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Swedish unaccompanied youth refugee trial

Submission date
13/12/2018

Recruitment status
No longer recruiting

Registration date
20/12/2018

Overall study status
Completed

Last Edited
17/01/2023

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

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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)
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Uppsala University

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Sponsor type
University/education

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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