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Accompanied refugeeS In Sweden Trial (ASsIST)

Submission date	Recruitment status	[X] Prospectively registered
29/05/2019	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/06/2019	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
12/12/2023	Mental and Behavioural Disorders	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
In 2015, 162,877 persons sought asylum in Sweden, 42% of whom were children and youth. Refugee children 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 children experiencing post-traumatic stress symptoms called 'Teaching Recovery Techniques'.

Who can participate?
Accompanied refugee children (aged 8-17 years) who score high on a post-traumatic stress survey and have spent 5 years or less in Sweden can take part in the study. They must be interested in taking part in a group intervention and agree to being randomly allocated to a group that receives the intervention straight away or a group that receives the intervention a little later. If the child is under 15 years old, their legal guardian must agree to them taking part.

What does the study involve?
Children 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 child mental health and wellbeing are measured using surveys at around 8 weeks and 20 weeks after the group allocation.

What are the possible benefits and risks of participating?
The potential benefit to participating children 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
http://www.pubcare.uu.se/forskning/chap/projekt/aktuella-projekt/accompanied-refugees-in-sweden-trial--assist-/

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Evaluation of the Teaching Recovery Techniques community-based intervention for accompanied refugee children experiencing post-traumatic stress symptoms – a randomized controlled study

Acronym
ASsIST

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

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

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/02/2019, Regional Ethical Review Board in Uppsala (Etikprövningsmyndigheten, Box 2110, 750 02 Uppsala, Sweden; Tel: +46 (0)10-475 08 00; Email: registrator@etikprovning.se), 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

Interventions
Current intervention as of 04/11/2019:
Randomization will use a small-cluster randomization design rather than a single participant randomization design. 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-behavioral programme includes 2 caregiver sessions and 5 child sessions. Child sessions focus on psychoeducation, intrusion, arousal and avoidance. Caregiver sessions focus on psychoeducation and are delivered in parallel with the first 2 child 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.

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

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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.

Intervention Type
Behavioural

Primary outcome measure
Parent- and self-reported child mental health, specifically post-traumatic stress, depression and anxiety symptoms, at pre-intervention (T1), c.8 weeks after randomisation (T2) and c.20 weeks after randomisation (T3):
1. Post-traumatic stress symptoms measured using Children's Impact of Events Scale (CRIES-13; Perrin, Meiser-Stedman, & Smith, 2005)

2. Depression symptoms measured using 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 pre-intervention (T1), c.8 weeks after randomisation (T2) and c.20 weeks after randomisation (T3):
1. Emotional and behavioural difficulties measured using Strengths and Difficulties Questionnaire (SDQ; Goodman, 1997)
2. Self-efficacy measured using General Self Efficacy Scale (GSE; Schwarzer & Jerusalem, 1995)
3. Wellbeing measured using The Cantril Ladder (Cantril, 1966; picture from 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
Participants eligible for the trial must comply with all of the following at randomization:
1. Child age ≥8 years
2. Time spent in Sweden 5 years or less
3. Arrived in Sweden accompanied
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

Participant type(s)
Patient

Age group
Child

Lower age limit
8 Years

Upper age limit
17 Years

Sex
Both

Target number of participants
160

Key exclusion criteria

1. Youth age >17
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 aged <15 years

Date of first enrolment
01/07/2019

Date of final enrolment
30/09/2020

Locations

Countries of recruitment
Sweden

Study participating centre
Child Health and Parenting (CHAP)
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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. Plan to publish internal pilot results (see date below). No plan to publish full results as recruitment target not met due to COVID-19 pandemic.

Previous publication and dissemination plan:
Trial protocol and results to be published.

Intention to publish date
31/12/2024

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	26/07/2020	28/07/2020	Yes	No