# Swedish unaccompanied youth refugee trial

Submission date	Recruitment status	[X] Prospectively registered		
13/12/2018	No longer recruiting	[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
20/12/2018	Completed	[X] Results		
<b>Last Edited</b> 17/01/2023	<b>Condition category</b> Mental and Behavioural Disorders	Individual participant data		

### Plain English summary of protocol

Background and study aims

In 2015, 162,877 people sought asylum in Sweden, 42% of whom were children and youth. Refugee children, especially unaccompanied refugee minors, have often experienced traumas and are at significant risk of developing mental health problems, such as symptoms of post-traumatic stress disorder (PTSD) and depression, that can continue years after resettlement. This study aims to evaluate a community-based intervention for refugee youth experiencing post-traumatic stress symptoms called 'Teaching Recovery Techniques'.

#### Who can participate?

Unaccompanied refugee youths who score high on a post-traumatic stress survey, who arrived in Sweden when aged under 18 years and have spent less than 6 years in Sweden.

#### What does the study involve?

Youths referred for 'Teaching Recovery Techniques' who meet the study criteria are randomly allocated to a group that receives the intervention straight away or a group that receives the intervention a little later. Changes in youth mental health and wellbeing are measured using surveys at 8 weeks and 20 weeks after the group allocation.

## What are the possible benefits and risks of participating?

The potential benefit to participating youths is improved mental health and wellbeing. A safety protocol to prevent self-harm among participants has been developed. In case of a positive answer on wishing one were dead on a depression survey, an individual assessment is performed using the Columbia Suicide Severity Rating Scale, screener version. The guidelines include clear instructions on who to call and what to do depending on the score. The safety protocol is revised for each site and signed by local senior managers.

#### Where is the study run from?

The Child Health and Parenting (CHAP) research group at Uppsala University (Sweden)

When is the study starting and how long is it expected to run for? April 2018 to September 2021

Who is funding the study? The Kavli Trust

Who is the main contact? Prof. Anna Sarkadi anna.sarkadi@pubcare.uu.se

#### Study website

www.pubcare.uu.se/forskning/chap/projekt/aktuella-projekt/swedish-unaccompanied-youth-refugee-trial--support-/

# Contact information

### Type(s)

Scientific

#### Contact name

Prof Anna Sarkadi

#### Contact details

BMC, Husargatan 3 Uppsala Sweden 751 22 +46 (0)18 471 6572 anna.sarkadi@pubcare.uu.se

### Type(s)

**Public** 

#### Contact name

Ms Elin Lampa

#### Contact details

BMC, Husargatan 3 Uppsala Sweden 751 22 +46 (0)18 471 6574 elin.lampa@pubcare.uu.se

# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

# Secondary identifying numbers

N/A

# Study information

#### Scientific Title

Evaluation of the Teaching Recovery Techniques community-based intervention for unaccompanied refugee youth experiencing post-traumatic stress symptoms – a randomised controlled study

#### Acronym

Swedish UnaccomPanied yOuth Refugee Trial (SUPpORT)

#### Study objectives

It is hypothesised that, when compared with youths who have not received the intervention (the waitlist control arm), youths who have received Teaching Recovery Techniques (the intervention arm) will demonstrate fewer self-reported symptoms of mental ill-health, specifically post-traumatic stress, depression and anxiety symptoms.

It is further hypothesised that, when compared with the control arm, the intervention arm will report greater self-efficacy and wellbeing.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Regional Ethical Review Board in Uppsala, 28/11/2018, ref: 2018/382

## Study design

Two-arm randomised waitlist control superiority trial

### Primary study design

Interventional

## Secondary study design

Cluster randomised trial

## Study setting(s)

Community

# Study type(s)

Treatment

### Participant information sheet

Not available in web format at time of registration, please use contact details to request a participant information sheet.

# Health condition(s) or problem(s) studied

Post-traumatic stress disorder (symptoms)

#### Interventions

Current intervention as of 04/11/2019:

Randomization will use a small-cluster randomization design rather than a single participant

randomization design. A new randomization system has been created using sealedenvelope. com. The target cluster size is 6 participants, based on recommended TRT group size. The estimated intraclass correlation coefficient is 0.05. Therefore, the minimum required sample size will be adjusted by a factor of 1.25.

The intervention arm will receive the Swedish translation of the Teaching Recovery Techniques (TRT) programme. This group-based cognitive-behavioural programme includes 2 caregiver sessions and 5 youth sessions. Youth sessions focus on psychoeducation, intrusion, arousal and avoidance. Caregiver sessions focus on psychoeducation and are delivered in parallel with the first 2 youth sessions. A 'getting to know each other session' will be offered prior to the core TRT sessions and a 'follow-up session', which consolidates learning and enables participants to talk about their experience of taking part in the programme, will be offered afterwards. Sessions will be delivered over 7 consecutive weeks. Each session will last 2 hours (including a break). TRT facilitators will receive 3 days of training in programme delivery.

The waitlist control arm will receive services as usual, meaning services to which they are entitled and could potentially receive in the absence of the trial. Once the 20-week follow up data has been collected for the intervention arm, the waitlist control arm will be offered TRT.

Concomitant care: Parallel individual intervention/therapy for PTSD or psychosocial support is allowed, but the therapist must be informed and recommend participation. A parallel, different, group intervention is not recommended.

#### Previous intervention:

Block randomisation of block sizes 4, 6, or 8 will be generated in a computerized randomisation schedule (with 1:1 allocation ratio).

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#### Intervention Type

Behavioural

#### Primary outcome measure

Measured at baseline, 8 and 20 weeks:

1. Post-traumatic stress symptoms, measured using the Children's Revised Impact of Event Scale (CRIES-8; Perrin, Meiser-Stedman et al. 2005)

- 2. Depression symptoms, measured using the Patient Health Questionnaire-9 (PHQ-9; Kroenke, Spitzer, & Williams, 2001)
- 3. Anxiety symptoms, measured using the Generalized Anxiety Disorder-7 (GAD-7; Spitzer, Kroenke, Williams, & Löwe, 2006)

#### Secondary outcome measures

Measured at baseline, 8 and 20 weeks:

- 1. Self-efficacy, measured using the General Self Efficacy Scale (GSE; Schwarzer & Jerusalem, 1995)
- 2. Wellbeing, measured using the Cantril Ladder (Cantril, 1966; picture from från Sawatzky et al., 1966; modified for use in the present study)

#### Overall study start date

01/04/2018

## Completion date

30/09/2021

# **Eligibility**

#### Key inclusion criteria

Current inclusion criteria as of 04/11/2019:

Participants eligible for the trial must comply with all of the following at randomization:

- 1. Aged under 18 years at time of arrival in Sweden (self-reported)
- 2. Lived in Sweden <6 years
- 3. Arrived in Sweden unaccompanied
- 4. Screening positive on the CRIES-8 PTSD screening tool (≥17 points)
- 5. Interest to participate in a group intervention & consent to be randomized
- 6. Legal guardian consenting to participation if child is aded <15 years

Previous inclusion criteria:

Participants eligible for the trial must comply with all of the following at randomization:

- 1. Youth age ≥14 years
- 2. Time spent in Sweden < 5 years
- 3. Arrived in Sweden unaccompanied
- 4. Screening positive on the CRIES-8 PTSD screening tool (≥17 points)
- 5. Interest to participate in a group intervention & consent to be randomized
- 6. Legal guardian consenting to participation if child is <15 years

#### Participant type(s)

Patient

## Age group

Mixed

#### Sex

Both

### Target number of participants

160

#### Key exclusion criteria

- 1. Youth age >20
- 2. Time spent in Sweden > 5 years
- 3. Current treatment where therapist advises against intervention
- 4. Not screening positive on the CRIES-8 PTSD screening tool (≤16 points)
- 5. No interest to participate in a group intervention
- 6. Legal guardian not consenting to participation if child is <15 years

#### Date of first enrolment

01/01/2019

#### Date of final enrolment

28/02/2021

# Locations

#### Countries of recruitment

Sweden

## Study participating centre Child Health and Parenting (CHAP)

BMC, Husargatan 3 Uppsala Sweden 751 22

# Sponsor information

#### Organisation

**Uppsala University** 

#### Sponsor details

Box 256 Uppsala Sweden 751 05 +46 (0)18 471 00 00

contact@uu.se

#### Sponsor type

University/education

#### Website

www.uu.se

#### **ROR**

https://ror.org/048a87296

# Funder(s)

#### Funder type

Charity

#### **Funder Name**

The Kavli Trust

# **Results and Publications**

### Publication and dissemination plan

Current publication and dissemination plan as of 17/01/2023:

Trial protocol published. Internal pilot results published (see date below). No intention to publish results as recruitment target was not met due to the COVID-19 pandemic.

Previous publication and dissemination plan:

Trial protocol and results to be published.

## Intention to publish date

31/12/2021

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Anna Sarkadi (anna.sarkadi@pubcare.uu.se).

# IPD sharing plan summary

Available on request

## **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	10/01/2020	13/01/2020	Yes	No
Results article	Feasibility study	14/02/2022	17/01/2023	Yes	No