Evaluation of the Teaching Recovery Techniques Plus Parenting skills-focused intervention for Ukrainian children experiencing post-traumatic stress symptoms: study protocol for a cluster randomised controlled trial

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

A cluster randomised controlled trial will be conducted in which schools will be randomly allocated 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. Outcome data will be collected at three points: pre-intervention (T1), post-intervention (T2; c.8 weeks after randomisation) and follow-up (T3; c.20 weeks after randomisation).

The objective of the trial is to evaluate whether the 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. The trial will also measure change in parenting and parent/caregiver signs of post traumatic stress.

A two-arm cluster randomised waitlist-control superiority trial will be conducted to evaluate the effectiveness of the TRT+P programme in improving mental health outcomes in accompanied refugee children who have parent-reported and self-reported symptoms of PTSD.

TRT+P -trained 'group leaders' will deliver the intervention; two group leaders deliver each group. The groups will be delivered in schools in Ternopil.

Children are eligible to participate if all of the following criteria are satisfied at the time of randomisation:

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

TWO CAREGIVERS CAN BE INVITED TO ATTEND, BUT IT IS ESSENTIAL THAT AT LEAST ONE PRIMARY CAREGIVER ATTENDS ALL SESSIONS AND THIS SAME CAREGIVER COMPLETES THE QUESTIONNAIRES AT ALL DATA COLLECTION TIME POINTS. EVEN IF BOTH CAREGIVERS ATTEND, THE SAME ONE DESIGNATED CAREGIVER WILL COMPLETE THE TOOLS EACH TIME.

THE DESIGNATED PRIMARY CAREGIVER MUST ANSWER THE QUESTIONNAIRES WITH THE SAME ONE CHILD IN MIND AT EVERY TIME QUESTIONNAIRES ARE ANSWERED. EVEN IF MORE THAN ONE CHILD IS ATTENDING, THE CAREGIVER SHOULD KEEP ONE OF THEIR ATTENDING CHILDREN (THE SAME CHILD), IN MIND AT EACH DATA COLLECTION POINT.

Recruitment

All schools in Ternopil will be invited to take part in the study. Schools whose management consents to take part in the study will be randomly allocated to either TRT+P or to the waitlist-control arm. All parents will receive information about the study with an opt-out consent option prior to the screening with CRIES-8. Children will be referred to TRT+P groups by school psychologists following the whole-school screening with CRIES-8 in those schools randomised to the TRT+P arm. Schools randomised to waitlist control will be offered the intervention after approximately 20 weeks.

Commented [1]: Specify that children will be answering the questions.

Commented [2]: Add a point about the primary caregiver to answer the questions regarding their trauma but also that the same caregivers will be attending the intervention. It can be mother, father or any other primary caregiver.

Sample size

Recruitment of 226 eligible children to the project will allow the detection of an effect size of 0.5 at $p<0.05$ with 80% power. This allows for an estimated intraclass correlation coefficient of 0.05 and a study dropout rate of up to 41%. We anticipate that a total of 20 schools (10 in each arm) will be required to achieve the recruitment target.

Outcome measures

The study will primarily measure changes in parent-reported or self-reported child mental health, specifically symptoms of PTSD (CRIES-8, primary outcome measure) as well as symptoms of anxiety the Screen for Childhood Anxiety-Related Disorders (SCARED) and depression the Depression Self-Rating Scale for Children (DSRS). Parenting will be measured using the Parenting Scale (PS). Carers symptoms of PTSD will be measured using the Impact of Events Scale Revised (IES-R)

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Outcome data will be collected using a secure online platform (Google docs (Qualtrics). It is estimated the survey will take around 15 min for children and 15 minutes for their carers.

Statistical methods

Pre-intervention and demographic characteristics will be summarised using means and SDs (or medians and IQRs) for continuous variables and percentages for categorical variables.

The primary comparison of the trial arms will use an intention-to-treat framework with participants analysed according to the trial arm they were randomised to, regardless of whether or not they received the intervention. The primary outcome is total score group differences on CRIES-8 after programme delivery (T2). The secondary outcomes are mental health outcome measures at T2 and total scores at the endpoint (T3).