be measured using a session measure and a daily self-report diary technique as used in previous studies (Varese et al., 2012).

6.54 Secondary Outcome Measures:

Psychological distress: CORE-10 (Barkham et al, 2013) is a 10-item scale of psychological distress, with four-point likert-responses. Daily stress, avoidance and paranoia will also be measured using a structured self-assessment diary technique, as used in previous studies (Varese et al, 2012).

Therapeutic Alliance: Working Alliance Inventory (Horvath & Greenberg, 1989). The WAI is a self-report scale consisting of 36 items rated on a seven-point likert scale. The WAI has good reliability and validity with moderate correlation to clinical outcomes (r=0.24; Martin et al., 2000).

6.55 Post-intervention/supplementary measures:

Participant experience: Satisfaction with Therapy Questionnaire (STQ) (Lawlor et al., 2017) is a 22-item self-report to assess satisfaction with CBTp. Items are scored on a scale ranging from 1 to 5, with higher scores corresponding to higher satisfaction

Reflective journal: the researcher will keep a reflective journal to qualitatively aid interpretation of analysis and identify any processes issues or research biases that may emerge.

6.6 Design/Procedure

This study utilises a randomised multiple baseline Single-Case Experimental Design (SCED) with assessment at four time points (baseline, start of intervention, end of intervention and follow-up). *Randomisation:* Participants will be randomised to baseline periods of two, three or four weeks using a pre-determined simple randomisation method. Randomisation will be completed using a computer-generated sequence before recruitment begins. The researcher will be blind to the baseline allocation until the point of consent and screening, when the researcher will open a sealed envelope to reveal this.

Fig. 1: Summary of research-participant contact points.

All sessions will be audio recorded using an encrypted digital recorder provided by the University of Glasgow. Recordings will be used for supervision purposes to ensure the intervention is of high quality and to assess for content and fidelity of intervention.

Interpreters will be accessed as part of routine practice within the GPTS. The researcher will endeavor to meet with the interpreter before the information sharing appointment to ensure minimal impact to the study procedure. The researcher will also endeavor for participants to have the same interpreter for the duration of the study. The field supervisor has noted this to be feasible within the GPTS.

6.7 Data Analysis

Tau-U analysis will be used to analyse changes in outcome variables between the four assessment time-points. Tau-U is a non-parametric rank order correlation statistic with promising application for SCED research (Brossart et al., 2018). Visual data analyses will be conducted to analyse changes between and within phases. Visual analysis is routinely used in SCED research and will be conducted according to established guidelines (Barlow et al., 2009; Kazdin, 2011; Gast & Spriggs, 2010; Spriggs et al., 2018).

6.6 Justification of Sample Size

This study aims to recruit a sample of six participants. As per SCED methodology, the participants in this study will serve as their own baseline (Evans et al., 2014). Guidelines for SCED research suggest that change ought to occur across a minimum of three participants, with a minimum of three time points per participant in order to account for between-

participant variance and chance (Tate et al., 2013). Previous case series of a similar nature have included between nine and ten participants (Keen et al., 2017; Au et al., 2017) however participants in these studies did not have as much outcome data as the current study. Each participant in this study will have outcome data for four assessment points, as well as daily and in-session measures during baseline and intervention phases, thus having above the required three measures per phase (Tate et al., 2013). However, it is acknowledged that small sample size may result in limited generalizability to wider population. Therefore, demographic information will be taken into consideration when interpreting the results.

7. Health & Safety Issues

7.1 Researcher Safety Issues

The study will be carried out in a safe and secure NHS building that patients regularly attend. Should any health and safety issues arise the researcher will abide to NHSGG&C Health and Safety policies and respond accordingly. The researcher will also have access to the wider GPTS clinical team should any issues arise.

To combat working with clients with high levels of arousal and distress, the researcher will prioritise self-care and keep a reflective journal throughout the study. The researcher will utilize her existing self-awareness and coping skills to manage any distress she may encounter and signs of vicarious or secondary trauma will be closely monitored. The researcher will also use weekly supervision with the field supervisor to discuss any issues that may arise.

7.2 Participant Safety Issues

It is not foreseen that the current study will impact on participant safety. The study will be conducted in the GPTS (a safe and secure setting which meets NHSGGC Health & Safety standards). Should any risks arise during the project (e.g. fire, physical injury), NHSGGC policies and procedures will be followed accordingly. The researcher will also have access to the wider GPTS team. It is not foreseen that the research will impact on routine care available within the GPTS . Participants will not be negatively affected if they withdraw.

While it is not anticipated that this therapy will have unexpected adverse effects, in the unlikely event that participants experience any negative side-effects, participants will be encouraged to describe these, and this will be documented in the scientific report from this research. Support from supervisors will also be available. Any unexpected adverse incidents will be reported to relevant bodies within 24 hours of the events, according to HREC guidelines and standards.

7.3 Other Safety Issues

As this study may involve interpreters, the researcher will be vigilant of health and safety issues that may impact them. As per good practice when working with interpreters, the researcher will endeavor to check-in with interpreters and will sign-post them to relevant supports available should any issues arise. This procedure is not out-with routine clinical practice within the GPTS or the researchers' role as a Trainee Clinical Psychologist.

8. Ethical Issues

This study consists of a number of ethical issues, including the use of self-report measures on sensitive topics such as unusual experiences, dissociation and traumas. Other more common ethical issues that present in most studies such as confidentiality, the right to withdraw and reducing risk of harm have also been considered.

Care will be taken to ensure that individuals fully consent to taking part in this study. Participants will be asked questions and complete measures to ensure the inclusion criteria is met. The participant information sheet (PIS) will be shared, which contain details of the study including its purpose, what it will involve, risks and benefits and contact details of the study investigators. If the participants' first language is not English, a translated version of the PIS and consent form will be provided. Adequate time will be spent to ensure that participants are fully informed about the study and have sufficient time to independently decide whether or not they wish to take part. Participants will be encouraged to discuss any concerns or questions with the researcher to ensure they are fully informed and thus can give informed consent. If participants are happy to take part, they will sign the consent form. Before the participant gives consent, the researcher will work to ensure that they have retained and understood information will only gain written consent when an awareness of this has been evidenced e.g. by the researcher asking the individual to summarise the information and repeat back to the researcher. Participants will be informed that their participation is voluntary and they have the right to withdraw from the study at any point without consequence.

A series of measures will be employed to protect participants' privacy. All participants will have an anonymous research ID, with all data gathered throughout the study identifiable only by this ID. All data will be stored in a locked cabinet and on a secure, password-protected site file on an encrypted laptop. Following sign-up to the study, names and contact details will be kept in a separate physical and electronic location to the to the research ID and research data. Following analysis and write-up of results, participant contact information will be deleted unless the participant has consented to be informed about further follow-up relating to the study and/or receiving a summary of the results. As per routine clinical practice, discussions about confidentiality would include and extend to the interpreters, who will maintain and respect participants' confidentiality.

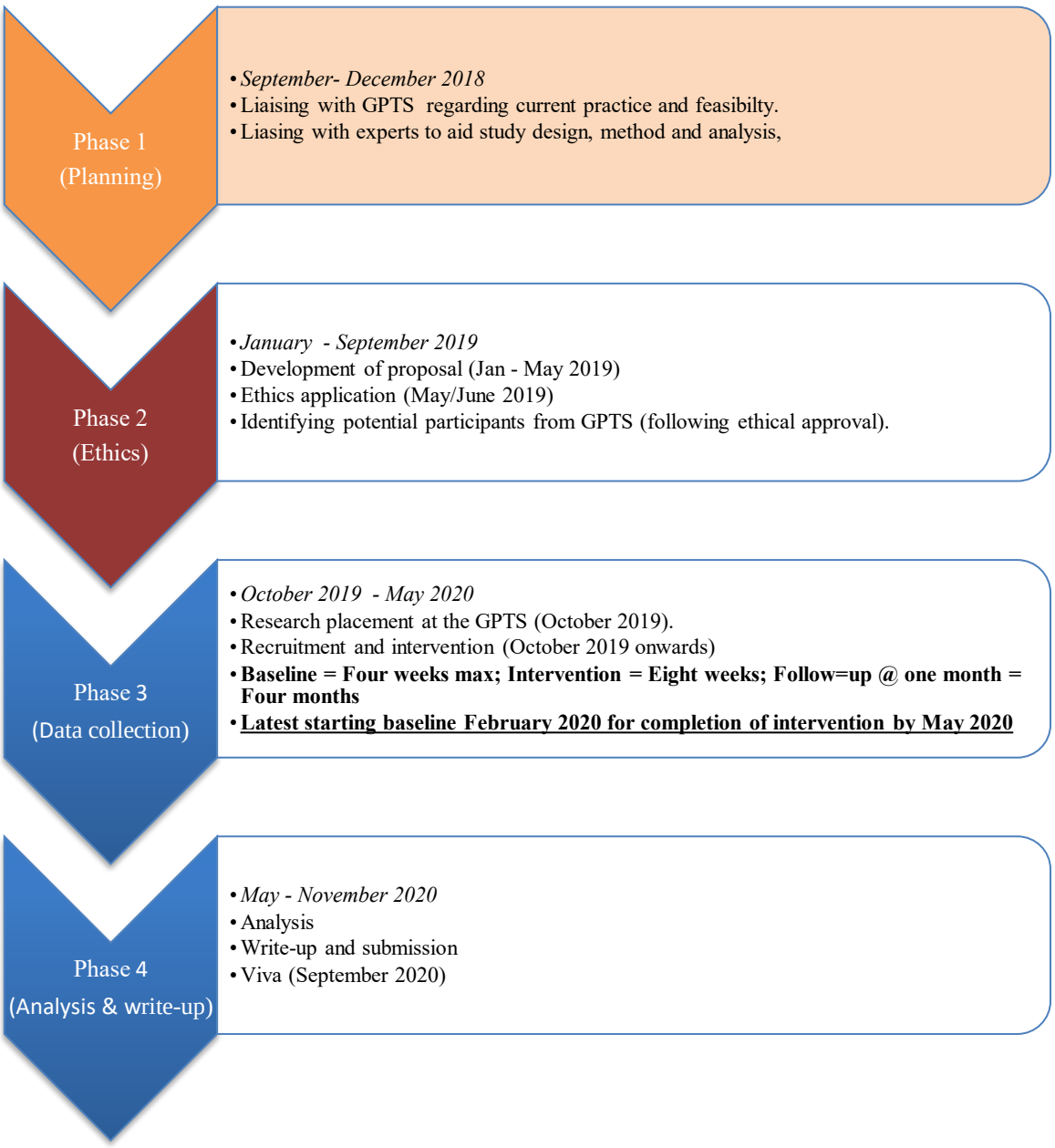
The rationale for audio recording will be discussed during the information sharing appointment. The researcher will be clear regarding the purpose of these and will highlight confidentiality. Recordings will not be accessed beyond the research team and will not be linked to patient records.

It is recognised that data collection for this study may be potentially burdensome for participants. This study proposes collecting data from participants on a daily basis, as well as the main assessment points. In practice, individuals are often required to keep daily records, particularly as part of Cognitive Behavioural Therapy (CBT). We have attempted to minimize this burden by having only four questions, in the hope that this procedure will soon become quick and easy to do. During the baseline period, participants will get used to filling these in and incorporating this into their daily routine. Participants will be encouraged to fill these in at the same time each day and any issues with completing measures will be addressed with the researchers' support.

9. Financial Issues

Participants will not receive payment for participating in this study. Expenses include printing, translation of key study documents and purchasing grounding materials for the intervention toolbox e.g. aroma oils. In keeping with implementing a feasible intervention, simple and affordable grounding objects will be used, with a focus on personal meaning and ease-of-access rather than cost.

10. Timeline:



11. Practical Applications

11.1 Dissemination

The results will be submitted as part of the Doctorate in Clinical Psychology and will be read by staff from the Institute of Health and Wellbeing as well as external examiners. This work will be published in an academic journal, presented at conferences, and other clinical forums.

Dissemination plans will be discussed with participants who will receive a summary of the results upon completion.

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Appendices

Appendix I: GPTS Referral Criteria

Accessed from :https://www.nhsggc.org.uk/your-health/health-services/glasgow-psychological-trauma-service/

People aged 16 and over (and unaccompanied asylum seeking children who are under 16 years) and who live in Greater Glasgow and Clyde

- who have a history of complex trauma (that **is repeated interpersonal trauma, including violence, abuse or neglect)**
- **that has led to Complex Post Traumatic Stress Disorder** including symptoms of PTSD **and** mood and emotion regulation difficulties **and** changes to people's beliefs about themselves and the world. PTSD symptoms include: re-experiencing the traumatic event(s); avoidance of trauma related stimuli; trauma related arousal and reactivity; negative thoughts and feelings
- **or other mental health difficulties that are severe and disabling responses to trauma (e.g. complicated dissociative disorders, mutism, enduring personality change after catastrophic events etc)**

The service prioritises people who experience additional social inequalities or barriers to accessing health care such as those who are homeless or leaving care; asylum seekers and refugees who are victims of torture and organised violence; trafficking victims for all forms of exploitation; vulnerable female offenders.