

# Narrative exposure therapy in victims of trafficking and other forced migrants

<b>Submission date</b> 31/01/2017	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 08/02/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 10/10/2022	<b>Condition category</b> 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  
Bruges Place  
15-20 Baynes Street  
London  
United Kingdom  
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## Additional identifiers

**Protocol serial number**  
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

## **Study type(s)**

Treatment

## **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(s)**

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.

## **Key secondary outcome(s)**

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.

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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**

United Kingdom

England

**Study participating centre**  
**Helen Bamber Foundation**  
Bruges Place  
15-20 Baynes Street  
London  
United Kingdom  
NW1 0TF

## Sponsor information

**Organisation**  
Helen Bamber Foundation

**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

### 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](mailto:cornelius@helenbamber.org)

## IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		28/10/2021	16/11/2021	Yes	No
<a href="#">Participant information sheet</a>	version V2	08/02/2017	21/02/2017	No	Yes
<a href="#">Participant information sheet</a>	version V2	08/02/2017	21/02/2017	No	Yes
<a href="#">Protocol file</a>			10/10/2022	No	No