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Evaluation of the Teaching Recovery Techniques plus Parenting, a Cluster Randomised Controlled Trial in Ukrainian Schools in Ternopil (TRUST)

Submission date
13/03/2023

Recruitment status
No longer recruiting

Registration date
28/04/2023

Overall study status
Completed

Last Edited
26/03/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Children exposed to war-related trauma are at significant risk of developing mental health problems, such as symptoms of post-traumatic stress disorder (PTSD). The aim of this study is to evaluate a community-based intervention called 'Teaching Recovery Techniques Plus Parenting' (TRT+P) for Ukrainian children experiencing PTSD symptoms.

Who can participate?
All schools in Ternopil will be invited to take part in the study. All parents will receive information about the study with an opt-out consent option prior to the screening with CRIES-8. Children are eligible to participate if all of the following criteria are satisfied at the time of randomisation:
1. The child is aged 8 to 13 years old
2. The child screens positive on the Children's Revised Impact of Event Scale (CRIES-8) PTSD screening tool (≥17 points)
3. The child is interested in participating in a group intervention
4. The legal guardian does not object to participation and a parent or other primary caregiver wishes to participate
5. The participating caregiver has not taken part in another parenting programme in the past 12 months
6. Children have not taken part in a trauma recovery intervention in the last 12 months
All children that meet this criteria will be included, except children with high risk to self or others, as judged by school psychologists.

What does the study involve?
Schools will be randomly allocated to one of the two possible groups: the intervention group will be offered the TRT+P programme and the waitlist-control group will receive services as usual, followed by the TRT+P programme around 20 weeks later. Outcome data will be collected at three points: pre-intervention (T1), post-intervention (T2; about 8 weeks after randomisation)

and follow-up (T3; about 20 weeks after randomisation). The objective is to evaluate whether the TRT+P programme influences child mental health, specifically symptoms of post-traumatic stress, in comparison to similar children who only receive services as usual. TRT+P -trained ‘group leaders’ (school psychologists) will deliver the intervention; two group leaders deliver each group. The study will primarily measure changes in self-reported child mental health, specifically symptoms of PTSD. Parenting and carers' symptoms of PTSD will also be measured. Outcome data will be collected using a secure online platform (Google Forms). It is estimated the CRIES-8 and demographic questionnaire will take around 10 minutes.

What are the possible benefits and risks of participating?
Young people and parents/carers will help researchers better understand the effectiveness of the intervention for young people experiencing PTSD symptoms and could help TRT+P be rolled out to other young people impacted by the recent war. The participants may become distressed during the intervention and/or completing outcome measures. Participants will be signposted to appropriate support by trained clinicians and research team members.

Where is the study running from?
The host institution is Queen Mary, University of London (UK). The study will be based in Ternopil (Ukraine).

When is the study starting and how long is it expected to run for?
December 2022 to December 2025

Who is funding the study?
Queen Mary, University of London (UK)
Other funding options are currently being considered.

Who is the main contact:
Dennis Ougrin, d.ougrin@qmul.ac.uk

Contact information

Type(s)
Principal investigator

Contact name
Prof Dennis Ougrin

Contact details
Newham Centre for Mental Health
London
United Kingdom
E13 8SP
+44 (0)2075404210
d.ougrin@qmul.ac.uk

Type(s)
Scientific

Contact name
Ms Saba Masood

Contact details
Newham Centre for Mental Health
London
United Kingdom
E13 8SP
+44 (0)7462528705
wpw090@qmul.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Evaluation of the Teaching Recovery Techniques plus Parenting, a Cluster Randomised Controlled Trial in Ukrainian Schools in Ternopil (TRUST)

Acronym
TRUST

Study objectives
Current study hypothesis as of 23/11/2023:
The objective of the trial is to evaluate whether the Teaching Recovery Techniques Plus Parenting (TRT+P) programme influences child mental health, specifically symptoms of post-traumatic stress, in comparison to similar children who only receive services as usual.

Previous study hypothesis:
The objective of the trial is to evaluate whether the Teaching Recovery Techniques Plus Parenting (TRT+P) programme influences child mental health, specifically symptoms of post-traumatic stress, anxiety and depression, in comparison to similar children who only receive services as usual.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 21/11/2024, Ethics committee of Volodymyr Ternopil National Pedagogical University (2, Maksyma Kryvonosa St, Ternopil , 46000, Ukraine; +38(0352)43-58-80; pk@tnpu.edu.ua), ref: None provided

Study design

Cluster randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Young children screening positive for PTSD.

Interventions
A cluster randomized controlled trial will be conducted in which schools will be randomly allocated using an open-source randomization platform to one of the two possible arms: the intervention arm (generating n = 113 children) will be offered the TRT+P programme and the waitlist-control arm (n = 113) will receive services as usual, followed by the TRT+P programme around 20 weeks later.

The intervention is 5 weeks long. Outcome data will be collected at three points: pre-intervention (T1), post-intervention (T2; about 8 weeks after randomisation) and follow-up (T3; about 20 weeks after randomisation).

Intervention Type
Behavioural

Primary outcome(s)
Parent-reported or self-reported child mental health, specifically symptoms of PTSD measured using the Children's Revised Impact of Event Scale (CRIES-8) at three points: pre-intervention (T1; baseline), post-intervention (T2; c. 8 weeks after randomisation) and follow-up (T3; c. 20 weeks after randomisation)

Key secondary outcome(s))
Current secondary outcome measures as of 23/11/2023:

There are no secondary outcome measures

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Previous secondary outcome measures:

All outcome data will be collected at three points: pre-intervention (T1; baseline), post-intervention (T2; c. 8 weeks after randomisation) and follow-up (T3; c. 20 weeks after randomisation):
1. Symptoms of anxiety measured using the Screen for Childhood Anxiety-Related Disorders (SCARED) five-item version
2. Depression measured using the Depression Self-Rating Scale for Children (DSRS)
3. Parenting measured using the Parenting and Family Adjustment Scale (PAFAS)
4. Carers' symptoms of PTSD measured using the Impact of Events Scale Revised (IES-R)
5. Depression, anxiety and stress among caters measured using the Depression Anxiety and Stress Scale (DASS 21)

Completion date
30/12/2025

Eligibility

Key inclusion criteria
1. The child is aged 8 to 13 years old
2. The child screens positive on the Children's Revised Impact of Event Scale (CRIES-8) PTSD screening tool (≥17 points)
3. The child is interested to participate in a group intervention
4. The legal guardian does not object to participation and a parent or other primary caregiver wishes to participate
5. The participating caregiver has not taken part in another parenting programme in the past 12 months
6. Children have not taken part in a trauma recovery intervention in the last 12 months

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Child

Lower age limit
8 years

Upper age limit
13 years

Sex
All

Key exclusion criteria
Severe mental health disorders requiring specialist treatment

Date of first enrolment
01/02/2024

Date of final enrolment
01/09/2025

Locations

Countries of recruitment
Ukraine

Study participating centre
Hnatiuk National Pedagogical University
2, Maksyma Kryvonosa St
Ternopil
Ukraine
46000

Sponsor information

Organisation
Queen Mary University of London

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
University/education

Funder Name
Queen Mary University of London

Alternative Name(s)
Queen Mary Uni of London, Queen Mary, Queen Mary and Westfield College, The London Hospital Medical College, St Bartholomew's Hospital Medical College, Westfield College, East London College/Queen Mary College, QMUL, QM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generation during and/or analysed during the current study are not expected to be made available due to confidentiality issues.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	in Ukrainian		23/11/2023	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 1.2		22/03/2023	No	No
Protocol file			23/11/2023	No	No