Impact of a Classroom-based Sensitization Intervention on Demand for Mental Health Care Among Adolescents in India

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Contents

1. Purpose and scope of the document

The purpose of this document is to describe procedures and considerations for analysis of data from the PRIDE trial in India on evaluating the impact of sensitization interventions, in accordance with the published study protocol(1).

2. Description of the trial

The trial aims to evaluate the impact of a one-off classroom-level information and engagement session conducted by a 'lay' counsellor as compared to school-level sensitization activities on the demand for school counselling program among adolescents in government-run secondary schools in New Delhi, India. This trial is part of a larger research program called PRIDE (PRemIum for aDolEscents) whose overall goal is to develop and evaluate a trans-diagnostic, stepped-care intervention targeting common mental disorders in school-going adolescents in India. The PRIDE intervention architecture involves two sequential psychological treatments of incremental intensity. The first step is a brief problem-solving intervention delivered by lay counsellors. Adolescents with enduring mental health problems are referred to a higher intensity trans-diagnostic treatment delivered by psychologists. The trial described here is embedded within a trial testing the effectiveness of the low-intensity problem-solving intervention (host trial). The trial protocols for both these trials are elaborated in a journal publication(1). The trial is registered prospectively on ClinicalTrials.gov and identified through protocol number NCT03633916 (available at: https://clinicaltrials.gov/ct2/show/NCT03633916).

3. Objectives and Hypothesis

The primary objective of this stepped-wedge, cluster randomised controlled trial is to evaluate the impact of a classroom sensitization session (intervention condition), over and above school-level sensitization activities (control condition), on the rate of referred adolescents (i.e. the proportion of adolescents referred as a function of the total sampling frame in each condition) into the host trial.

The secondary objectives are:

- To evaluate the proportion of such referrals meeting the eligibility criteria of the host trial across the control and intervention conditions
- To evaluate the proportion of such referrals that are self-referrals across the control and intervention conditions
- To explore the severity of mental health symptoms reported by referred adolescents across the control and intervention conditions
- To explore the symptom sub-types (internalising and externalising symptoms) reported by referred adolescents across the control and intervention conditions

The primary hypothesis is that the classroom-level sensitization intervention will be associated with a higher referral rate into the host trial, compared with referrals arising from school-level sensitization activities in isolation.

The secondary hypotheses are:

- Compared with the control condition, the intervention condition will be associated with a greater proportion of referred students who meet eligibility criteria for inclusion in the host trial.
- Compared with the control condition, the intervention condition will be associated with a greater proportion of students who self-refer.
- Compared with the control condition, the intervention condition will be associated with adolescents reporting a greater severity of total symptoms experienced and a greater severity of internalising and externalising symptom types.

Table 1 Primary, secondary and exploratory outcomes for the sensitization trial

Outcome	**Explanation**	**Measures/ Source**
PRIMARY OUTCOME		
Referral rate into the host trial	The referral rate will be calculated as the number of referred students from a given condition divided by the total number of students in corresponding classes. This will be calculated from researchers' referral logs. Referrals will be recorded continuously and reported for each 4 weeks' time period, for the total study duration of 12 weeks. It will be entered as a binomial variable at the student level indicating if student was referred during the trial.	Referral logs
SECONDARY OUTCOMES		
Eligibility rate	Eligibility rate is defined as the proportion of referred participants meeting eligibility criteria for the host trial, as a function of the number of referred adolescents in a given condition. Host trial eligibility criteria are as follows: (i) Total Difficulties score on the adolescent-reported Strengths and Difficulties Questionnaire (SDQ) >/= 19 for boys & >/= 20 for girls (2); (ii) SDQ Impact Supplement score of >/=2; and (iii) chronicity of mental health problems for >/= 1 month. Referred students will complete the SDQ as part of the host trial's screening assessment, within 7 working days of the referral date. Eligibility rate will be calculated for each of the 4-week time periods and reported for the entire study duration of 12 weeks. It will be entered as a binomial variable at the student level indicating if referred student is “eligible” to receive counselling.	Adolescent reported SDQ
Self-referral rate	Self-referral rate is defined as the proportion of referrals which are self-initiated as a function of the number of referred adolescents in a given condition. Self-referral rate will be calculated for each of the 4-week time periods and reported for the entire study duration of 12 weeks, based on data from	Referral logs

Outcome	Explanation	Measures/ Source
	researchers' referral logs. It will be entered as a binomial variable at the student level indicating if the referral was a self-referral.	
EXPLORATORY OUTCOMES		
Severity of mental health symptoms	The SDQ total difficulties score will be used to assess the severity of mental health symptoms. It is calculated by adding the scores of all the SDQ sub-scales except the pro-social scale.	Adolescent reported SDQ
Severity of symptom types	Internalizing and externalizing symptom subtypes will be assessed as an exploratory outcome for the students referred across the control and intervention conditions. Externalising score is calculated as the sum of the conduct and hyperactivity scales (ranges from 0 to 20). Internalising score is calculated as the sum of the emotional and peer problems scales (ranges from 0 to 20).	Adolescent reported SDQ

3.1 Trial Design

The trial will be implemented as a Stepped Wedge Cluster Randomised Controlled Trial (SW-CRCT). The essential feature of a SW-CRCT is that random allocation determines the time period in which clusters begin an intervention. All clusters start with the first time period of control intervention, and cross-over from the control to the intervention condition across pre-defined time periods, in a random, but sequential, order(4).

We will select 70 classes using stratified randomisation to represent each of the grades 9th, 10th, 11th, 12th across the six participating schools in Delhi with probability proportional to size.

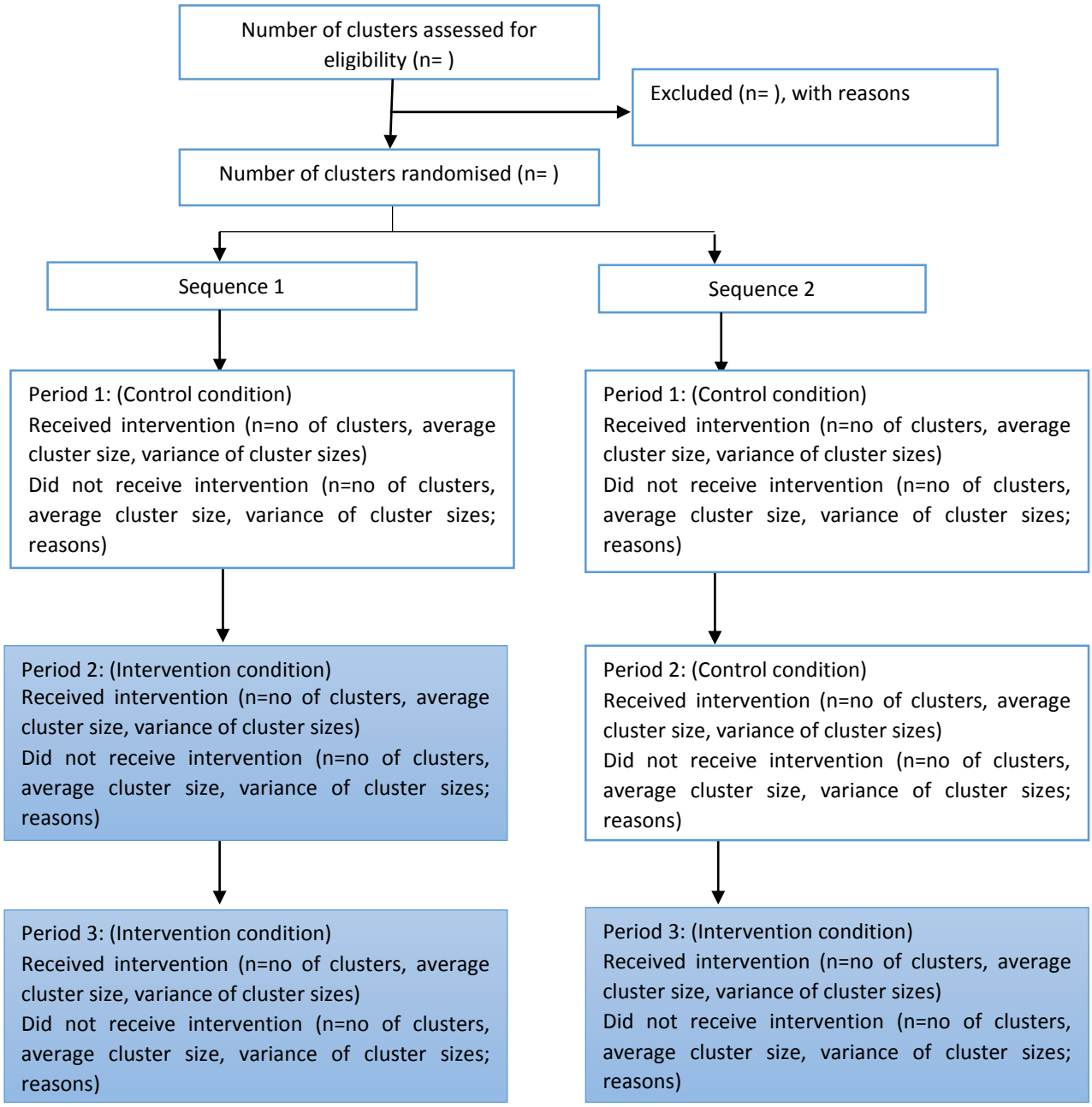
Figure 1: Illustration showing implementation of the control and intervention conditions.

		Step 1 ↓	Step 2 ↓	Sequence of receiving treatments*
Sequence 1 (1-35 classes)	Control condition	Intervention condition	Intervention condition	011
Sequence 2 (36-70 classes)	Control condition	Control condition	Intervention condition	001
Time	1st time period (4 weeks)	2nd time period (4 weeks)	3rd time period (4 weeks)	

Notes: The white boxes indicate the group of classes in the control condition and the coloured boxes indicate the group of classes in the intervention condition.
**0=control condition; 1=intervention condition*

The 70 classes will be randomised to be a part of either of 2 sequences as shown in Figure 1. A small block size of 2 will be used to allocate the 70 classes across the two sequences in order to ensure balance, as the number of classes within each grade from the individual schools is relatively small. In the rare instance that a selected class has been dissolved or merged with another class, the next class in the random list will be included to replace the unavailable class. Each sequence will be implemented over three consecutive 4-week intervals. The trial will be conducted over 12 weeks except for breaks due to exams and holidays. All classes will begin with the control intervention period of 4 weeks, where only school level activities will be rolled out.

Figure 2: CONSORT flowchart for the trial



Notes: The white boxes indicate the group of classes in the control condition and the coloured boxes indicate the group of classes in the intervention condition.

3.2 Study setting

The trial will be conducted in six Government-run secondary schools in New Delhi, India. The schools were purposively selected in consultation with the Department of Education, Government of New Delhi, to focus on relatively under-served, low-income communities. Of the six schools, three are boys' schools, two are girls' schools and one is co-educational. As of August 2018, there were 172 classes in grades 9^{th} – 12^{th} with a total student population of 8448 (ranging from 1050 to 1632 per school; mean=1408, SD=225), including 4694 (56%) boys and 3754 (44%) girls.

3.3 Eligibility criteria

CLASSES (CLUSTERS)
Inclusion criteria:

- Classes from grades 9^{th} – 12^{th} in the six collaborating schools.

Exclusion criteria:

- Classes that have received classroom sensitization sessions during earlier pilot work.

ADOLESCENT PARTICIPANTS
Inclusion criteria:

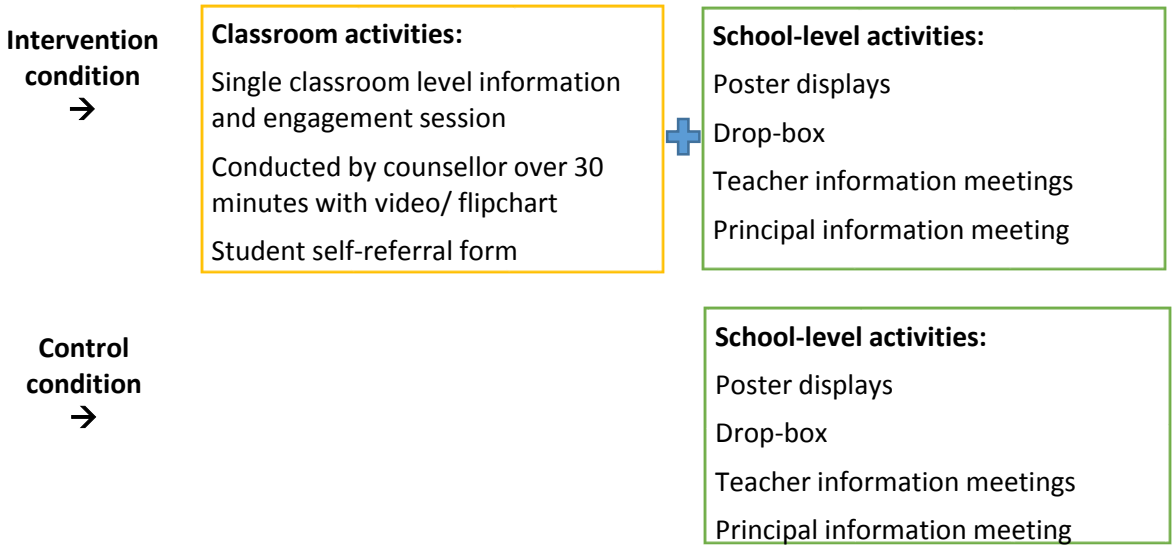
- Enrolled as a student in grades 9^{th} – 12^{th} (aged 13-20 years) at one of the collaborating schools
- Adolescent willing and able to consent for participation in the research

Exclusion criteria:

- Adolescent not proficient in written and spoken Hindi, as needed to participate fully in study procedures
- Adolescent needing urgent medical or mental health care

3.4 Interventions

Figure. 3: Intervention and control condition Interventions



Intervention condition. This will comprise a one-off 30-minute classroom session that is intended to improve understanding about signs and symptoms of mental health problems, raise awareness about the school counselling service, and generate demand for the service. The session will be delivered for individual classes (approximately 50 students per class) by a counsellor (drawn from the same group responsible for the problem-solving intervention in the host trial) with assistance from a researcher who has additional responsibilities for processing referrals and conducting eligibility assessments. The classroom session will start with a short animated video (link to video) which provides age-appropriate information about types, causes, impacts and ways of coping with common mental health problems. The video is followed by a guided group discussion, structured around a standardized script that builds on the topics covered in the video. In case of technical difficulties that may prevent the video from being shown, the counsellor will use a flipchart based on printed images from the video. At the end of the session, students will be handed a self-referral form which includes normalizing information and question-based prompts to assist with self-identification of mental health problems. Interested students can approach the facilitators immediately after the session with self-referral forms, or else deposit the forms discreetly in a secure drop-box located outside or near to the counsellor's usual room.

The counsellors and researchers delivering the classroom sensitization sessions will be provided with a structured manual and complete a one-day office-based training. Training will be conducted by master's level psychologists (who will also serve as supervisors) and comprise lectures, demonstrations and role-plays. The training will be followed by a period of supervised field practice, when the counsellors and researchers will be required to complete at least two classroom sessions independently under direct observation from supervisors. Fidelity of intervention delivery will be assessed on a checklist of observable procedures which have been distilled from the intervention manual. Each procedure will be rated on a three-point Likert scale (not completed, partially completed, fully completed). A 'refresher' training session will also be conducted before the trial begins.

Control condition. This will comprise whole-school sensitization activities. The supervisor will meet the principal of each school individually to inform them about planned counselling and research activities and to seek their cooperation for the same. This meeting will also provide structured information about common mental health problems faced by adolescents, and address any concerns related to planned procedures and resource demands. Teachers will be invited to participate in separate group sensitization meetings (up to 30 teachers at a time). A standardized script will mirror the topics covered in the meetings with the school principals, but with additional emphasis placed on referral procedures for the host trial. Up to three meetings will be held in each school to maximize coverage of teaching staff. The meeting will be conducted by the same counsellor and researcher pairing responsible for delivering the classroom intervention. Posters will be placed in highly visible locations such as noticeboards or common corridors, in addition to signage on the drop-box, which will remind students (and teachers) of the counselling service.

Across both the conditions, students deemed ineligible for participation in the host trial will be allowed to re-refer themselves after a gap of 4 weeks, offering a suitable time period to re-assess mental health status in line with the host trial's inclusion criterion about symptom chronicity.

3.5 Measures

Strengths and Difficulties Questionnaire (SDQ):

The SDQ is a 25-item self-report measure of youth mental health difficulties(2). A Total Difficulties score is derived by summing items from four problem subscales (Emotional, Conduct, Hyperactivity/inattention, and Peer relationship), while a fifth subscale measures prosocial functioning and does not contribute to the overall severity score. Individual problem scale items are scored from 0-2 (with higher scores indicating greater problem severity), giving a range of 0-40 for Total Difficulties.

The SDQ has been validated in more than 80 languages (including Hindi and other Indian languages) and used in over 100 countries, making it the most widely used clinical and research instrument in the field of child and adolescent mental health globally. It has been applied in a number of surveys and as an outcome measure in trials with school-going adolescents in India(5-8). Singh et al, 2015(7) reported acceptable internal consistency for the adolescent-reported Total Difficulties Score (English version, Cronbach's alpha=0.62; Hindi version, Cronbach's alpha=0.61). In pilot work leading up to the current trial, the SDQ was administered to 48 adolescents from secondary schools in New Delhi, demonstrating acceptable internal consistency for the Total Difficulties Score (Cronbach's alpha=0.63)

Eligibility for the PRIDE counselling service/host trial will be determined by a score in the borderline or abnormal range adapted for the Indian sample ($\geq$19 for boys and $\geq$20 for girls) on the SDQ Total Difficulties Score(9), as well as scoring in the abnormal range ($\geq$2) on the Impact Supplement(2). To ensure that participants are experiencing persistent and disabling difficulties rather than transient distress/impairment, the SDQ Chronicity item will be used to confirm the presence of self-reported mental health difficulties for 1 month or longer.

For describing the symptom types, we will use the broader sub-scales for internalising and externalising symptoms that are calculated by adding scores of specific sub-scales. The use of these broader sub-scales is preferred over individual sub-scale score in general population(3).For calculating externalising symptoms score, we will add scores of the conduct and hyperactivity scales. The range of the externalising sub-scale score is 0 to 20. Similarly, for calculating internalising symptoms score, we will add scores of the emotional and peer problems scales. The score of internalising sub-scale ranges from 0 to 20.

3.6 Power calculation

We based our power calculation on a within-period comparison for a stepped wedge design(10), using Stata package "clustersampsi". Based on pilot data, we anticipated referral rates of 5% and 15% on the control and intervention conditions respectively, with an intra-cluster correlation coefficient (ICC) of 0.124. We assumed the same ICC for the between-time correlation given the short time period of follow-up. In practice, it may be smaller than 0.124 and both ICCs will be reported. Using these parameters, a sample size of 70 classes (average class size of 50 students) will have 92% power to detect a difference of 10 percentage points (treating the outcome as a binomial variable), at a significance level of 0.05.

3.7 Recruitment, allocation concealment and blinding

The 70 classes will be selected through stratified randomisation, with stratification for schools and grades (9^{th}, 10^{th}, 11^{th} and 12^{th}) from the overall sampling frame of 118 classes (54 classes had received classroom sensitisation in earlier pilot work). The stratification is proposed to ensure a similar composition of classes across schools in both the sequences. The detailed step by step description of the stratified randomisation is placed at the appendix.

No allocation concealment or blinding is planned as the intervention providers as well as the researchers recording referrals will be aware of the allocation of the classes.

3.8 Data collection and management

3.8.1 Data collection

Data will be sourced from the following sources:

1. Referral logs maintained by school-based researchers recording the numbers and sources of referrals to the PRIDE counselling service. Case by case information on the referrals received is collected via the tablets digitally including the self-reported student data such as class, gender and age obtained at the time of referral and assessment.
2. Logs for the school-level and the classroom level sensitization that are recorded on the sensitization logs.
3. Strengths and Difficulties Questionnaire completed by students on digital tablets as part of the standard eligibility screen for the PRIDE counselling service/host trial.
4. Additionally, the classroom information and engagement sessions, and the data collection process will be audio-recorded or assessing fidelity of the intervention.

3.8.2 Data management

Data will be collected digitally using the customized STAR software program(11), and will be remotely uploaded as comma-separated values (CSV) files on a secured server. The date and time stamps for original data entry will be included, and an audit trail documenting any subsequent changes will be maintained. All paper-based data will be entered manually in SQL Epi-info forms and linked by participant ID with digitally collected data. Range and consistency checks will be performed at weekly intervals, with all inconsistencies and corrections logged to maintain an audit trail. All data will be anonymized and backed-up on external hard disks on a daily basis.

All referred adolescents will receive a unique identification number (student ID) which will be included on the SDQ forms and other process data documents. These IDs will include codes for school, grade, division and a unique serial number. The names and contact details received from students as a part of referral process will be stored separately. The name and the student ID will never be used together in any document, to ensure confidentiality.

Access to pre-locked data will be password-protected at multiple levels. After the dataset is locked, it will remain password-protected and trial investigators will have access to the datasets.

4. Variables

4.1 School, class and Demographic variables

The following school, class and demographic data will be included in the data-set for all the referred adolescents. From students who refuse participation in the study, reasons for such refusal will be additionally collected.

- Student ID
- School ID
- Class ID
- Age
- Gender
- Reason for exclusion from the trial
- Reason for refusal to participate in this trial

Additionally, following class level data will be recorded:

- Class ID
- School ID
- Allocation to sequence
- Time period for receiving classroom sensitization
- Number of students in the class
- Number of boys in the class
- Number of girls in the class

4.2 Outcome variables

The following outcome variables will be prepared at the student level. All individual data pertaining to the variables of referral, referral source, and assessment using SDQ, will be collected only from referred students. Data will be organised in the long format and record the following variables. A code-book will be developed explaining all the variables included in the data sheet.

- Time period of receiving classroom sensitization
- Referral status in each of the three time periods of the trial
- Date of referral
- Eligibility to receive counselling for all referred students (binary variable), determined through the following (table 1):
    - Total Difficulties score on SDQ
    - Impact score
    - Chronicity
- Scores for symptom sub-types:
    - Externalising score = the sum of the conduct and hyperactivity scales
    - Internalising score = the sum of the emotional and peer problems scales
- Source of referral: categorized as self-referral and others

4.3 Intervention delivery and fidelity variables

1. Control condition:

School based sensitization activities are reported by the school counsellors using the Intervention logs. These include the following:

1) Display of posters and drop-box

- Number of posters displayed in the school
- Number of drop-box installed in the school

2) Meetings with school principals and teachers:

- Number of teachers attending the meeting in the school
- Duration of the teachers' meeting (minutes)
- Number of meetings held with school Principals
- Duration of the meetings with Principals (minutes)

2. Intervention condition:

Classroom sensitization sessions are also recorded in the intervention logs maintained by school counsellors. These include the following:

- Date of Classroom sensitization received in the time period
- Number of students attending the sensitization session
- Duration of the sensitization session (minutes)
- Fidelity rating provided by an independent provider for 20% of all the sessions conducted.

4.4 Severe adverse events

There are no severe adverse events (SAE) anticipated from the participation in the classroom sensitization sessions and referral and assessment of students. Any potential harms or SAE discovered during the assessment will be recorded and reported along the protocol developed for the PRIDE trials(1).

5. Data analysis plan

Quantitative analysis will be conducted using STATA (version 15.1). Findings will be reported as per CONSORT extension for reporting of stepped-wedge cluster randomised trials for the embedded recruitment trial(12).

5.1 Baseline characteristics of the participants by randomised sequence

The baseline characteristics of the participating 70 classes, including grade, gender composition, will be described across each of the two sequences of allocation. As the allocation of classes is based on stratified randomisation, no systematic differences are expected across the two conditions.

Table 2 Baseline characteristics of the classes randomised in each of the two sequences

	Total	Sequence 1		Sequence 2	
	N (%)	**N**	**%**	**N**	**%**
Gender: Male Female					
Grade: 9th 10th 11th 12th					
School: GBSSS, Mahipalpur GBSSS, Molarband SBV, Molarband GGSSS, Molarband ASMS-SKV, Mahipalpur SBV Co-Ed, Vasant Vihar					

5.2 Recruitment and representativeness of participants

The number of adolescents not available or refusing to participate in the trial will be reported, overall and within each condition. The reasons for exclusion and refusal to participate will be summarized. Additionally, adolescents lost to follow-up post referral will also be reported, overall and within each condition.

Differences between adolescents consenting to participate in the trial and those refusing to participate or lost to follow-up will be assessed for differences in age, gender, grades and school, severity of mental health symptoms and eligibility to receive problem solving intervention, if their SDQ score are available.

Table 3 Characteristics of the participants in the trial

Characteristic (all Classes)	Total		Consenting to participate in trial		Refusing to participate or lost to follow-up		Statistic
	N	**%**	**n**	**%**	**n**	%	
Age (Mean (SD))							T-test
Gender Female Male							McNemer's Chi square

Characteristic (all Classes)	Total		Consenting to participate in trial		Refusing to participate or lost to follow-up		Statistic
	N	**%**	**n**	**%**	**n**	%	
Grade 9th 10th 11th 12th							McNemer's Chi square
School GBSSS, Mahipalpur GBSSS, Molarband SBV, Molarband GGSSS, Molarband ASMS-SKV, Mahipalpur SBV Co-Ed, Vasant Vihar							McNemer's Chi square
Total SDQ score (Mean, SD)							T test
Proportion of students eligible for receiving problem solving intervention							McNemer's Chi square

5.3 Adherence to allocated interventions and intervention fidelity

The intervention characteristics will be described for both the control and intervention conditions. Fidelity assessment of the classroom sessions will be additionally arrived from ratings provided by an independent intervention coordinator for 20% of the classes in the trial intervention.

Table 4: Intervention delivery across the school-based and classroom-based sensitization sessions

Time period	School based sensitization activities							Classroom sensitization sessions		
	Posters	Drop-box	School Principal & Teacher meetings							
	N	N	Number of School Principal meetings (N)	Duration of the Principal Meetings (min)	Number of Teacher meetings (N)	Number of teachers participated in meeting (N, % of total teachers)	Duration of the teacher meetings (min)	Number of sessions (N)	Number of students attended the session (N, % of total)	Fidelity rating Mean (SD)
Period 1:										
Period 2:										
Period 3:										

6. Outcome analysis

6.1 Summary of referrals across the two conditions

The numbers and proportion of students referred from each class across the intervention and control conditions will be summarised along with pertinent contextual factors. Similarly, number and proportion of these referrals referred through each of the different sources, and the number, and proportion of the students eligible to receive problem solving intervention across the control and intervention conditions will be summarised through tables/ graphs. The severity of mental health symptoms and the scores internalising and externalising symptom sub-types will also be presented across the two conditions.

6.2 Analysis of primary outcome

In this section, we describe the statistical analysis for the primary outcome. The intervention delivery in the intervention condition at class level (cluster). As we know the size of classes and have the data for all the referred students in each of the time periods, we are able to construct the data at the individual level:

$$Y_{ijk} = \begin{cases} 1 & if\ student_{ijk}\ referred \\ 0 & else \end{cases}$$

where $i = 0\ or\ 1$ (0 = control condition, 1 =intervention condition), $j = 1,..,m_i$ (number of classes in each condition), $k = 1,..,n_{ij}$ the number of students in class j in condition i. We therefore have observations nested within students and students nested within classes. The primary analysis takes data of all three time periods into account. So, we have

$$Y_{ijkl} = \begin{cases} 1 & if\ student_{ijk}\ referred\ in\ period\ l \\ 0 & else \end{cases}$$

where $l = 1, 2\ or\ 3$ to indicate the period.

Figure 3: Trial schematic indicating the effects that can be measured (adapted from figure 1)

		↓ Step 1	↓ Step 2
Sequence 1 (1-35 classes)	Control condition (immediate control effect)	Intervention condition (immediate intervention effect)	Intervention condition (continued intervention effect)
Sequence 2 (36-70 classes)	Control condition (immediate control effect)	Control condition (continued control effect)	Intervention condition (immediate intervention effect)
Time	1st time period (4 weeks)	2nd time period (4 weeks)	3rd time period (4 weeks)

We can describe the following effects of the intervention (figure 3):

- The classes in sequence 1 and sequence 2 underwent the immediate effect of the school level sensitization intervention (control condition) at the first period.
- The classes in sequence 1 and sequence 2 underwent immediate effects of receiving classroom sensitization intervention (intervention condition) in the second and third time periods respectively – the main parameter of interest.
- The classes in sequence 2 underwent continued effects of receiving school level sensitization intervention (control condition) in second time period.
- The classes in the sequence 1 underwent continued effects of receiving the classroom sensitization intervention (intervention condition) in the third time period.

These effects can be described in the following equation

$$logit\left(P\left(Y_{ijkl}\right)\right) = \theta_0 + \theta_1 X_{li} + \theta_2 T_{2l} + \theta_3 T_{3l}$$

Where:

Y_{ijkl} is as before, $logit\left(P\left(Y_{ijkl}\right)\right)$ is the log odds of being referred to the counselling program

θ_0 is a constant that reflects the immediate effect of school-level activities (for all classes in first time period),

θ_1 reflects the immediate effect of the classroom activities and is the main parameter of interest (corresponding to the classes receiving the classroom intervention - classes of sequence 1 in the second time period and classes of sequence 2 in the third time period),

θ_2 reflects the continued effects of the school-level activities (corresponding to the sequence 2 classes continuing in the control condition in second time period),

θ_3 reflects the continued effect of the classroom activities (corresponding to the classes of sequence 1 continuing in the intervention condition in the third time period)

X_{li} is an indicator for the time periods when classroom intervention in introduced (equals 1 if $i = 1\ and\ l = 2$ (sequence 1 classes that received classroom intervention at period 2) or if $i = 1\ and\ l = 3$ (sequence 2 classes that received classroom intervention at period 3)),

T_{2l} is an indicator for second time period where classes of sequence 2 experienced continued effect of school sensitization activities (equals 1 if $i = 0\ and\ l = 2$),

T_{3l} is an indicator for the third time period where classes of sequence 1 experienced continued effects of the classroom sensitization intervention (equals 1 if $i = 0\ and\ l = 3$)

We have data with three records for each student, for time period 1, 2 and 3, with students nested in classes. The calculation of the parameters will need to account for this clustering of data at the class level. Analysis will be undertaken using Generalized Estimating Equations (GEE) with robust standard errors that are measured using the sandwich estimator method. GEE is a general statistical approach to fit a marginal model for longitudinal/ clustered data analysis. GEE was introduced by K. Liang and S. Zeger(13) to analyse longitudinal data without resorting to fully specified random effect models and can be applied to both continuous and categorical outcomes. It is a recommended method for analysis of the stepped wedge cluster randomised controlled trials(14), and provides population averaged effects of exposure to the interventions across the control and intervention conditions. GEE provides both parameter estimates and standard errors that are corrected for clustering of data and are consistent despite misspecifications in the correlation structure. For these reasons, GEE is a suitable method for analysis of primary outcome in this trial.

The analysis will be carried out using “xtgee” command using Stata 15.1. The panel structure of data and clustering of data at class level will be specified through stata command “xtset”. The following will be specified in the GEE model:

- Family of distribution of the response variable: Binomial as the outcome variable is binary.
- Link function: Logit link function.
- The within-group correlation structure will be specified as independent.
- Standard error type: robust.

Having a variable for indicating the class in which student observations are nested (class_id), outcome variable indicating the referral status of the adolescent (referred), time indicator (t2) for period 2 for classes that continue to experience school based sensitization activities, indicators for the immediate and continued effects of classroom sensitization activities (effect_lag0 and effect_lag1), the parameters will be estimated using the stata command as illustrated below:

"xtset class_id"
"xtgee referred t2 effect_lag0 effect_lag1, family(binomial) link(logit) corr(independent) vce(robust)"

6.3 Analysis of Secondary and exploratory outcomes

As with the primary outcomes, analysis for secondary outcomes will be undertaken using GEE with robust errors for both continuous and binary outcomes. The secondary and exploratory outcomes are explained in table 1.

1) Eligibility rate – secondary outcome

Eligibility of an adolescent to receive counselling is defined as per the eligibility criteria outlined in table 1. The 'eligibility' of a referred adolescent in period $'l'$ can be described as

$$Y_{ijkl} = \begin{cases} 1 & if\ student_{ijk}\ identified\ as\ 'eligible'\ in\ period\ l \\ 0 & else \end{cases}$$

where Y_{ijkl} is as before (in section 6.2). The analysis of effect of the school sensitization (control) and classroom sensitization (intervention) on the referral of eligible adolescents will be modelled on the method described in section 6.2 for primary outcome using GEE and the specification of family: binomial, link function: logit, correlation structure: independent and with robust standard errors.

2) Self-referral rate – secondary outcome

The referral source will be described as a binary variable, coded as 1 for referrals through self (including those that were referred through direct walk-in or through the drop-box), and 0 for all other sources combined (including teachers, parents, friends, siblings).

$$Y_{ijkl} = \begin{cases} 1 & if\ student_{ijk}\ is\ referred\ by\ self\ in\ period\ l \\ 0 & else \end{cases}$$

Analysis will be undertaken to describe the population averaged odds of self-referral across the two conditions, using GEE method with robust standard errors as described in section 6.2 for analysis of the primary outcome and include the specification of family: Binomial, link function: logit, correlation structure: independent and with robust standard errors.

3) Severity of mental health symptoms – exploratory outcome

For every student referred, the severity of the mental health symptoms will be assessed using the Total Difficulties score measured on SDQ. We will use SDQ Total Difficulties score as a continuous measure. We will use GEE with robust standard errors for estimating the effects of the intervention on the reported severity of mental health symptoms. The regression equation will be modelled to include the effects of immediate and continued effects of school and classroom sensitization activities

as outlined for analysis of primary outcome in section 6.2. The GEE model will include specifications of family: Gaussian, link function: identity, correlation structure: independent, standard errors type: robust.

4) **Severity of mental health symptom sub-types – exploratory outcome**

Along the lines of the analysis described for the severity of mental health symptoms above, mean scores (provided the student was referred and then assessed on SDQ), for each of the sub-scales for internalising symptoms and externalising symptoms will be calculated as described in table 1. Using these scores as continuous variable, we will analyse for the severity of internalising and externalising symptoms separately, across the control and the intervention conditions.

We will use GEE with robust standard errors for estimating the effects of the intervention on the reported severity of mental health symptoms with model specifications as described for analysis of secondary outcome – severity of mental health symptoms. The GEE model will include specifications of family: Gaussian, link function: identity, correlation structure: independent, standard errors type: robust.

6.4 Sensitivity analysis

The sensitivity analyses is based on the methods described in Thompson et al, 2018 (10) which is also used for calculating the power of the study. It uses data from the 2nd period only, since it is in this period where the two conditions differ most transparently: sensitization intervention versus no sensitization intervention. We will use GEE method to arrive at population averaged estimates of the effects of exposure to the interventions across the control and intervention conditions. As the power calculation for this trial is based on this method, we will assess the robustness of the results obtained by the primary method of analysis using this method.

To estimate the intervention effect, we need to estimate the parameters in the following regression equation

$$logit\left(P\left(Y_{ijkl}\right)\right) = \mu + \theta X_i$$

where Y_{ijkl} is as before, μ is a constant, θ is the parameter of interest (the population-averaged estimate of the effect of the intervention), X_i is in indicator variable ($X_i = 0$ for the control condition and $X_i = 1$ for the intervention condition).

A separate file with a sub-set of data with all observations pertaining to time period 2 will be created for the analysis. Having data with one record for each student, and a variable to indicate the class in which the observations are nested (class_id), an indicator for being assigned to the intervention condition (intervention) and an indicator for the outcome variable of being referred (referred), the following stata commands will be used to analyse the intervention effect in period 2. We will first specify the panel data structure with clustering of data at class level using the command “xtset” and then specify the GEE model through the stata command “xtgee”.

“xtset class_id”

“xtgee referred intervention, family(binomial) link(logit) corr(independent) vce(robust)”

6.5 Statistical considerations

95% confidence intervals and p-values will be calculated for all outcomes.

Intention to treat analysis: All the classes randomised to receive the classroom sensitization intervention throughout the trial will be included in the analysis and will be considered to be in the respective condition to which they were assigned initially, irrespective of the receipt of the intervention.

Missing data: The number (%) of participants with complete data will be reported. The primary analyses will be complete cases, with adjustments made for baseline variables which are associated with the outcome and/or missingness, to account for missing data.

No interim analysis of outcomes will be undertaken.

6.6 Other analysis

The intracluster correlation coefficient will be calculated and its impact on the assumed power of the trial will be assessed post-hoc.

7. Ethical considerations

Ethical approval has been obtained from the ethics committees of Sangath, Goa (Ref:RP_2018_47), and Harvard Medical School (Ref:MOD17-0379-03). The trial is registered prospectively on ClinicalTrials.gov and identified through protocol number NCT03633916 (available at: https://clinicaltrials.gov/ct2/show/NCT03633916).

References

1. Parikh R, Michelson D, Malik K, Shinde S, Weiss HA, Hoogendoorn A, et al. The effectiveness of a low-intensity problem-solving intervention for common adolescent mental health problems in New Delhi, India: protocol for a school-based, individually randomized controlled treatment trial with an embedded stepped-wedge cluster randomized controlled recruitment trial. Trials. submitted.
2. Goodman R, Ford T, Simmons H, Gatward R, Meltzer H. Using the Strengths and Difficulties Questionnaire (SDQ) to screen for child psychiatric disorders in a community sample. The British journal of psychiatry : the journal of mental science. 2000;177:534-9.
3. Goodman A, Lamping DL, Ploubidis GB. When to use broader internalising and externalising subscales instead of the hypothesised five subscales on the Strengths and Difficulties Questionnaire (SDQ): data from British parents, teachers and children. Journal of abnormal child psychology. 2010;38(8):1179-91.
4. Hussey MA, Hughes JP. Design and analysis of stepped wedge cluster randomized trials. Contemporary clinical trials. 2007;28(2):182-91.
5. Srikala B, Kishore Kumar K. Empowering adolescents with life skills education in schools - School mental health program: Does it work? Indian Journal of Psychiatry. 2010;52(4):344-9.
6. Srinath S, Kandasamy P, Golhar TS. Epidemiology of child and adolescent mental health disorders in Asia. Curr Opin Psychiatry. 2010;23(4):330-6.
7. Singh K, Junnarkar M, Sharma S. Anxiety, stress, depression, and psychosocial functioning of Indian adolescents. Indian journal of psychiatry. 2015;57(4):367-74.
8. Kanuri N, Newman MG, Ruzek JI, Kuhn E, Manjula M, Jones M, et al. The Feasibility, Acceptability, and Efficacy of Delivering Internet-Based Self-Help and Guided Self-Help Interventions for Generalized Anxiety Disorder to Indian University Students: Design of a Randomized Controlled Trial. JMIR research protocols. 2015;4(4):e136.
9. Bhola P, Sathyanarayanan V, Rekha DP, Daniel S, Thomas T. Assessment of Self-Reported Emotional and Behavioral Difficulties Among Pre-University College Students in Bangalore, India. Indian journal of community medicine : official publication of Indian Association of Preventive & Social Medicine. 2016;41(2):146-50.
10. Thompson JA, Davey C, Fielding K, Hargreaves JR, Hayes RJ. Robust analysis of stepped wedge trials using cluster-level summaries within periods. Statistics in medicine. 2018;37(16):2487-500.
11. OPSPL. STAR: Sangath digital tool for advanced research. 2013.
12. Hemming K, Taljaard M, McKenzie JE, Hooper R, Copas A, Thompson JA, et al. Reporting of stepped wedge cluster randomised trials: extension of the CONSORT 2010 statement with explanation and elaboration. BMJ. 2018;363.
13. Liang K-Y, Zeger SL. Longitudinal data analysis using generalized linear models. Biometrika. 1986;73(1):13-22.
14. Barker D, McElduff P, D'Este C, Campbell MJ. Stepped wedge cluster randomised trials: a review of the statistical methodology used and available. BMC medical research methodology. 2016;16:69.

Appendix 1: Stratified randomisation for the cluster randomised controlled trial

The following steps were undertaken to identify 1) the 70 classes to be included in this trial, and 2) random allocation of these 70 classes into two sequences that will receive the classroom sensitisation (intervention condition) across the two steps (figure 1).

1. List the population of classes for sensitization trail

The population of classes includes all classes in the 6 schools from 9th-12th grades = 172 classes. The schools are of a variable size with differing numbers of classes across grades 9-12. 54 classes had received classroom sensitisation in earlier pilot work, reducing the available classes for the trial to 118 (Tables 1.1a and 1.1b).

Table 1.1a: Total number of classes and available classes (not exposed to sensitization till date) in each of the participating schools

Schools	**9th**	**10th**	**11th**	**12th**	**Total**
GBSSS Mahipalpur = 1* (total classes)	11	11	5	3	30
--Classes available for TRIAL	6	10	5	0**	21
GBSSS, Molarband = 2* (total classes)	10	5	5	6	26
--Classes available for TRIAL	5	5	5	6	21
SBV, Molarband = 3* (total classes)	8	8	5	5	26
--Classes available for TRIAL	8	7	3	5	23
GGSSS Molarband = 4* (total classes)	14	7	5	5	31
--Classes available for TRIAL	9	7	5	0**	21
ASMS-SKV, Mahipalpur = 5* (total classes)	14	8	6	6	34
--Classes available for TRIAL	0*	7	4	6	17
SBV Co-Ed, Vasant Vihar = 6* (total classes)	12	4	4	5	25
--Classes available for TRIAL	6	0**	4	5	15
Total number of classes (across the 6 schools)	**69**	**43**	**30**	**30**	**172**
--Classes available for TRIAL	**34**	**36**	**26**	**22**	**118**

*Notes: *Unique numerical code assigned to each of the participating schools*
***Inadvertently all classes from some grades in some schools were used in pilot activities, where no classes are available for the trial*

Table 1.1b: List of all the available classes (n=118) for the sensitization trial

	School no. 1	School no. 2	School no 3	School no 4	School no 5	School no 6
9th grade	1-9-E	2-9-A	3-9-A	4-9-A		6-9-B
	1-9-F	2-9-B	3-9-B	4-9-B		6-9-D
	1-9-G	2-9-G	3-9-C	4-9-C		6-9-E

	School no. 1	School no. 2	School no 3	School no 4	School no 5	School no 6
	1-9-H	2-9-J	3-9-D	4-9-D		6-9-F
	1-9-I	2-9-K	3-9-E	4-9-F		6-9-J
	1-9-K		3-9-F	4-9-G		6-9-K
			3-9-G	4-9-J		
			3-9-H	4-9-K		
				4-9-L		
10th grade	1-10-B	2-10-A	3-10-A	4-10-A	5-10-A	
	1-10-C	2-10-B	3-10-B	4-10-B	5-10-C	
	1-10-D	2-10-C	3-10-C	4-10-C	5-10-D	
	1-10-E	2-10-D	3-10-D	4-10-D	5-10-E	
	1-10-F	2-10-E	3-10-E	4-10-E	5-10-F	
	1-10-G		3-10-F	4-10-F	5-10-G	
	1-10-H		3-10-H	4-10-G	5-10-H	
	1-10-I					
	1-10-J					
	1-10-K					
11th grade	1-11-A	2-11-A	3-11-A	4-11-A	5-11-A	6-11-A
	1-11-B	2-11-B	3-11-B	4-11-B	5-11-D	6-11-B
	1-11-C	2-11-C	3-11-D	4-11-C	5-11-E	6-11-C
	1-11-D	2-11-D		4-11-D	5-11-F	6-11-D
	1-11-E	2-11-E		4-11-E		
12th grade		2-12-A	3-12-A		5-12-A	6-12-A
		2-12-B	3-12-B		5-12-B	6-12-B
		2-12-C	3-12-C		5-12-C	6-12-C
		2-12-D	3-12-D		5-12-D	6-12-D
		2-12-E	3-12-E		5-12-E	6-12-E
		2-12-F			5-12-F	

Notes: All classes are uniquely identified here using "school number-grade-section" format

2. Decide number of classes from each grade and school:

The numbers of classes from each grade to be selected (n) were calculated using the formula for proportional allocation (Table 1.2a):

n = total number of classes in the strata * (N/T)

where, n= sub-sample of a classes from a specific grade to be selected; N = total sample size = 70; T = Total number of classes = 172

When the classes were not available in a specific grade/school, these were balanced with other grades in the same school to achieve the total number of classes required per school. This was then balanced with classes from within the same grade across other schools to ensure that the numbers to be selected for each grade were also maintained (Table 1.2b)

Table 1.2a: Number of classes to be selected for sensitization trial from each school

Schools	**9th**	**10th**	**11th**	**12th**	**Sample to be selected**
GBSSS Mahipalpur = 1					**12**
GBSSS, Molarband =2					**11**
SBV, Molarband = 3					**11**
GGSSS Molarband 4					**13**
ASMS-SKV, Mahipalpur = 5					**13**
SBV Co-Ed, Vasant Vihar = 6					**10**
Numbers to select for the trial	**28**	**18**	**12**	**12**	**70**

Table 1.2b: Sample to be selected from each school and for each grade

Schools	**9th**	**10th**	**11th**	**12th**	**Sample to be selected**
GBSSS Mahipalpur = 1	6	4	2	0*	**12**
GBSSS, Molarband =2	5	2	2	2	**11**
SBV, Molarband = 3	4	2	2	3	**11**
GGSSS Molarband 4	7	4	2	0*	**13**
ASMS-SKV, Mahipalpur = 5	0*	6	2	5	**13**
SBV Co-Ed, Vasant Vihar = 6	6	0*	2	2	**10**
Numbers to select for the trial	**28**	**18**	**12**	**12**	**70**

3. Select the sample of 70 classes through stratified randomisation

Stratification is planned at two levels – first school and then grade to account for unknown school level factors that may influence the referral (e.g., general support or lack thereof to school counselling service, and researcher/counsellor related factors) and factors associated with grades (e.g. younger students in grade 9th compared to 12th, and inherent academic pressure in specific grades, such as those with board exams).

70 classes as per the sub-samples drawn in table 1.2b were then selected from the 118 available classes using steps as follows:

- First, the entire list of classes was entered on excel. Each class was identified by a unique id (school code – grade – division).
- Then random numbers were allocated to each class by using the rand() command.
- After the random numbers were generated they were pasted as values on the same cells so that the numbers will not change subsequently.
- Then the list was sorted by school, grade and value of random number (smallest to largest) in that order using the “custom sort” dialog box.
- Using the smallest value of random number as a guide, the required numbers of classes were selected within each school and standard.

- The complete list of 70 classes arrived after this process is included in Table 1.3. The selected classes are highlighted in yellow and is used for further process of creating blocks and randomisation.
- It was decided that in the rare instance that a selected class was dissolved or merged with another class – which was anticipated as the admission process was incomplete when the randomisation was undertaken – the next class in the random list will be included to replace the unavailable class.

Table 1.3: List of n=118 classes and selection of n=70 classes (yellow) for the sensitization trial using random numbers generated in excel

School number	Standard (9^{th}/10^{th}/11^{th}/12^{th})	Class (school no. – standard – division)	Random number (using function =rand())
1	9	1-9-H	0.192594
1	9	1-9-E	0.430515
1	9	1-9-G	0.541229
1	9	1-9-F	0.663142
1	9	1-9-I	0.704873
1	9	1-9-K	0.752422
1	10	1-10-G (class dissolved)	0.147472
1	10	1-10-F	0.15537
1	10	1-10-C	0.208894
1	10	1-10-K (class dissolved)	0.340698
1	10	1-10-I (class is dissolved)	0.359488
1	10	1-10-E	0.419727
1	10	1-10-H (class dissolved)	0.482554
1	10	1-10-J (class dissolved)	0.626517
1	10	1-10-B (class dissolved)	0.681298
1	10	1-10-D	0.770563
1	11	1-11-E	0.061504
1	11	1-11-A	0.379209
1	11	1-11-C	0.595781
1	11	1-11-D	0.714406
1	11	1-11-B	0.854851
2	9	2-9-J	0.184087
2	9	2-9-G	0.284391
2	9	2-9-A	0.462558
2	9	2-9-K (class dissolved)	0.503076
2	9	2-9-B	0.717554
2	10	2-10-B	0.012059
2	10	2-10-E	0.060256

School number	Standard (9^{th}/10^{th}/11^{th}/12^{th})	Class (school no. – standard – division)	Random number (using function =rand())
2	10	2-10-C	0.09483
2	10	2-10-A	0.315278
2	10	2-10-D	0.338341
2	11	2-11-A	0.076932
2	11	2-11-D	0.151911
2	11	2-11-B	0.382449
2	11	2-11-C	0.793082
2	11	2-11-E	0.799644
2	12	2-12-D	0.347844
2	12	2-12-C	0.412709
2	12	2-12-F	0.440067
2	12	2-12-B	0.509551
2	12	2-12-E	0.588307
2	12	2-12-A	0.974578
3	9	3-9-G	0.084368
3	9	3-9-E	0.220811
3	9	3-9-H	0.29292
3	9	3-9-A	0.295531
3	9	3-9-B	0.483728
3	9	3-9-C	0.518274
3	9	3-9-F	0.75435
3	9	3-9-D	0.966725
3	10	3-10-C	0.146656
3	10	3-10-E	0.179899
3	10	3-10-D	0.481394
3	10	3-10-H	0.499846
3	10	3-10-F	0.505348
3	10	3-10-A	0.739538
3	10	3-10-B	0.954587
3	11	3-11-A	0.129143
3	11	3-11-B	0.452066
3	11	3-11-D	0.580499
3	12	3-12-D	0.089252
3	12	3-12-E	0.178107
3	12	3-12-A	0.369123
3	12	3-12-B	0.39269
3	12	3-12-C	0.879363
4	9	4-9-K	0.02463
4	9	4-9-B	0.058254

School number	Standard (9^{th}/10^{th}/11^{th}/12^{th})	Class (school no. – standard – division)	Random number (using function =rand())
4	9	4-9-G	0.282987
4	9	4-9-L	0.425811
4	9	4-9-F	0.544048
4	9	4-9-J	0.741914
4	9	4-9-A	0.877333
4	9	4-9-D	0.896587
4	9	4-9-C	0.988156
4	10	4-10-G	0.184097
4	10	4-10-C	0.361362
4	10	4-10-D	0.434305
4	10	4-10-F	0.722952
4	10	4-10-A	0.779491
4	10	4-10-E	0.83026
4	10	4-10-B	0.862193
4	11	4-11-B	0.123751
4	11	4-11-A	0.370797
4	11	4-11-D	0.767838
4	11	4-11-E	0.856566
4	11	4-11-C	0.867977
5	10	5-10-F	0.286355
5	10	5-10-E	0.393016
5	10	5-10-A	0.460435
5	10	5-10-C	0.488292
5	10	5-10-G	0.596692
5	10	5-10-H	0.760017
5	10	5-10-D	0.858051
5	11	5-11-A	0.194647
5	11	5-11-F	0.503224
5	11	5-11-E	0.570214
5	11	5-11-D	0.628346
5	12	5-12-D	0.213647
5	12	5-12-A	0.335742
5	12	5-12-C	0.478392
5	12	5-12-E	0.549698
5	12	5-12-B	0.795617
5	12	5-12-F	0.966802
6	9	6-9-K (class dissolved)	0.142101
6	9	6-9-F	0.152092
6	9	6-9-E	0.250829

School number	Standard (9^{th}/10^{th}/11^{th}/12^{th})	Class (school no. – standard – division)	Random number (using function =rand())
6	9	6-9-B	0.935468
6	9	6-9-J	0.939516
6	9	6-9-D	0.966047
6	11	6-11-A	0.192713
6	11	6-11-B	0.201508
6	11	6-11-C	0.666467
6	11	6-11-D	0.987525
6	12	6-12-C	0.027382
6	12	6-12-E	0.255308
6	12	6-12-A	0.585509
6	12	6-12-D	0.713415
6	12	6-12-B	0.895144

4. Creating blocks and randomisation

- Blocks: As the selected numbers of classes within each school-grade combination is often small, block size of 2 was used to assign the classes to one of the two groups, so that allocation of classes can be balanced across both the treatment groups.
- Creating blocks: 2 classes within the same school and standard were grouped together to form a block. If this was not possible, then classes were clubbed together within the classes from same grade from other schools to form blocks of two.
- Each of the blocks thus created were numbered sequentially from 1-35.
- Randomisation is required to allocate the classes across two sequences:
    - Sequence 1 - Group A: 1-35 classes to receive the intervention condition in the second time period.
    - Sequence 2 - Group B: 36-70 classes to receive the intervention condition in the third time period.
- The first 17 blocks were labelled AB and subsequent 18 blocks were labelled BA. Using excel command rand() a random number was allocated to each of these blocks. With sorting on random number, AB and BA were randomly allocated to each of the 35 blocks (Table 1.4).
- These classes within each block was then assigned to the treatment group as per the sequence generated in table 1.4. The final list of classes randomised in two groups as per the above process is re-produced in table 1.5, and will be used for the trial.

Table 1.4: Random allocation of the blocks

Block number for randomisation	Blocks	Random number
1	AB	0.997221
2	BA	0.804859
3	AB	0.814548
4	AB	0.773763
5	AB	0.152418
6	BA	0.007255
7	BA	0.356458
8	BA	0.654178
9	AB	0.817778
10	BA	0.212944
11	AB	0.115815
12	AB	0.22788
13	AB	0.673958
14	BA	0.031788
15	AB	0.00872
16	BA	0.298582
17	BA	0.282199
18	AB	0.43279
19	BA	0.716775
20	AB	0.874177
21	AB	0.262606
22	BA	0.936284
23	BA	0.805721
24	BA	0.319226
25	BA	0.24751
26	AB	0.953943
27	BA	0.809131
28	BA	0.609128
29	BA	0.485599
30	BA	0.924817
31	BA	0.28247
32	AB	0.7649
33	AB	0.171817
34	AB	0.636414
35	AB	0.042925

Table 1.5: Allocation of 70 classes equally across sequence 1 (Group A) and sequence 2 (Group B)

Sequence 1: Group A (Classes 1-35)			Sequence 2: Group B (Classes 36-70)		
School code	Grade	Class	School code	Grade	Class
1	9	1-9-E	1	9	1-9-F
1	9	1-9-H	1	9	1-9-G
1	9	1-9-I	1	9	1-9-K
1	10	1-10-C	1	10	1-10-F
1	10	1-10-E *	1	10	1-10-D *
1	11	1-11-E	1	11	1-11-A
2	9	2-9-B	2	9	2-9-A
2	9	2-9-J	2	9	2-9-G
2	9	2-10-C *	2	10	2-10-B
2	10	2-10-E	2	11	2-11-D
2	11	2-11-A	2	12	2-12-D
2	12	2-12-C	3	9	3-9-E
3	9	3-9-A	3	9	3-9-G
3	9	3-9-H	3	10	3-10-E
3	10	3-10-C	3	11	3-11-A
3	11	3-11-B	3	12	3-12-A
3	12	3-12-D	4	9	4-9-A
3	12	3-12-E	4	9	4-9-B
4	9	4-9-F	4	9	4-9-J
4	9	4-9-G	4	9	4-9-L
4	9	4-9-K	4	10	4-10-C
4	10	4-10-D	4	10	4-10-F
4	10	4-10-G	4	11	4-11-A
4	11	4-11-B	5	10	5-10-A
5	10	5-10-C	5	10	5-10-F
5	10	5-10-E	5	10	5-10-G
5	10	5-10-H	5	11	5-11-A
5	11	5-11-F	5	12	5-12-A
5	12	5-12-C	5	12	5-12-B
5	12	5-12-E	5	12	5-12-D
6	9	6-9-D	6	9	6-9-B
6	9	6-9-E	6	9	6-12-D *
6	9	6-9-J	6	9	6-12-A *
6	11	6-11-A	6	11	6-11-B
6	12	6-12-C	6	12	6-12-E

*Notes: *classes were added as replacements for the classes that were dissolved before the commencement of the trial.*