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

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 in comparison to similar children who only receive services as usual.

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 self-reported symptoms of PTSD.

TRT+P -trained 'group leaders' (school psychologists) 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 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 that 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.

All children that meet these criteria will be included, except children with high risk to self or others, as judged by school psychologists.

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 demographic questionnaires. The designated primary caregiver must answer the demographic questionnaires for each of their children involved in the study. Teachers or school psychologists must complete child-related demographic questions if parents are unavailable.

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.

Sample size

To detect an effect size of 0.5 in the mean difference of CRIES-8 scores, the minimum sample size required (assuming no clustering or attrition) would be 128 (64 per randomised

arm), for 5% significance and 80% power. Inflating this to allow for clustering, assuming cluster sizes of 10 pupils per school and an intraclass correlation coefficient of 0.05 (Warner, et al., 2020), gives 186. Allowing for 25% attrition gives a total of 248, which is rounded up to 260 to allow for a cluster size of 10 with 13 clusters (schools) in each arm. These figures assume that there will be one group per school. All eligible schools will be invited to participate; if fewer than 26 schools are recruited then more than one group per school will be permitted. Although this introduces an additional level of clustering to be accounted for in the analysis the potential loss of power will be small and balanced out by the gain in allowing for baseline CRIES-8 score in the analysis of the primary outcome. It is important to note that a study conducted in 2022 (Rosenthal et al, in preparation) found that 56.8% of Ukrainian children aged 7-14 years old met the clinical cut-off for PTSD (≥17 on CRIES-8) allowing for a large pool of potential participants.

Outcome measures

The study will measure changes in self-reported child mental health, specifically symptoms of PTSD (CRIES-8). Outcome data will be collected using a secure online platform (Google Forms. It is estimated the CRIES and demographic questionnaire will take around 10 minutes.

Statistical methods

The baseline characteristics of participants in the intervention and control groups will be summarised using descriptive statistics appropriate for continuous or categorical data. Compliance with allocated treatment will be summarised for each group. The primary outcome (CRIES-8 score) will be compared between the intervention and control groups using a longitudinal mixed linear regression model including random effects for school and individual and a fixed effect for randomised allocation. The model will include outcome measurements at T1 (pre-intervention), T2 and T3, with the treatment effect at T1 constrained to be zero. The treatment effect will be estimated as a mean difference in CRIES-8 between the randomised groups (with a 95% confidence interval) and significance assessed using the Wald test. The primary analysis will be intention-to-treat, and a

sensitivity analysis will use the per-protocol population. A secondary analysis of the CRIES-8 score dichotomised according to the cut-off of ≥17 for PTSD symptoms will use the same mixed models methodology as described above but with logistic regression. Secondary outcomes will be analysed using the same models as described for the primary outcome, for continuous or binary scales accordingly. Full details of the quantitative analyses will be specified in a Statistical Analysis Plan.