

Swedish unaccompanied youth refugee trial

Submission date 13/12/2018	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 20/12/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/01/2023	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> 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
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Contact information

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Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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)

Key secondary outcome(s)

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)

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 aged <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

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

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
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Sponsor information

Organisation
Uppsala University

ROR
<https://ror.org/048a87296>

Funder(s)

Funder type
Charity

Funder Name
The Kavli Trust

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 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?
Results article	Feasibility study	14/02/2022	17/01/2023	Yes	No
Protocol article	protocol	10/01/2020	13/01/2020	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes