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Narrative exposure therapy in victims of trafficking and other forced migrants

Submission date
31/01/2017

Recruitment status
No longer recruiting

Registration date
08/02/2017

Overall study status
Completed

Last Edited
10/10/2022

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 disordered 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
Bruges Place
15-20 Baynes Street
London
United Kingdom
NW1 0FT

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 from (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
Bruges Place
15-20 Baynes Street
London
United Kingdom
NW1 0TF
+44 (0)20 3058 2020
reception@helenbamber.org

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

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