Preventing Violence Against Children in Schools (PVACS) in Nyarugusu Refugee Camp: A Cluster Randomised Controlled Trial

Statistical Analysis Plan

Document Version: 6

Date: 28/05/2020

Name and Address of Chief Investigator:

Karen Devries

Name and Address of Trial Statisticians:

Elizabeth Allen

Department of Medical Statistics

London School of Hygiene and Tropical Medicine

Keppel Street

London WC1E 7HT

Tel: +44 207 927 2943

APPROVAL

The undersigned hereby declare that they have prepared/examined the Statistical Analysis Plan and agree to its form and content. In addition, they confirm that to the best of their knowledge the Statistical Analysis Plan contains all information relevant for the conduct of Statistical Analysis of the study.

Prepared by: Trial Statistician

_____ _____

Elizabeth Allen Date

Approved by: Chief Investigator

Karen Devries_____

Date

REVISION HISTORY

Version	Author	Date of Implementation	Description of Modification
1	Camilla Fabbri	29/05/2019	Original version of the document
2	Camilla Fabbri and Karen Devries	05/08/2019	Includes comments and revisions from PI and implementing partner
3	Camilla Fabbri and Elizabeth Allen	20/11/2019	Addresses comments by Melissa Neuman (TSC independent statistician) and includes comments raised during PVAC TSC
5	Camilla Fabbri	03/02/2020	Cleaned all remaining edits and replied to outstanding comments.
6	Baptiste Leurent	28/05/2020	Minor clarifications before endline data analysis. Educational score outcome removed.

1 SCOPE

This Statistical Analysis Plan (SAP) describes the methods and summaries that will be provided for the final analysis as described in the trial protocol. The current document describes the PVACS trial and provides details of the planned analyses to evaluate the effectiveness of the intervention.

2 Introduction

School is one of the most common settings where children may experience violence[1, 2]; and emerging evidence suggests that in some settings, school staff may be one of the most common perpetrator of violence against children[2, 3]. Levels of violence may be even higher in emergency settings, where people have been displaced and have recent histories of trauma, both of which may contribute to an increased likelihood of violence. Few statistics exist documenting the prevalence of violence against children in schools in refugee camps.

Very few interventions have been rigorously tested for their effectiveness in prevention violence from school staff to students in any settings. In non-emergency settings, the Good School Toolkit in Uganda, and the Irie Classroom Toolbox in Jamaica, are two exceptions, which are effective in reducing physical and emotional violence from school staff to students[4-6]. Both of these interventions are implemented in low resource but stable settings. The Toolkit is a whole school intervention, involving school administration, teachers and students as well as surrounding communities, which is implemented over an 18 month period. The intervention aims to change school operational culture and contains a number of different activities and behaviour change techniques to engage all school members.

3 Study Description

3.1 Study Design

The PVACS study is a school based two parallel-arm cluster randomised trial in the Nyarugusu Refugee Camp in Tanzania which seeks to provide evidence on the impact of the EmpaTeach intervention to improve student and teacher well-being, self-regulation, teacher classroom management, and teacher's use of positive discipline techniques compared to a wait listed control group. The study population comprises primary and secondary students (typically aged between 9 and 21 years) attending schools in the Nyarugusu Refugee Camp in Tanzania. The camp hosts refugee populations from Burundi and Democratic Republic of Congo. The primary outcome is past-week physical violence from school staff reported by children in Nyarugusu primary and secondary schools. Allocation to study group will be by school.

All 27 primary and secondary schools in Nyarugusu will be randomised into the two arms in the ratio 14: 13 with 50 children sampled from each school at three time points: baseline before the beginning of the intervention, midline shortly after the end of the 10-week intervention, and endline at least 6 months after the end of the intervention.

Schools allocated to the intervention arm will receive the EmpaTeach intervention during a 10 week period. The aim of the EmpaTeach intervention is to improve student and teacher well-being, self-regulation, teacher classroom management, and teacher's use of positive discipline techniques. Teachers in the intervention arm will receive a 10-week group intervention. Groups meet 14 times for 1-1.5 hour length sessions, which are led by peer teachers from the same school. The intervention uses cognitive behavioural therapy techniques to change negative thought and

behaviour patterns related to corporal punishment. The teachers receive information on alternatives to corporal punishment, planning exercises and reinforcement SMS sent to participating teachers twice a week during the intervention period. The SMS contained content such as" "(Name), remember you have a session (on this day) at (time) at (meeting location)! We will discuss how to co-create rules with your classroom. Remember to bring your booklet and homework!", and since the intervention is in a group setting, participants will also receive social support to change their behaviours. They will discuss their experiences and challenges in group sessions.

Schools in the control arm of the trial will be put on a waiting list for the intervention should it prove effective. During the trial, they will have the same schedule of assessments as schools in the intervention arm of the trial.

The main research question to be addressed is:

- Does the EmpaTeach intervention reduce the amount of past-week physical violence from school staff reported by children in Nyarugusu primary and secondary schools at midline?

Secondary research questions are as follows:

- Does the EmpaTeach intervention improve students' self-reports of physical violence from school staff assessed at the endline?
- Does the EmpaTeach intervention improve students' self-reports of emotional violence from school staff at midline and endline?
- Does the EmpaTeach intervention improve students' depressive symptoms at midline and endline?
- Does the EmpaTeach intervention improve school attendance?

3.2 Sample Size

Sample size calculations were adjusted for clustering within schools. Assuming a 50% prevalence of past week physical violence at baseline, an intra-class correlation of 0.1, and allowing for possible loss to follow up of one school per arm, a conservative sample of 50 students in 25 schools will provide 80% power to detect a 19% reduction in the past-week prevalence of reported violence in the intervention arm at 5% statistical significance. Calculations were carried out using the 'power' command in Stata (StataCorp. 2017. *Stata Statistical Software: Release 15*. College Station, TX: StataCorp LLC)

3.3 Sampling

Schools will be recruited by approaching headteachers, explaining the research and intervention elements of the study, and inviting the headteachers to consent to school participation. Teachers in participating schools will be randomly selected from lists of all teachers in the schools, and a simple random sample of at least 500 teachers will be invited to participate in an individual survey. At least 1500 students aged 9 years and over in participating schools will be randomly selected from lists of all students aged 9 years and over in the schools. We will oversample by about 10% to allow for non-response and refusal to participate (so in total we will invite about 60 students per school and about 20 teachers per school; n students =1620 and n teachers=540 across all 27 schools). The allocation list will be generated by the statistician on the trial in Stata.

Allocation will take place at a public meeting of all headteachers, where each headteacher or school representative will place their school name in an opaque bag according to their stratum. Names will be drawn in turn from each stratum specific bag by one person (IPA's Research Associate), and

allocated to either the intervention or wait-list control condition in the sequence on the allocation list.

Eligibility criteria for children will be as follows:

- Children aged 9 years and over
- Speakers of either Kirundi or Kiswahili

Eligibility criteria for teachers will be as follows:

- Speakers of either Kirundi or Kiswahili

Exclusion criteria for all participants are as follows:

- Inability to understand consent procedures

4 Randomisation

Schools will be allocated in a 14:13 ratio to either the intervention or the control arm of the study at a public meeting in December 2018. Stratified randomisation will be used to ensure that the two study arms are balanced on the following school level characteristics:

- Primary or Secondary location
- Burundian or Congolese

The table below gives details of the schools.

Table 1 Random allocation of schools

School strata	Treatment	Control
Congolese primary	7	6
Congolese secondary	2	2
Burundian primary	4	4
Burundian secondary	1	1
Total	14	13

4.1 Blinding and Unblinding

Given the nature of the intervention, it is not possible to blind the data collectors or the study participants to allocation. However, all analyses will be carried out blind to the allocation.

5 Trial flow chart

Data on the number of schools randomised (with exclusions and reasons for exclusion) and the number of students sampled at baseline and follow up will be presented in one or more CONSORT flow charts.

If a school (or participant) chooses to withdraw from the trial at any time, we will ask for consent to keep data already collected. If this is not given, then all data for that school (participant) will be removed from further analyses from the point at which consent was withdrawn with reasons for withdrawal noted.

6 Outcome Measures

Data will be collected by a team of trained enumerators under the supervision of Innovations for Poverty Action Tanzania in three cross sectional surveys at the following time points:

- Baseline – prior to commencement of the EmpaTeach intervention (November/December 2018)
- Midline – shortly after at the end of the 10-week intervention period (May/June 2019)
- Endline – at least 6 months after the completion of the intervention (Jan/Feb 2020)

6.1 Primary outcomes

The primary outcome is:

- Students' self-reported experience of at least one incident of physical violence by school staff during the past week (binary) at midline. This will be assessed using an adapted version of the International Society for the Prevention of Child Abuse and Neglect Screening Tool-Child Institutional (ICAST).

The questions "*Has a teacher ever made you clean toilets, pick up trash, fetch water or do other labour as punishment*?" and "*Has this happened in the past week?"* were excluded from the calculation of the physical violence outcome since it was agreed with the implementing partners that these activities did not represent violence in the local context.

6.2 Secondary outcomes

The secondary outcomes are as follows:

- Students' self-reported experience of physical violence by school staff during the past week at endline
- Students' self-reported experience of emotional violence by school staff during the past week at midline and endline
- Students' depressive symptoms (short Mood and Feelings Questionnaire, continuous score, scale 0 to 26, scores 12 and above suggest presence of depression) at midline and endline
    - Binary outcome will be, coded as 1 if the MFQ score >=12[1]
- Students' school attendance (number of school days attended in the past week) at midline and endline.

7 Analysis levels and general principles of analysis

7.1 Intention-to-treat and Per-protocol analyses

Primary analyses will be conducted using intention-to-treat data sets. Results will be reported following the CONSORT guidelines for the analysis of cluster randomised trials.

<u>The intention-to-treat</u>

These will include data pertaining to all outcomes. Individuals will be analysed based on assignment to one of the two arms of the trial according to their cluster irrespective of whether the intervention was entirely or partly taken up.

[1] Angold, A., Costello, E. J., Messer, S. C., Pickles, A., Winder, F., & Silver, D. (1995) The development of a short questionnaire for use in epidemiological studies of depression in children and adolescents. *International Journal of Methods in Psychiatric Research*, 5, 237 – 249.

7.2 Per protocol

A number of measures will be collected to assess degree of exposure to the programme (see section 9). One or more of these measures will be used for exploratory dose response type analyses.

8 Demographics and Baseline Characteristics

Demographic and other baseline characteristics of schools, students and staff will be compared to check for imbalances between study arms. Tabulation of these measures will be generated using the intention to treat data sets. No significance tests will be performed to test for differences between groups at baseline. Descriptive statistics for continuous variables will include the number of observations, mean and standard deviation (or median and interquartile range as appropriate). Categorical variables will be presented as numbers and percentages.

School-level characteristics to be compared include the following:

- Primary or Secondary location
- Burundian or Congolese

Student characteristics to be compared include the following:

- Age
- Sex
- Country of origin
- Grade
- Disability
- Number of meals eaten on previous day
- Lives with biological mother/father?

Student outcomes (at baseline) to be compared include the following:

- Experience of physical violence from school staff
- Experience of emotional violence from school staff
- Depression status
- School attendance

Staff characteristics to be compared include the following:

- Age
- Sex
- Country of origin
- Religion
- Marital status
- Number of meals eaten yesterday
- Number of children

In addition to baseline characteristics, student characteristics at midline and endline will also be tabulated as supplementary results.

9 Measurements of Compliance with the interventions

A number of measures will be collected to assess degree of exposure to the programme, including classroom observations, student and staff members' self-reports of exposure to the programme and data on the nature and extent of activities conducted in schools (attendance data as reported by group coordinators will be collected, and random group observations to observe attendance as well as group dynamics, participation, etc. will be conducted during the intervention), which will be collected by a separate monitoring officer during site visits. One or more of these measures will be subject to exploratory dose response type analyses. As there are a number of possible ways of assessing exposure to the programme, and measures of exposure to this complex intervention are likely to involve triangulation between several different data sources, this is a substantial piece of work which will be performed separately to the main intention to treat analysis.

10 Assessment of Effectiveness

10.1 Analysis of effectiveness of the intervention

10.1.1 Primary analyses

Primary analysis will be carried out on groups as randomised ('intention to treat'). All analyses will account for the nature of the distribution of the outcome and results will be presented as appropriate effects sizes (mean difference between arms and risk ratios) with a measure of precision (95% confidence intervals). Generalised Estimating Equations (GEE) will be used to account for clustering, assuming an exchangeable correlation structure and using robust standard errors. Our main analysis of the primary outcomes, and other secondary outcomes will be based on adjusted cross-sectional analyses comparing the outcome at midline or endline between study groups. For binary outcomes in order to estimate the risk ratio we will use the log-binomial GEE. For continuous outcomes we will use GEE with a normal distribution. Appropriate methods will be used to analyse continuous measures which are not normally distributed (for example, 95% CI will be estimated using the bootstrap method).

10.2 Statistical/analytical issues

10.2.1 Examination of Subgroups

All sub-group analyses will be performed by including a variable (or variables, as appropriate) for the sub-group and its interaction with the treatment effect in the primary outcome model. Then differences between sub-groups will be identified by significance of the interaction. A forest-type plot will be used to display the difference between subgroups.

Planned subgroup analyses for all outcomes will include:

- Student's Sex
- Burundian or Congolese school
- Primary or Secondary school
- School level of violence at baseline
- Student's disability

For the school level of violence at baseline, we will define two groups of schools based on the median, and also test for a linear interaction.

10.2.2 Adjustments for Covariates

Unadjusted and adjusted results will be presented for all analyses. The primary focus will be on adjusted analysis, and significance testing (p-values) will be reported only for the adjusted models. Covariates in adjusted analyses will be specified *a priori* and will include the strata – primary or secondary and Burundian or Congolese – and the baseline measure of the outcome for continuous outcomes. In addition, any major imbalances between randomised groups in prognostic factors will be adjusted for in exploratory secondary analyses.

10.2.3 Sensitivity analyses

Sensitivity analyses regarding missing data such as best- and worst-case scenario may be conducted for the primary outcomes.

As an additional analysis for depression, we will also compare the mean MFQ score between arms (as a continuous measure).

10.2.4 Dropouts and Missing Data

The design of the study is a repeat cross sectional design therefore missing data relating to loss to follow up of specific individuals is not an issue. Questionnaire completion rates are expected to be high therefore only a small amount of missing data is expected and it is not thought likely that it will have to be accounted for in any analysis. However we would consider using inverse probability weighting or multiple imputation if missing data were larger than expected and/or there was differential attrition between the trial arms. We would also attempt ensure that the reason for the differential attrition was fully understood. Sensitivity analyses (as detailed above) will however be conducted for the primary outcomes.

10.2.5 Multiple Comparisons/Multiplicity

We will restrict formal testing to the adjusted analysis of the primary and secondary outcomes and no adjustment for multiple comparisons will be made.

A number of subgroup analyses have been pre-specified and the results of these will be treated with appropriate caution in light of the problems of a Type 1 error with a large number of tests.

10.3 Statistical Software

All statistical analysis will be performed using Stata.

11 Safety Evaluation

The intervention under study is behavioural and we do not anticipate adverse events occurring as a result of the intervention itself. However qualitative data on unexpected or adverse consequences of the intervention that become apparent during implementation is being collected from representatives of the International Rescue Committee, the implementing agency and agency responsible for managing the schools in Nyarugusu Camp. Any serious adverse events reported will be summarised by study arm.

Although we do not anticipate adverse events resulting from the intervention itself, during data collection this study will identify children who have experienced violence. The study also has a comprehensive protocol in place to refer children to local child protection agencies for further support.

12 Supplementary and Exploratory Analyses

Further exploratory analyses may be performed to provide context to the results of the main analyses or to generate hypotheses for future testing. Any statistical analyses not specified in this plan will be considered exploratory in nature. In particular, the following exploratory analyses are envisaged:

12.1 Nested cohort

The study is composed of repeat cross sectional surveys. Children will be selected at random from each participating school at baseline, and separate random samples will be taken at each follow-up (midline and endline).

The study will not intentionally set out to follow up a cohort of children, but attempts will be made to link students across survey rounds as much as possible. It is expected that some of the younger children who participate at baseline would also be randomly selected for inclusion in the follow up surveys (for example, a child in early grades at baseline may have progressed to higher grades by the end of the study), forming a small nested longitudinal cohort.

A series of analyses will examine the impact of the intervention within this small nested cohort. Statistical analysis will be performed on the primary and secondary outcomes listed above. Statistical methods will be similar to the main intention to treat analysis, but will adjust for baseline levels of outcomes at the individual child level (rather than via cluster summaries).

12.2 Other types of violence

Data on other types of violence (for example, sexual violence and violence experienced by other perpetrators) has also been collected. The impact of the intervention on these outcomes will be performed using statistical methods similar to those used for the main intention to treat analysis.

12.3 School staff data analyses

Data from school staff (which includes demographics, teaching experience, job satisfaction and wellbeing, self-efficacy, self-control, self-reported use of violence, own experiences of violence, mental health) will be analysed separately. The impact of the intervention on staff outcomes will be performed using statistical methods similar to those used for the main intention to treat analysis.