1. Can imagination change upsetting memories of trauma?

Protocol Short Title/ Acronym: Can imagination change upsetting memories of trauma?

Trial Identifiers

ISRCTN:			
REC Number:	18/LO/0684		
UKCRN Number:			
Protocol Version Number:	1.2	Date:	16/03/2018

(Co) Sponsor(s)

Name:	Professor Reza Razavi, Vice President & Vice Principal (Research), King's College London
Address:	Room 5.31, James Clerk Maxwell Building, Waterloo Campus, King's College London, London, SE1 8WA
Telephone:	020 7848 3224
Fax:	
Email:	reza.razavi@kcl.ac.uk

Name:	Jennifer Liebscher, R&D Department, South London & Maudsley Foundation Trust
Address:	Room W1.11, Institute of Psychiatry, Psychology & Neuroscience (IoPPN), De Crespigny Park, London, SE5 8AF
Telephone:	020 7848 0251
Fax:	
Email:	Jennifer.liebscher@kcl.ac.uk

Student (Doctorate in Clinical Psychology)

Name:	Rachel Clarke
Address:	Addiction Sciences Building, Department of Psychology, Institute of Psychiatry, Psychology & Neuroscience, 4 Windsor Walk, London, SE5 8AF
Telephone:	07486854611

Fax:	
Email:	Rachel.clarke@kcl.ac.uk

Academic Supervisors

Name:	Dr Amy Hardy
Position/ Role:	First/Primary Supervisor & Chief Investigator
Address:	Henry Wellcome Building, Department of Psychology, Institute of Psychiatry, Psychology & Neuroscience, King's College London, De Crespigny Park, London, SE5 8AF
Telephone:	0207 8485178
Fax:	0207 8485006
Email:	amy.hardy@kcl.ac.uk

Name:	Dr Rebecca Kelly
Position/ Role:	Second/Secondary Supervisor
Address:	PICuP Clinic, P079, Maudsley Psychology Centre, Denmark Hill, London, SE5 8AZ
Telephone:	020 3228 3952
Fax:	
Email:	Rebecca.kelly@slam.nhs.uk

2. Study Synopsis

TITLE OF CLINICAL TRIAL:	Can imagination change upsetting memories of trauma?
Protocol Short Title/ Acronym:	Can imagination change upsetting memories of trauma?
Sponsor Name:	King's College London
Chief Investigator:	Rachel Clarke
UKCRN Number:	
REC Number:	

Medical Condition Or Disease Under Investigation:	Psychosis
Purpose Of Clinical Trial:	Explore the feasibility and impact of imagery rescripting in individuals diagnosed with schizophrenia spectrum disorder or a mood disorder with psychotic features using a multiple baseline case series design
Primary Objective:	To explore the feasibility and impact of imagery rescripting as a therapeutic technique for traumatic memories in individuals with psychosis
Secondary Objective(s):	
Trial Design:	Nonconcurrent multiple baseline case series
Endpoints:	The project is completed once all the data has been analysed and submitted for publication.
Sample Size:	6-12
Summary Of Eligibility Criteria:	- Age 18-65 - Diagnosis of a Schizophrenia-spectrum disorder or mood disorder with psychotic features - Able to identify an intrusive traumatic memory occurring at least twice in the past week, as assessed by the Post-Traumatic Stress Diagnostic Scale. - Sufficient English to participate in the project - Open to a care team within the Psychosis CAG
Intervention (Description, frequency, details of delivery)	Three sessions of Imagery Rescripting delivered by a therapist
Maximum Duration Of Treatment Of A Subject:	Three Weeks
Version And Date Of Final Protocol:	V1.2 16/03/2018
Version And Date Of Protocol Amendments:	N/A

3. Revision History

Document ID - (Document Title) revision X.Y	Description of changes from previous revision	Effective Date
Protocol v1.0	Chief investigator changed in line with IRAS to primary supervisor; appendices deleted for separate version controlled documents; included medical records will be accessed with participant's permission; reworded section 10.3 surrounding participants giving consent to be contacted by the research team;	11/03/2018

Protocol v1.1	Changes made to recording device.	14/03/2018

4. Glossary of terms

ImRs – Imagery Rescripting

Psychosis – Individuals with a diagnosis of schizophrenia spectrum disorder or mood disorder with psychotic features

5. Protocol Contents

6. Background & Rationale

Intrusive images are a key mechanism in many disorders, including posttraumatic stress disorder (DSM-5, American Psychiatric Association, 2013) and other anxiety disorders (e.g. Hirsch & Holmes, 2007). Negative intrusive images are also common in individuals with psychosis, and are associated with memories (Morrison et al., 2002). Traumatic memories are argued to be central to the development and maintenance of PTSD (Ehlers & Clark, 2000), and are also proposed to play a role in some people's experience of psychosis (Hardy, 2017; Morrison et al., 2002; Steel, 2015).

Therapeutically, imagery interventions have been posited as effective techniques for individuals with a range of disorders characterised by negative imagery (Hackmann, Bennett-Levy, & Holmes, 2011; Holmes, Arntz, & Smucker, 2007). Imagery rescripting, an intervention where one changes the content of pre-existing traumatic memories, has been used as a therapeutic intervention with a variety of psychological disorders (Hackmann et al., 2011). In a recent meta-analysis of 19 trials on individuals with a variety of disorders, including posttraumatic stress disorder, social anxiety disorder and major depression, the large effect sizes suggest a high reduction in symptoms after therapy, and in comparison, to passive treatment controls (Morina, Lancee, & Arntz, 2016). Although the mechanism for change has yet to be identified, it has been argued that therapeutic change occurs due to a change in meaning given by the rescripted memory (Arntz, 2012).

In people with psychosis, there is currently limited, but promising, evidence for the use of imagery rescripting (Ison, Medoro, & Kuipers, 2014; Morrison et al., 2002; Schulze et al., 2013; Serruya & Grant, 2009; Sheaves et al., 2015). Many of these studies show that a brief intervention of imagery rescripting is a viable method of working with intrusive imagery in people with psychosis, however to date only Ison, Medoro, & Kuipers (2014) has looked at rescripting traumatic memories. However, as this project did not use a multiple-baseline design, it did not control fully for the effects of time. It also restricted its sample to voice hearers, which may not represent individuals with psychosis more generally. This project aims to explore the impact of imagery rescripting in individuals diagnosed with schizophrenia spectrum disorder or a mood disorder with psychotic features using a multiple baseline design. The imagery rescripting intervention will be provided over three weekly sessions and will focus on one traumatic memory chosen by the client.

Burden: The burden placed on participants has been minimised as much as possible by carefully considering the inclusion of each measure in the case series. Furthermore, the assessment session can be split into several shorter sessions, should the participant wish. Breaks will be offered in each therapeutic and assessment session and the research therapist will support the participant to ensure that the delivery of the research and therapeutic procedures is acceptable to them and modify if needed. For example, participants will complete daily ratings about their memory via text, email, or phone. The research therapist will discuss with participants how many ratings (up to a maximum of four a day) they are able to complete, and how they would like to be prompted to answer them. This will be reviewed throughout the project.

Risks: The focus of this project is distressing, traumatic memories, and participants will be required to focus on and discuss them during their participation which may be difficult. However, there is robust evidence to suggest that trauma-focused therapies can be safely applied in psychosis and that imagery rescripting can be used with this group to reduce distress associated with images (Ison et al., 2014; van den Berg et al., 2016). Participants will be selected as they regularly experience intrusive trauma memories, and therefore the study will only focus on eliciting experiences which they already have. Further, the project supervisors have extensive experience of working with traumatic memories in psychosis and will be able to ensure the intervention is delivered safely and sensitively. Participants will be giving informed consent to participate in the study.

Should the participant become distressed at any point and feel unable to continue with the therapy, then the study will be terminated, and the research therapist will discuss this with them. The supervisors of this project have extensive clinical experience in this group and will be available for consultation should this situation arise. In addition, the research therapist has experience working with this group of people and will manage the situation should it arise with the support of the supervisors. Information pertaining to risk will be shared as needed with the clinical team, in accordance with local risk management protocols. Coping strategies will be discussed with participants at the beginning of the intervention to support them in managing any distress that arises.

Benefit: It is hoped that participants will benefit from the intervention, as research has previously suggested a positive effect of imagery rescripting in individuals with psychosis (Ison et al., 2014). However, participants will be given this information alongside the fact that this study is exploratory and therefore potential benefits cannot be guaranteed. Despite this, disclosure of trauma in a supportive, therapeutic context can be

beneficial on its own, with trauma-focused therapy for psychosis trials finding that even control group participants improve (Steel et al., 2017; van den Berg et al., 2015).

7. Trial Objectives and Design

7.1 Trial Objectives

7.1.1 Primary endpoints

The overall aim of this project is to investigate the feasibility and impact of imagery rescripting as a therapeutic technique for traumatic memories in individuals with psychosis.

7.1.2 Secondary endpoints

7.2 Trial Design

A nonconcurrent multiple baseline case series (A1BA2) design will be utilised. Participants will be randomised to a baseline of 1-3 weeks symptom monitoring before receiving three sessions of ImRs and two weeks follow-up.

7.3 Trial Flowchart

	Recruitment visit	Assessment visit	Waitlist 1-3 weeks	Treatment period 3 weeks	Week 1 post treatment	1-week appointment post-treatment	Week 2 post-treatment
Patient information	X						
Informed consent		X					
30-minute Semi-structured interview		X					
Psychotic Symptom Rating Scale (PSYRATS)		X					
The Warwick-Edinburgh Mental Well-Being Scale (WEMWBS)		x				x	
The Posttraumatic Diagnostic Scale for DSM-5 (PDS-5)		x				x	
Mini-Trauma and Life Events Checklist (mini-TALE)		x					
Credibility and Expectancy				x			

Questionnaire (CEQ)							
Client Satisfaction Questionnaire (CSQ-8)						x	
Daily trauma index memory dimensions			x		x		x
Imagery Rescripting				x			

8. Trial Intervention

8.1 Therapy/Intervention Details

Participants will receive three sessions of imagery rescripting. The first session will include psychoeducation, recapping the identified memory, practicing the protocol on a non-threatening memory, and recapping coping strategies. The next two sessions will include rescripting the memory and problem-solving the rescript ImRs protocol will be personalised to the participants needs, drawing on several imagery rescripting protocols (e.g. Arntz, Tiesema, & Kindt, 2007; Jung & Steil, 2013; Lee & James, 2011).

8.2 Frequency and duration of intervention

Three weekly sessions of imagery rescripting will be delivered. Sessions will last approximately one hour, and no longer than 90 minutes.

8.3 Intervention records

Access to medical records will be used to confirm the participants' diagnosis. Furthermore, the researcher will need to access and add brief entries to the participant's electronic medical records through the electronic Patient Journey System within SLaM.

Personal Data

This will be needed to contact participants both to arrange appointments and to contact them in the future should any relevant information arise. It will be stored separately from the anonymised data and it will not be possible to link this data to that which is collected during the project.

Audio/Visual Recording

Participants will be audio-recorded during their assessment and treatment, they will be asked to sign a separate consent form for this recording. The recording will be done on a password protected, encrypted mobile and the researcher will ensure no identifiable information is recorded. This mobile will be stored in a locked filing cabinet at King's College London when not being used by the research therapist, and recordings will be stored on Office 365 as soon as the research therapist returns to the office environment. GPS will be activated on the phone and remote lock and erase will be enabled.

Manual Files

All data will be collected using paper questionnaires and interviews - these will be identified using participant codes only and will not contain any identifiable information. These will be kept in a locked filing cabinet at King's College London.

University Computers

All data will be entered into Kings College London computers and password-protected. It will be stored in office 365 one drive which is a secure cloud-based service offered by the university.

Direct Quotations

Consent for anonymised quotations from participants to be included in publications arising from the project will be

included in the consent form. It will be clear to participants that this is optional.

8.4 Subject Compliance.

Compliance will be assessed by recording therapy session attendance.

8.5 Study adherence

The research therapist's adherence to the intervention protocol will be ensured through training and supervision by the project supervisors. Participant adherence to the intervention will be supported by the research therapist, with additional prompts to attend sessions and adhere to the intervention protocol provided as needed.

8.6 5.5 Concomitant Medication

Concurrent medication and therapeutic treatment would not preclude participation in the project, however individuals who are receiving concurrent therapeutic treatment focusing on trauma will not be able to participate (because of the difficulty in attributing any change to the therapy approach being tested in this project).

9. Research environment

Potential participants will be recruited through liaison with the identified clinical teams or self-referral. The researchers will visit team meetings to introduce the research and give brief information. Regular contact will be maintained with the teams to identify suitable participants. Recruitment leaflets about the research will be given to teams to distribute to potential clients, who can then be contacted by the research therapist if they say they are interested in participating. Posters will also be put up in identified teams' waiting rooms. These will detail contact information for the research therapist, so that potential participants can contact the research therapist directly with their interest. The research therapist will ask the participant for an identified clinician to contact in order to check eligibility before meeting with the participant. Meetings with participants will be arranged in a community setting, either within South London and the Maudsley community outpatient setting or Kings College London University buildings.

10. Selection and Withdrawal of Subjects

10.1 Inclusion Criteria

- Age 18-65
- Diagnosis of a Schizophrenia-spectrum disorder or mood disorder with psychotic features
- Able to identify an intrusive traumatic memory occurring at least twice in the past week, as assessed by the Post-Traumatic Stress Diagnostic Scale.
- Sufficient English to participate in the project

10.2 Exclusion Criteria

- Concurrent trauma-focused psychological therapy
- Primary diagnosis of learning disability, substance use or organic disorder
- Acute suicide risk

10.3 Selection of Participants

This project will recruit 12 participants from teams in the Promoting Recovery care pathway, Psychosis CAG of SLaM NHS foundation trust. Potential participants will be recruited through liaison with the identified clinical teams or self-referral. The researchers will visit team meetings to introduce the research and give brief information. Regular contact will be maintained with the teams to identify suitable participants. A leaflet about the research will be given to teams to distribute to potential clients. Posters will also be posted in identified teams' waiting rooms detailing the study and research therapist's contact details to allow participants to self-refer to the project.

The recruitment strategy will be flexible and adapted depending on the capacity of the team to be involved in the research at any given time. Initially, the recruitment focus will be on teams where the researchers already have clinical roles (e.g. PiCuP) with the possibility of recruitment from other services considered in close collaboration with service leads and managers.

The researcher will liaise closely with clinicians and teams throughout the research. The project supervisors and researchers all have trust contracts and the supervisors are very experienced at working with the service user group.

Potential participants will only be approached by the research therapist when participants' have given consent to their clinical care team to be approached, and when they have the capacity to consent. The first contact will only be to introduce the project and pass on the information sheet. Both written and verbal information will explain the purpose and potential efficacy of the intervention to participants but will be transparent that this study seeks to find out whether the intervention is effective for people with psychosis, and therefore positive outcomes are not guaranteed.

The potential participant will have at least 24 hours to consider whether they wish to take part, during which the researcher will only contact them to answer questions if they wish. It will be made clear to participants that the intervention will take place after a wait-list time of 1-3 weeks.

10.4 Randomisation Procedure / Code Break

Participants will be randomised to a waitlist time of 1, 2, or 3 weeks. Randomisation will occur at assessment using a computer program.

10.5 Withdrawal of Subjects

Participants have the right to withdraw from the project at any time for any reason. The investigator also has the right to withdraw participants from the project in the event of unanticipated distress, unanticipated risk to self or others, or lack of capacity. It is understood by all concerned that an excessive rate of withdrawals can render the project uninterpretable; therefore, unnecessary withdrawal of participants should be avoided. Should a participant decide to withdraw from the project, all efforts will be made to report the reason for withdrawal as thoroughly as possible. Should a participant withdraw from project, efforts will be made to continue to obtain follow-up data, with the permission of the participant.

10.6 Expected Duration of Trial.

The project is completed once all 12 participants have completed their final follow-up appointments, two weeks after finishing therapy. The project is anticipated to be complete before the end of September 2020

11. Trial Procedures

11.1 By Visit

Initial Assessment: The full battery of questionnaires will include a semi-structured interview to identify an intrusive trauma memory (adapted from Hackmann, Clark, & McManus, 2000), a measure of well-being (The Warwick-Edinburgh Mental Well-Being Scale, WEBWMS), traumatic events (Mini-Trauma and Life Events Checklist, Mini-TALE), posttraumatic stress disorder (The Posttraumatic Diagnostic Scale for DSM-5, PDS-5), and psychosis symptoms (Psychotic Symptom Rating Scales, PSYRATS). Four visual analogue scale questions will be completed daily by the participant throughout the project. These questions will focus on the participant's conviction in the distressing appraisal, frequency, distress, and sense of control associated with the memory. The initial assessment will take approximately 90 minutes. The assessment can be split into

smaller sessions, as needed by the participant. Participants will be randomised following the initial assessment to their baseline waitlist time (one, two, or three weeks).

For the duration of their participation, the participant will be contacted daily to answer the four visual analogue scale questions about their trauma memory. Participants will be introduced to the daily monitoring, and how to complete their ratings during the initial assessment. The research therapist will discuss with the participant whether they would prefer the questions to be texted, emailed, or delivered over the phone. Participants will be asked to return a number from 0 to 100 to rate each question using the medium agreed. This can be completed using their mobile phone, or a handset will be provided if required. Prompting participants to complete ratings will be discussed and the frequency of prompts will be contracted with the participant. This will allow the participant to decide how many prompts they wish, and whether they would like a courtesy call within the waitlist period, before barriers occur. The researcher will be flexible towards the participant's wishes and check in with the participant regularly, if they wish.

Waitlist: The participant will wait for their assigned one, two, or three weeks. The decision about how long the participant waits will be made randomly by a computer. As described above, daily ratings will be completed within this time, with prompting and courtesy calls given as contracted with the participant.

Imagery Rescripting (ImRs): Participants will receive three sessions of Imagery Rescripting. The first session will include educating the participant about the rescripting protocol, recapping the identified memory, practicing the protocol on a non-threatening memory, and discussing coping strategies. Measures of how well they expect the therapy to work will also be taken at this first ImRs session (Credibility and Expectancy Questionnaire, CEQ). To ensure there are no researcher effects to this measure, participants will rate confidentially and put their answer into an envelope that will not be opened until the participant has completed the study.

The next two sessions will include using imagination to change the trauma memory and problem-solving any problems that occur. Once a ‘rescript’ the participant is satisfied with is identified, it will then be practiced repeatedly and adapted if necessary. Sessions will last approximately one hour, and no longer than 90 minutes. Participants will continue daily measures during this time.

Post-intervention follow-up: Participants will continue to complete daily measures about the memory for two weeks. During this time, at the end of the first week, participants will be asked to meet with the research therapist to assess their posttraumatic stress disorder symptoms (PDS-5), their level of wellbeing (WEBWMS), and how satisfied they were with the intervention (Client Satisfaction Questionnaire, CSQ-8).

This concludes the participant's involvement in the research.

Overall, participation will last a minimum of six and a maximum of eight weeks. During this time, participants will meet with the research therapist five times. That includes three times for therapy and twice to answer questions. The research therapist will also be contacting participants every day to answer four questions, either over the phone, by text or email.

11.2 Laboratory Tests

NA

12. Assessment of Efficacy

12.1 Primary Efficacy Parameters

30-minute semi-structured interview and daily questions on dimensions of the index memory

Adapted from Hackmann, Clark, & McManus's (2000) work on social phobia, also used in Ison et al. (2014). This consists of a series of standardised questions asking clients to identify an index intrusive traumatic memory. The dimensions of this index memory will be assessed during the interview, including; conviction in the distressing appraisal, frequency, distress, and sense of control associated with the memory. A visual analogue scale ranging from 0 to 100 will be used.

12.2 Secondary Efficacy Parameters

Psychotic Symptom Rating Scales (PSYRATS; Haddock, McCarron, Tarrier, & Faragher, 1999)

The PSYRATS was developed to measure dimensions of delusional beliefs (6 item Delusions Scale) and auditory hallucinations (11 item Auditory Hallucination Scale). The six items on the auditory hallucination sub-scale consists of items such as negative content, frequency, loudness, intensity and amount of distress and degree of disruption and control. The six-item delusion subscale consists of items such as duration and amount of pre-occupation, intensity and amount of distress and disruption, and degree of conviction. All items are rated on a five-point scale of increasing severity (0= No problem to 4 = Maximum severity). The PSYRATS has been shown to have good validity and reliability, with sensitivity to change (Haddock et al., 1999). This project will use the PSYRATS to describe the project sample.

The Warwick-Edinburgh Mental Well-Being Scale (WEMWBS; Tennant et al., 2007)

The WEMWBS assessed wellbeing on 14 items rated on a 5-point Likert scale, ranging from “none of the time” to “all of the time”. A total score ranging from 14-70 is calculated. Higher scores indicate higher levels of mental wellbeing. WEWBS shows high reliability, low social desirability, and confirmatory factor analysis supported the single-factor hypothesis (Tennant et al., 2007). It also shows high correlations with other well-being scales and low to moderate positive correlation with overall health (Tennant et al., 2007).

The Posttraumatic Diagnostic Scale for DSM-5 (PDS-5; Foa et al., 2016)

A 49-item self-report measure including all DSM-IV symptom criteria. 20 of these items asks participants to rate symptoms, and two questions relate to distress and interference. It has high face validity, internal consistency and reliability (Foa et al., 2016). This project will use the symptom section assessed over the past week, in order to measure change over time.

Credibility and Expectancy Questionnaire (CEQ) (Borkovec & Nau, 1972; Devilly & Borkovec, 2000)

Is a 6-item self-report instrument that measures treatment credibility, and client expectancy for improvement. The CEQ has high internal consistency (α = 0.79–0.90). Retest reliability is r = 0.82 for the expectancy factor and r = 0.75 for the credibility factor (Devilly & Borkovec, 2000). The first four items are rated based on cognitive appraisal of the treatment (e.g. At this point, how successfully do you think this treatment will be in reducing your symptoms?), whereas the last two items are rated based on feelings about the treatment. To reduce demand characteristics, client forms will be sealed in an envelope upon completion, and clients will be told that the therapist will only see the forms after they have finished participation.

Client Satisfaction Questionnaire (CSQ-8) (Larsen et al., 1979)

An eight-item version, to evaluate patient satisfaction. The sum of the responses to the CSQ-8 ranges from 8 to 32, with higher scores indicating greater satisfaction. The CSQ-8 has demonstrated high internal consistency across a large number of studies (Attkisson & Greenfield, 1999).

12.3 Procedures for Assessing Efficacy Parameters

N/A

13. Assessment of Safety

13.1 Burden

The burden placed on participants has been minimised as much as possible by carefully considering the inclusion of each measure in the case series. Furthermore, the assessment session can be split into several shorter sessions, should the participant wish. Breaks will be offered in each therapeutic and assessment session and the research therapist will support the participant to ensure that the delivery of the research and therapeutic procedures is acceptable to them and modify if needed. For example, participants will complete daily ratings about their memory via text, email, or phone. The research therapist will discuss with participants how many ratings (up to a maximum of four a day) they are able to complete, and how they would like to be prompted to answer them. This will be reviewed throughout the project.

13.2 Risk of Distress

The focus of this project is distressing, traumatic memories, and participants will be required to focus on and discuss them during their participation which may be difficult. However, there is robust evidence to suggest that trauma-focused therapies can be safely applied in psychosis and that imagery rescripting can be used with this group to reduce distress associated with images (Ison et al., 2014; van den Berg et al., 2016). Participants will be selected as they regularly experience intrusive trauma memories, and therefore the study will only focus on eliciting experiences which they already have. Further, the project supervisors have extensive experience of working with traumatic memories in psychosis and will be able to ensure the intervention is delivered safely and sensitively. Participants will be giving informed consent to participate in the study.

Should the participant become distressed at any point and feel unable to continue with the therapy, then the study will be terminated, and the research therapist will discuss this with them. The supervisors of this project have extensive clinical experience in this group and will be available for consultation should this situation arise. In addition, the research therapist has experience working with this group of people and will manage the situation should it arise with the support of the supervisors. Information pertaining to risk will be shared as needed with the clinical team, in accordance with local risk management protocols. Coping strategies will be discussed with participants at the beginning of the intervention to support them in managing any distress that arises.

13.3 Specification, Timing and Recording of Safety Parameters.

N/A

13.4 Procedures for Recording and Reporting Adverse Events

Safety and adverse event assessment and monitoring: It is an important subsidiary goal of the case series to establish the safety of the intervention, and we will also take all appropriate steps during the conduct of the case series for ensuring participant safety. The occurrence of adverse events (AEs) will be monitored actively and systematically. AEs are defined as including deaths; self-harm; serious violent incidents; complaints about therapy; referrals to crisis care or admission to psychiatric hospital during therapy. A standard method of reporting will be employed, categorising events by severity (five grades, A-E). Investigators will also determine relatedness of an event to the intervention based on a temporal relationship, as well as whether the event is unexpected or unexplained given the participant's clinical course, previous conditions and history, and concomitant treatments, in five categories from 'not related' to 'related' (following Linden 2013). The following will be considered as serious adverse events (SAE, Categories A-C): All deaths (category A), incidents which acutely jeopardise the health or psychological wellbeing of the individual, resulting in immediate hospital admission and/or permanent disability (category B), or resulting in injury requiring immediate medical attention (category C). These SAEs will include but are not limited to: 1) Hospital admissions; 2) Home treatment team involvement; 3) Suicide attempts; 4) Any violent incident necessitating police involvement (whether victim or accused); 5) Self-harming behaviour; 6) All deaths. Reasons for withdrawal from the study will also be recorded. Furthermore, in the event of any AEs and participant withdrawal, the research therapist will review participant clinical notes and contact clinicians for any important additional information. For the final reports of the case series, the numbers, types and severity of AEs, as well as discontinuations, will be reported, using descriptive statistics.

13.4.1 Adverse events that do not require reporting

There are no AEs or SAEs that will not be reported for the case series. The period for reporting will commence when participants provide informed consent and continue until the final follow-up questions are completed.

13.5 Stopping Rules

The trial may be prematurely discontinued by the Sponsor or Chief Investigator on the basis of new safety information or other reasons given by the ethics committee.

14. Statistics

Through using a multiple baseline case series design, a waitlist period will control for demand characteristics and effects of time, talking about previous trauma and completing measures. Furthermore, a protocol has been developed for the assessments in order to ensure consistency. Data will not be analysed until all data is collected. Finally, this project will be registered on clinicaltrials.gov, ensuring that the method and data-analysis is predetermined.

14.1 Sample Size

12 participants.

14.2 Randomisation

N/A

14.3 Analysis

Planned analyses include; descriptive statistics, visually inspecting graphs, the Tau statistic, and reliable change (Jacobson & Truax, 1991).

15. Trial Steering Committee

N/A

16. Data Monitoring Committee

N/A

17. Direct Access to Source Data and Documents

The Investigator(s) will permit project-related monitoring, audits and REC review by providing the Sponsor(s), and REC direct access to source data and other documents.

18. Ethics & Regulatory Approvals

The project will be conducted in compliance with the principles of the Declaration of Helsinki (1996), the principles of GCP and in accordance with all applicable regulatory requirements including but not limited to the Research Governance Framework and the Mental Capacity Act 2005.

This protocol and related documents will be submitted for review to South London and the Maudsley Research Ethics Committee (REC)

The research therapist will submit a final report at conclusion of the trial to the CAG, REC, and the Sponsor

It is expected that the all approvals will be completed, and the research will commence on 01/05/2018.

19. Quality Assurance

Monitoring of this trial will be to ensure compliance with Good Clinical Practice and scientific integrity will be managed by the project team. Research supervisors will listen to part or full therapy session recordings to ensure they meet a high-quality standard.

20. Data Handling

The Chief Investigator will act as custodian for the trial data. The following guidelines will be strictly adhered

to:

Patient data will be anonymised.(amend as required)

- All anonymised data will be stored on a password protected computer.
- All trial data will be stored in line with the Data Protection Act.
- and archived in line with Sponsor requirements

21. Data Management

Data will be collected on paper files, and stored on computer software, including Microsoft excel and SPSS

21.1 Access to Medical Records

In order to confirm the diagnosis given to the participants and to record their participation in the project for their care team the researcher will need to access the patient's electronic medical records, with the consent of the participant, through the electronic Patient Journey System within SLaM.

21.2 Personal Data

Information such as names, addresses and telephone numbers will be needed to contact participants both to arrange appointments and complete measures between appointments. It will be stored separately from the anonymised data and it will not be possible to link this data to that which is collected during the project.

21.3 Audio/Visual Recording

Participants will be audio-recorded during their therapy and assessment sessions, they will be asked to sign a separate consent form for these recordings. Participants will be recorded using a password protected, encrypted mobile phone and the research therapist will ensure no identifiable information beyond the memories themselves is recorded. This mobile will be stored in a locked filing cabinet at Kings College London when not in use by the research therapist, and recordings will be stored on Office 365 as soon as the research therapist returns to the office environment. GPS will be activated on the phone and remote lock and erase will be enabled.

21.4 Manual Files

All data will be collected using paper questionnaires and interviews - these will be identified using participant codes only and will not contain any identifiable information.

21.5 University Computers

All data will be entered onto Kings College London computers and password-protected

22. Publication Policy

This project is part of a doctoral thesis and will be written up as part of the written requirement. It is intended that the results of the project will be reported and disseminated at international conferences and in peer-reviewed scientific journals.

23. Insurance / Indemnity

The lead sponsor, King's College London, will take primary responsibility for ensuring that the design of the project meets appropriate standards and that arrangements are in place to ensure appropriate conduct and reporting. King's College London also provides cover under its No Fault Compensation Insurance, which provides for payment of damages or compensation in respect of any claim made by a research subject for bodily injury arising out of participation in a clinical trial or healthy volunteer study (with certain restrictions). The co-sponsor, South London and Maudsley NHS Foundation Trust, takes responsibility for ensuring that appropriate standards, conduct and reporting are adhered to regarding its facilities and staff involved with the project.

24. Financial Aspects

This project is conducted for part-fulfilment of the Doctorate in Clinical Psychology thesis – it will receive £1000 funding from the course for this purpose.

25. Signatures

_____ _____

Chief Investigator Date

Print name

_____ _____

Statistician (if applicable) Date

Print name

26. References

Arntz, A., Tiesema, M., & Kindt, M. (2007). Treatment of PTSD: A comparison of imaginal exposure with and without imagery rescripting. *Journal of Behavior Therapy and Experimental Psychiatry*, *38*, 345–370.

Attkisson, C. C., & Greenfield, T. (1999). The Client Satisfaction Questionnaire-8. In M. Maruish (Ed.), *The Use of Psychological Testing for Treatment Planning and Outcomes Assessment* (Second Edi, pp. 1333–1346). New Jersey: Lawrence Erlbaum Associates.

Borkovec, T., & Nau, S. (1972). Credibility of analogue therapy rationales. *Journal of Behavior Therapy and Experimental Psychiatry*, *3*(4), 257–260. http://doi.org/10.1016/0005-7916(72)90045-6

Devilly, G. J., & Borkovec, T. D. (2000). Psychometric properties of the credibility/expectancy questionnaire. *Journal of Behavior Therapy and Experimental Psychiatry*, *31*(2), 73–86. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/11132119

Foa, E. B., McLean, C. P., Zang, Y., Zhong, J., Powers, M. B., Kauffman, B. Y., … Knowles, K. (2016). Psychometric properties of the Posttraumatic Diagnostic Scale for DSM–5 (PDS–5). *Psychological Assessment*, *28*(10), 1166–1171. http://doi.org/10.1037/pas0000258

Hackmann, A., Clark, D. M., & McManus, F. (2000). Recurrent images and early memories in social phobia. *Behaviour Research and Therapy*, *38*(6), 601–610. http://doi.org/10.1016/S0005-7967(99)00161-8

Haddock, G., McCarron, J., Tarrier, N., & Faragher, E. B. (1999). Scales to measure dimensions of hallucinations and delusions: the psychotic symptom rating scales (PSYRATS). *Psychological Medicine*, *29*(4), 879–89.

Ison, R., Medoro, L., & Kuipers, E. (2014). The Use of Rescripting Imagery for People with Psychosis Who Hear Voices. *Behavioural and Cognitive Psychotherapy*, *42*(2), 129–142. http://doi.org/10.1017/S135246581300057X

Jung, K., & Steil, R. (2013). A randomized controlled trial on cognitive restructuring and imagery modification to reduce the feeling of being contaminated in adult survivors of childhood sexual abuse suffering from posttraumatic stress disorder. *Psychotherapy and Psychosomatics*, *82*(4), 213–20. http://doi.org/10.1159/000348450

Larsen, D. L., Attkisson, C. C., Hargreaves, W. A., & Nguyen, T. D. (1979). Assessment of client/patient satisfaction: development of a general scale. *Evaluation and Program Planning*, *2*(3), 197–207. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/10245370

Lee, D., & James, S. (2011). *The compassionate-mind guide to recovering from trauma and PTSD : using compassion-focused therapy to overcome flashbacks, shame, guilt, and fear*. New Harbinger

Publications.
Tennant, R., Hiller, L., Fishwick, R., Platt, S., Joseph, S., Weich, S., … Stewart-Brown, S. (2007). The Warwick-Edinburgh Mental Well-being Scale (WEMWBS): development and UK validation. *Health and Quality of Life Outcomes*, *5*, 63. http://doi.org/10.1186/1477-7525-5-63

27. Appendices – see separate documents

27.1 Participant Information Sheet

27.2 Consent form

27.3 Therapy Information Sheet