

Narrative exposure therapy in victims of trafficking and other forced migrants

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| Submission date 31/01/2017 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 08/02/2017 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 10/10/2022 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

Forced migrants often experience a large number of traumatic events. Studies have found that asylum-seekers and refugees report high rates of post-traumatic stress disorder (PTSD; a type of anxiety disorder triggered by a traumatic event). Human trafficking is a form of modern slavery that involves the forced movement of people either internally within countries, or externally across borders. Victims who are trafficked are similarly subject to repeated, multiple trauma, and high rates of mental health problems including PTSD have been found. Narrative Exposure Therapy (NET) is a type of therapy for individuals who have PTSD following multiple traumatic events. This treatment aims to alleviate the symptoms of PTSD, thereby leading to an improvement in daily functioning. Whilst good evidence for its use in conflict zones exists and its efficacy amongst individuals who have left their countries of origin is emerging, little research has focused on its efficacy amongst victims of trafficking. The aim of this study is to evaluate how well this therapy works for different groups of people who have all experienced multiple traumas, and to make sure they are treated in the most efficient and effective way.

Who can participate?

Adult victims of human trafficking and other forced migrants.

What does the study involve?

Participants are randomly allocated to either start therapy straight away, or placed into the 'waiting list' group to start therapy about six months later. Once receiving therapy, participants are offered up to 20 sessions. Throughout the duration of the research study, participants are routinely asked to fill out questions about their mental health and well-being. This includes questions about particular symptoms they may be having, such as nightmares, and asking them to rate statements such as "Worrying thoughts go through my mind". Interpreters can be arranged where needed. The same set of questions are asked again at three, six and twelve months after having finished therapy to find out how things change for patients over time.

What are the benefits and risks of participating?

Participants may benefit from an improvement to their PTSD symptoms after having NET. There are no notable risks involved with participating in this study.

When is the study run from?
Helen Bamber Foundation (UK)

When is the study starting and how long is it expected to run for?
December 2016 to December 2018

Who is funding the study?
The Oak Foundation (UK)

Who is the main contact?
Professor Cornelius Katona

Contact information

Type(s)
Scientific

Contact name
Prof Cornelius Katona

Contact details
Helen Bamber Foundation
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
8331/002

Study information

Scientific Title
Treating Post-traumatic Stress Disorder in Victims of Trafficking and other Forced Migrants using Narrative Exposure Therapy: A Pilot Randomized Controlled Trial

Study objectives
Participants in the treatment condition (Narrative Exposure Therapy) will have significantly reduced symptoms of Post-traumatic Stress Disorder in comparison to waitlist controls.

Ethics approval required

Old ethics approval format

Ethics approval(s)

University College London (UCL) Ethics Committee, 30/01/2017, ref: 8133/002

Study design

Single-centre blinded randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

See additional files

Health condition(s) or problem(s) studied

Post-traumatic Stress Disorder in victims of trafficking and other forced migrants.

Interventions

Eligible participants will be randomized to either Narrative Exposure Therapy (N=15-20) or the waitlist control group (N=15-20). Randomization will be performed using stratification for victims of trafficking vs other forced migrants. It is intended to perform blinded assessments by keeping raters unaware of treatment condition and by instructing clients not to reveal treatment conditions if possible.

Participants in the treatment condition will be offered up to 20 sessions of NET. The anticipated average number of sessions is 16. Additional time will be allowed for participants needing an interpreter, and allow for additional sessions, if NET needs to be paused or if other issues come up during the course of treatment that need more urgent attention (such as concerns about legal or practical matter, as is common with this client group). Any additional sessions used for non-NET purposes will be noted, and the content of this will be documented.

Participants in the waitlist control condition will receive the same treatment approximately six months later.

Participants in both groups will be followed up at three, six, and twelve months.

Intervention Type

Behavioural

Primary outcome measure

Post-traumatic Stress Disorder rate is measured using the Clinician-administered PTSD Scale (CAPS-5) and the Post-traumatic Stress Disorder Checklist (PCL-5) at baseline, midway through

treatment (after 8 sessions), after 16 sessions, at the end of treatment (if this is more than 16 sessions), and at three, six and twelve month follow-up.

Secondary outcome measures

1. Depression is measured using Patient Health Questionnaire (PHQ-9)
2. Anxiety is measured using Generalised Anxiety Disorder (GAD-7)
3. Dissociation is measured using Shutdown Dissociation Scale (ShuDis)
4. Levels of generalized distress is measured using Clinical Outcomes in Routine Evaluation (CORE)
5. Self-Compassion using the Self-compassion Scale short form (SCS-SF)
6. Rumination is measured using Preservative Thinking Questionnaire (PTQ) and the Self-Critical Rumination Scale (SCRS)
7. Self-esteem is measured using Rosenberg Self-Esteem
8. General daily functioning and satisfaction is measured using Work and Social Adjustment Scale (WASA)

All outcomes will be measured at baseline, midway through treatment (after 8 sessions), after 16 sessions, at the end of treatment (if this is more than 16 sessions), and at three, six and twelve month follow-up.

Overall study start date

01/12/2016

Completion date

31/03/2019

Eligibility

Key inclusion criteria

1. Diagnosis of Post-traumatic Stress disorder according to DSM 5
2. A history of human trafficking or other human rights abuses
3. Provision of informed consent

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

30-40

Total final enrolment

25

Key exclusion criteria

Any internal or external factors that indicate the person is not stable enough for trauma-focused treatment to be appropriate (in accordance with NICE Guidelines for PTSD, 2005). This will include comorbid psychosis, substance misuse and high risk of suicide and/or self-harm, as well as destitution, street homelessness, risk of imminent removal from the UK and the inability of parents to organise childcare due to safeguarding and attendance issues.

Date of first enrolment

01/03/2017

Date of final enrolment

30/09/2018

Locations

Countries of recruitment

England

United Kingdom

Study participating centre**Helen Bamber Foundation**

Bruges Place

15-20 Baynes Street

London

United Kingdom

NW1 0TF

Sponsor information

Organisation

Helen Bamber Foundation

Sponsor details

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Sponsor type

Charity

Website

<http://www.helenbamber.org/>

ROR

<https://ror.org/05r8kh365>

Funder(s)

Funder type

Charity

Funder Name

Oak Foundation

Alternative Name(s)

Oak Foundation USA, Oak Philanthropy (US) Inc.

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United States of America

Results and Publications

Publication and dissemination plan

Plans to publish the results in an academic journal. It will not be possible to identify individual participants here as data will have been anonymised. All research participants will also be written to using simplified language to inform them of the results.

Intention to publish date

20/05/2021

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Professor Cornelius Katona, cornelius@helenbamber.org

IPD sharing plan summary

Available on request

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|------------|--------------|------------|----------------|-----------------|
| Participant information sheet | version V2 | 08/02/2017 | 21/02/2017 | No | Yes |

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|---|------------|------------|------------|-----|-----|
| Participant information sheet | version V2 | 08/02/2017 | 21/02/2017 | No | Yes |
| Results article | | 28/10/2021 | 16/11/2021 | Yes | No |
| Protocol file | | | 10/10/2022 | No | No |