ISRCTN51593856 https://doi.org/10.1186/ISRCTN51593856

Trauma-focused therapy for older adults: A clinical case series

Submission date
19/06/2024

Recruitment status
Recruiting

Registration date
09/07/2024

Overall study status
Ongoing

Last Edited
25/06/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Trauma and psychological difficulties linked to trauma (e.g., Post-Traumatic Stress Disorder and Complex Post-Traumatic Stress Disorder) are common but often overlooked in older adults. This has led to a limited amount of research surrounding how well trauma-focused interventions work for older adults, meaning there is not a clear agreement on or understanding of effective ways to support older adults who have experienced trauma. As a result, many older adults with lived experience of trauma, and especially those with more complex needs, do not receive enough support and continue to suffer as a result of the impact of trauma.

Eye-Movement Desensitization Reprocessing (EMDR) therapy and Trauma-focused CBT have been found to be an effective treatment for PTSD. However, most research has focused on children and working aged adults and older adults appear to be excluded from the majority of trials, thus generalisability of findings to this population is questionable. As people age, developmental issues such as retirement or death of a spouse and other challenges such as a change in cognitive function or physical limitations may impact treatment engagement, adherence, delivery and outcome

The aim of this study is to evaluate the feasibility of delivering a 24-session, adapted trauma-focused therapy for older people with complex mental health difficulties, under the care of community mental health teams and with probable PTSD/ complex PTSD according to ICD-11 or DSM-5 criteria. Other aims include to determine any potential preliminary clinical benefits associated with receiving an adapted trauma-focused therapy. This includes any potential reductions trauma, emotional regulation, affective and psychotic symptoms and increases in perceived recovery. In addition, a further aim of the study is to determine whether the adapted trauma-focused therapies cause any Adverse Events or Serious Adverse Events.

Who can participate?
Those who can participate are older adults who are over the age of 60 years, supported by an adult or an older adult community mental health team, and who have a probable PTSD/ complex PTSD diagnosis. Participants also need to score 22+ on the Montreal Cognitive Assessment, have

the capacity to provide informed consent, are not currently in a mental health crisis and/or actively suicidal and have sufficient English-language skills to comprehend the assessment and therapy content.

What does the study involve?
Following the participants successfully passing the eligibility assessment and completing the baseline assessments, researchers will screen the participants' electronic clinical notes from the point of their entry to the service, up until the date of the assessment. Relevant diagnostic and clinical information using a pre-specified Case Report Form, to confirm the PTSD diagnostic status of the participant (e.g. whether the participant has received ICD-10 diagnosis of PTSD) and whether there are any references to trauma or PTSD symptoms in their clinical notes.

The participant will then be offered 24 sessions of therapy, over a maximum 9-month time period by a Health and Care Professionals Council (HCPC) registered Clinical Psychologist or therapist with specialist training in EMDR or Trauma-focused CBT. In a typical session of EMDR, the therapist will work with the client to teach them strategies to deal with distressing thoughts and feelings. They will be then asked to call to mind a disturbing issue or event whilst the therapist will encourage the person to do some other tasks that can help reduce the distress caused by an event (for example, perform side-to-side eye movements). In a typical session of TF-CBT, the therapist will work with the person to improve difficulties brought about by trauma. They will be asked to work on memories or images linked to difficult events from their past. For example, they may be asked to recall a memory and talk through it and explore it. The idea behind this is that the more we revisit a memory the less distressing it may become. After each therapy session, therapists will be asked to complete a standardised session record form to monitor the content of the session in terms of the specific therapy milestones and permissible intervention strategies. After the end of therapy, participants will be asked to participate in an optional semi-structured interview that will aim to explore individuals' experiences of receiving the trauma-focused intervention in more detail. The semi-structured interviews will be completed once the therapy sessions have finished based on participant availability and will be carried out by the researcher, lasting approximately an hour.

The researcher will meet the potential participant for the 9-month follow up assessment appointment at either their home, an NHS site / University of Manchester / public site with a private space or a telephone or online appointment using Microsoft TEAMS.

The end of the study will be when the final post-intervention measure for the final participant has been collected and contact with participants has been completed. The total length of time of participation for participants is approximately 28 hours from the point of consent to their end of study.

What are the possible benefits and risks of participating?
The assessments:
Benefits
Although it is not anticipated that there will be any direct benefit from participating in this research, if participants decide to complete the questionnaires, they may find the study interesting. They will also be contributing to research in a group which is under-studied.
Risks
It is possible that talking about their trauma experiences during the assessment may upset participants. However, if this happens, participants will be offered the opportunity to pause or stop the assessment, and the researcher will offer emotional support. After the assessment, participants will receive a debrief sheet with contact information for the research team and information on helplines and support organisations.

The therapy:
Benefits
Participants will be receiving one of two trauma-focused therapies that have been found to be effective in reducing experiences of post-traumatic stress disorder and other trauma related symptoms in a number of research studies, and which, if adhered to, should reduce their experiences of trauma-related symptoms. Furthermore, participants may find it helpful or interesting to talk about some of their experiences with a registered Clinical Psychologist or other therapist with special training as they will help guide participants toward improving their understanding of some of their experiences.
Risks
It is possible that talking about their trauma experiences during the therapeutic process and calling these events to mind may upset or distress participants. However, should this happen, participants will be offered the opportunity to pause or stop the therapy, and participants will be offered time with the therapist during the session or the following week to discuss this. Participants will also have access to their usual support that they access through their community mental health team.

Where is the study run from?
University of Manchester (UK)

When is the study starting and how long is it expected to run for?
November 2023 to May 2027

Who is funding the study?
The study has been funded externally by the Eleanor Dowager Countess Peel Trust award (UK)

Who is the main contact?
Dr Elizabeth Tyler, Elizabeth.tyler@manchester.ac.uk

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Dr Elizabeth Tyler

ORCID ID
http://orcid.org/0000-0001-5955-5607

Contact details
Zochonis building, Manchester University, Division of Psychology and Mental Health, Faculty of Biology, Medicine and Health
Manchester
United Kingdom
M13 9PL
+44 7795047784
Elizabeth.tyler@manchester.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
336560

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 336560

Study information

Scientific Title
Trauma-focused therapy for older adults: A clinical case series

Study objectives
1. Is it feasible to deliver a 24-session, adapted trauma-focused therapy for older people with probable PTSD?/ complex PTSD?
2. Are there any clinical benefits associated with receiving an adapted trauma-focused therapy for older people with probable PTSD/ complex PTSD?
3. Are there any AEs or SAEs reported in relation to receiving an adapted trauma-focused therapy for older people with probable PTSD/ complex PTSD?

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 10/06/2024, North West - Liverpool Central REC (2 Redman Place, Stratford, E20 1JQ, United Kingdom; +44 207 104 8340; liverpoolcentral.rec@hra.nhs.uk), ref: 24/NW/0125

Study design
Multi-centre case series design

Primary study design
Interventional

Secondary study design
Case series

Study setting(s)
Community, Medical and other records

Study type(s)
Other, Treatment, Safety, Efficacy

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Trauma-focused therapies to reduce post-traumatic stress symptoms

Interventions
The participant will be offered 24 sessions of therapy, over a maximum 9-month time period by a Health and Care Professionals Council (HCPC) registered Clinical Psychologist or therapist with specialist training in Eye-Movement Desensitization Reprocessing (EMDR) therapy or Trauma-focused Cognitive Behavioural Therapy (CBT). The therapy offered will be based on the clinician' s area of expertise and will either be an adapted version of either an Eye Movement Desensitization and Reprocessing manual (EMDR; Shapiro et al., 2018) or an adapted version of trauma focused CBT for PTSD, based on Ehlers and Clark's (2000) model.

Participants will continue to receive treatment as usual throughout the therapy period.

Participants will complete baseline assessments to confirm eligibility and eligible participants will complete further baseline assessments.

As part of the informed consent process, participants will have agreed for members of the research team to access their clinical notes. Researchers will screen the participants' electronic clinical notes from the point of their entry to the service, up until the date of the assessment. Relevant diagnostic and clinical information using a pre-specified Case Report Form, to confirm the PTSD diagnostic status of the participant (e.g. whether the participant has received ICD-10 diagnosis of PTSD) and whether there are any references to trauma or PTSD symptoms in their clinical notes. This is so they can check correspondence between clinical information on file and the results from the PTSD assessments conducted during the study.

At the end of each therapy appointment the participant will be asked to complete brief sessional measures consisting of 8 questions relating to the person's current problems.

After the end of therapy, participants will be asked to participate in an optional semi-structured interview that will aim to explore individuals' experiences of receiving the trauma-focused intervention in more detail.

The researcher will meet the potential participant for a 9-month follow up assessment.

Any AE observed over the course of the participants involvement in the research, up until the final follow-up point will be documented and reported according to HRA safety reporting procedures for non-CTIMP studies, Sponsor's requirements, and local R&D policies of participating NHS organisations.

Intervention Type
Behavioural

Primary outcome measure
Feasibility of the adapted trauma focused therapy intervention using the following metrics:
1. Individuals approached regarding the study measured using total numbers at the end of the recruitment period.
2. Individuals approached who are eligible and consent to take part in the study measured using

total numbers at the end of the recruitment period.
3. Individuals approached who are eligible and do not take part in the study measured using total numbers at the end of the recruitment period.
4. Therapy sessions attended measured using total numbers at the end of the therapy sessions.
5. Participants who drop-out and at which point in the therapy measured using total numbers at the point of drop-out.
6. Adverse Events and Serious Adverse Events measured using total numbers at the end of the follow-up period.

Secondary outcome measures
Any preliminary potential clinical benefits will be determined using the following outcome measures; changes in outcome measure scores from first baseline to 9 month follow-up will be calculated. The suitability of outcome measures will also be measured (determined by % completion).
1. The International Trauma Questionnaire (ITQ; Cloitre et al., 2018),
2. The Post Traumatic Stress Checklist for DSM-5 (PCL-5; Wheathers et al., 2013),
3. the Dissociative Subtype of PTSD Scale (DSPS; Wolf et al., 2017),
4. The 9-item version of the Patient Health Questionnaire (PHQ-9; Kroenke et al, 2001)
5. The Altman Self-Rating Mania Scale (Altman et al., 1997)
6. 7-item version of the General Anxiety Disorder scale (GAD-7; Spitzer et al., 2006)
7. The Community Assessment of Psychic Experiences- Positive Scale (CAPE-15; Capra et al., 2017)
8. The Questionnaire about the Process of Recovery (QPR; Neil et al., 2007)

Potential clinical benefits will also be determined by plotting the weekly sessional scores to examine treatment effects in more detail.

After the end of therapy, participants will be asked to participate in an optional semi-structured interview that will aim to explore individuals' experiences of receiving the trauma-focused intervention in more detail.

Overall study start date
06/11/2023

Completion date
01/05/2027

Eligibility

Key inclusion criteria
1. A probable PTSD/ complex PTSD according to the following thresholds:
1.1. At least one trauma event on the TALE
1.2. A probable diagnosis of PTSD or Complex PTSD as defined by the standard diagnostic algorithm for the ITQ (Cloitre et al., 2018)
1.3. A score of 31 or more on the PCL-5
2. Aged 60 years and above
3. Score of 22+ on the MOCA (Nasreddine et al., 2004).
4. Supported by an adult or an older adult community mental health team.
5. Capacity and willingness to provide informed consent.

Participant type(s)

Patient, Service user

Age group
Senior

Lower age limit
60 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
6-8

Key exclusion criteria
1. Currently in a mental health crisis and/or actively suicidal
2. Insufficient English-language skills to comprehend the assessment and therapy content.

Date of first enrolment
01/09/2024

Date of final enrolment
01/09/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Greater Manchester Mental Health NHS Foundation Trust
Prestwich Hospital
Bury New Road
Prestwich
Manchester
United Kingdom
M25 3BL

Sponsor information

Organisation
University of Manchester

Sponsor details
Ms Lynne Macrae, Faculty Research Practice Governance Coordinator
Faculty of Biology, Medicine and Health
5.012 Carys Bannister Building
Manchester
England
United Kingdom
M13 9PL
+44 161 275 5436
FBMHethics@manchester.ac.uk

Sponsor type
University/education

Website
http://www.manchester.ac.uk/

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Charity

Funder Name
The Dowager Countess Eleanor Peel Trust

Results and Publications

Publication and dissemination plan
The research team and the Sponsor own the data generated from this study. Upon completion of data collection, the research team, led by the Chief Investigator will be in charge of analysing, synthesising and producing a final report of the data. The full study report and protocol will be accessible via the Sponsor's service within 12 months of the completion of the study. The research team retain the right to publish the study in peer-reviewed scientific journals, internal reports, and conference presentations. The role of the Sponsor will be acknowledged within individual publications.

Intention to publish date
31/05/2028

Individual participant data (IPD) sharing plan

The data will be made available to other researchers upon request to Elizabeth. tyler@manchester.ac.uk

IPD sharing plan summary

Available on request