Increasing demand for school counselling through a lay counsellor-delivered classroom sensitisation intervention: a stepped-wedge cluster randomised controlled trial in New Delhi, India


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Increasing demand for school counselling through a lay counsellor-delivered classroom sensitisation intervention: a stepped-wedge cluster randomised controlled trial in New Delhi, India

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ABSTRACT

Introduction: We evaluated a classroom-based sensitisation intervention that was designed to reduce demand-side barriers affecting referrals to a school counselling programme. The sensitisation intervention was offered in the context of a host trial evaluating a low-intensity problem-solving treatment for common adolescent mental health problems.

Methods: We conducted a stepped-wedge, cluster randomized controlled trial with 70 classes in six secondary schools serving low-income communities in New Delhi, India. The classes were randomized to receive a classroom sensitisation session involving a brief video presentation and group discussion, delivered by a lay counsellor over one class period (intervention condition, IC), in two steps of 4 weeks each. The control condition (CC) was whole-school sensitisation (teacher-meetings and whole-school activities such as poster displays). The primary outcome was the proportion of students referred into the host trial. Secondary outcomes were the proportion of students who met mental health caseness criteria and the proportion of self-referred adolescents.

Results: Between 20th August 2018 and 9th December 2018, 835 students (23.3% of all students) were referred into the host trial. The referred sample included 591 boys (70.8%), and had a mean age of 15.8 years, SD=0.06; 194 students (31.8% of 610 with complete data) met mental health caseness criteria. Referral rates were substantially higher in the IC (IC=21.7%,CC=1.5%, OR=111.36, 95%CI=35.56-348.77, p<0.001). The proportion of self-referred participants was also higher in the IC (IC=98.1%,CC=89.1%, Pearson chi2(1)=16.92, p<0.001). Although the proportion of referred students meeting caseness criteria was similar in both conditions (IC=32.0% vs CC=28.1%), the proportion weighted for the total student population was substantially higher in the IC (IC=5.2%,CC=0.3%, OR=52.39, 95%CI=12.49-219.66, p<0.001), indicating that significantly more cases were referred in the IC.

Conclusion: A single, lay counsellor-delivered, classroom sensitisation session increased psychological help-seeking for common mental health problems among secondary school pupils from urban, low-income communities in India.

Trial registration number: NCT03633916.

KEY WORDS: Adolescents, schools, global mental health, help-seeking, stepped wedge cluster randomisation trial
KEY QUESTIONS

What is already known?

- Low mental health literacy and high stigma restrict adolescents’ help-seeking for mental health problems.
- Previous studies suggest that demand-side interventions are more effective at increasing access to mental health care when targeted directly at young people rather than focusing primarily on parents and other adult gatekeepers.
- The existing evidence base is derived almost entirely in high-income countries, limiting inferences to diverse global contexts.

What are the new findings?

- We report findings from the first randomized controlled trial of the effects of a youth-focused intervention seeking to increase demand for school-based mental health care in a low-resource context.
- As compared with a typical whole-school sensitisation programme (which targeted teachers and school principals, with adolescent engagement limited to poster displays and installation of drop boxes for receiving referrals), a single classroom sensitisation session (involving a video presentation and facilitated discussion with a lay counsellor) led to a large increase in demand for school-based mental health care.
- The vast majority of help-seeking adolescents were self-referred.
- Most of the help-seeking students who met mental health case criteria originated from the sensitised classes.

What do the new findings imply?

- Compared with whole-school sensitisation, this study demonstrates that a relatively brief, scalable, and student-targeted intervention, delivered at the classroom level using contextually sensitive content and facilitation by a lay counsellor, can greatly increase demand for mental health care among socio-economically disadvantaged adolescents.
- In conjunction with evidence-based psychological treatment, this approach has the potential to reduce the mental health care gap for young people in low-resourced and probably also in high-resourced settings.
INTRODUCTION

Help-seeking for adolescent mental health problems is low in all contexts, but particularly so in low- and middle-income countries (LMICs).1-4 A range of demand-side barriers have been described, such as low levels of mental health literacy (associated with difficulties in self-identification of symptoms and poor knowledge of mental health services); stigma; a preference towards self-reliance and informal sources of help; perceived low effectiveness of treatments; concerns regarding confidentiality; and negative past experiences with mental health services.1-5 These are compounded by systemic-level barriers such as scarcity of acceptable and effective mental health services, and associated costs.1-5 Schools are a recommended platform to improve adolescents’ access to effective mental healthcare, with the potential to address a number of these barriers. However, even when school-based mental health services are available, adolescents may be reluctant to seek help.  

There has been growing interest in developing and testing interventions to increase the demand for mental health care by adolescents, especially in the past decade. However, a recent meta-analysis reported no effects of demand-side interventions on formal help seeking for adolescent mental health problems; notably, most of the interventions included were targeted towards caregivers or gatekeepers rather than adolescents directly.7 Interventions targeting adolescents themselves, such as universal school-based mental health awareness programmes, have been shown to improve mental health literacy and influence more positive help-seeking attitudes and intentions among adolescents. These variables are in turn considered to promote actual help seeking.8-10 Only seven studies (none in LMICs) have assessed the impact of such interventions on actual help-seeking behaviour, four of which were conducted in schools11-14 and focused variously on general mental health literacy,11 and, suicide literacy.12-14 However, none of the school-based intervention studies showed any positive impact on help-seeking behaviour. 

India is home to the largest number of adolescents in any single country and growing policy attention has been devoted to their mental health, with a particular focus on school-based provision of mental health care.15 Given the very low coverage of school mental health services in most populations in India and an estimated treatment gap for common mental disorders in adults of 85%,16 we speculate that the unmet mental health needs for adolescents exceed 90%. The PRemlum for aDolEscents (PRIDE) programme aims to develop and evaluate a stepped-care intervention model for adolescents with common mental health problems in low-income schools in India. The PRIDE stepped-care architecture involves two sequential psychological interventions of incremental intensity: the first step is a brief low-intensity problem-solving intervention,17 while the second step is a higher-intensity psychological treatment that is offered to those students who do not respond to the problem-solving intervention.18 An iterative process of intervention development highlighted access barriers such as low mental health literacy and concerns regarding confidentiality in the target population, with consequent needs for clear and non-stigmatising information about the purpose and intended recipients of school counselling services, referral processes and
assurances about confidentiality.\textsuperscript{19} To address these barriers, we designed an adolescent-facing classroom-level sensitisation intervention to be implemented as a universal intervention to improve mental health literacy and stimulate help-seeking behavior among school going adolescents\textsuperscript{19}, and then evaluated its impacts in a trial that was embedded in a host trial of the first-step problem-solving intervention.\textsuperscript{21} This paper presents the results of this embedded sensitisation trial, and complements the findings of the host trial.\textsuperscript{22}

The primary objective of the sensitisation trial was to evaluate the impact of a classroom sensitisation session (intervention condition, IC), over and above whole-school sensitisation activities (control condition, CC), on the proportion of adolescents referred into the host trial as a function of the total sampling frame in each condition. We hypothesised that the IC would be associated with a higher proportion of students referred from the corresponding school population. The secondary objectives were to assess the effects of the intervention on (1) the proportion of students who met mental health case criteria (as required to participate in the host trial); and (2) the proportion of students who were self-referred. We also sought to explore whether there would be any differences in the severity of symptoms and symptom subtypes among help-seeking students after exposure to the respective sensitisation conditions.

\textbf{METHODS}

\textbf{Study design}

We conducted a stepped-wedge cluster randomised controlled trial (SW-CRCT)\textsuperscript{23} with two sequences and three time periods in six Government-run secondary schools in New Delhi, India. Three were boys’ schools, two were girls’ schools and one was co-educational (mixed boys and girls), all catering to low-income communities. The design has been described in detail in the published study protocol.\textsuperscript{21} In brief, we randomly selected 70 classes (sampled from grades 9-12) covering 3,587 students, from a pool of 118 classes that had not received classroom sensitisation previously during pilot work. We restricted the number of classes included in the trial to 70, based on the numbers of cases we expected by modelling of pilot data, so that the counsellors in the host problem-solving intervention trial could manage the demand. Classes formed natural clusters.

All classes began in the control condition (first time period), and subsequently received the intervention in two steps (figure 1). Classes were randomised to one of the two allocation sequences that determined the step in which they received the intervention. Thus, the trial had three time periods of four weeks each, and a total duration of 12 weeks.

\textbf{Randomisation and masking:}

Random numbers were generated using the rand() command in Microsoft Excel and assigned to the 118 available classes arranged in strata by school and grade. The final sample of 70
classes was selected through proportional sampling from each of these strata using the smallest value of the assigned random number as a guide. The randomisation sequence for allocating these 70 classes to one of the two sequences was generated (in Excel) using a block size of two (as the numbers of classes in individual strata was often less than 4). The randomisation was completed before the initiation of the trial. Blinding of the researchers was not possible as they were involved in the implementation of sensitisation activities across both the intervention and control conditions. However, teachers were not informed about the trial hypotheses in order not to influence their willingness to refer into the study.

**Procedures**

**Control condition (CC)**

This comprised a set of whole-school sensitisation activities intended to generate referrals of students with common mental health problems into a counselling service on school premises. These activities were: meetings with school principals and teachers to provide them with structured information about common mental health problems among students and the referral routes; displaying posters with information about the counselling service in highly visible locations throughout the school, such as noticeboards, corridors and outside the counsellor’s room; and establishing drop-boxes (one per school) with appropriate signage installed near the counsellor’s room, for receiving referrals discreetly. A liaison teacher was identified in each of the schools to coordinate these activities. Meetings with the principal were conducted by master’s-level psychologists while lay counsellors (also responsible for providing the problem-solving intervention in the host trial) and researchers (responsible for processing referrals and conducting mental health assessments for the current and the host trial) convened meetings with the teachers. The lay counsellors and researchers were Hindi-speaking college graduates. The counsellors had no prior training or experience of mental health care.

**Intervention condition (IC)**

This comprised a single classroom sensitisation session offered in addition to the whole-school sensitisation activities. A typical session was delivered over 20-25 minutes (to fit into a typical class period) by a lay counsellor aided by a researcher. The session began with a short animated video (link to video) providing age-appropriate information on common stressors and ways of coping. This was followed by a guided group discussion to facilitate engagement and clarify understanding of the material. Additionally, adolescents were handed a self-referral form which included normalizing information and question-based prompts to assist with self-identification of mental health problems. Fidelity of the intervention was assessed for 20% of sessions by an independent assessor using a checklist of 16 observable procedures (e.g., accuracy of explanations given about confidentiality, referral pathways and use of self-referral forms; responsiveness to queries raised by students during the class discussion). Each item was evaluated on a three-point Likert scale. Fidelity score (maximum score=2) was arrived at after averaging the individual scores across all assessed procedures.
Across both the conditions, adolescents could be referred into the host trial through three routes: self-referral either by meeting a counsellor/researcher personally; depositing a referral slip in a drop-box; or referral by a teacher. Consent was obtained through a two-stage consent process covering both this and the host trial, approved by the Institutional Review Boards of Sangath and Harvard Medical School. Referred adolescents were provided with structured verbal information and a written information sheet about the use of their referral/screening data, with the opportunity to opt-out. The information sheet was retained by adolescents and shared with parents/guardians. Adolescents, meeting eligibility criteria for the host trial were provided with additional structured verbal and written information and an opt-in procedure was implemented, as outlined in the published protocol. It was not viable to obtain informed consent from all the 3587 students in the selected classes prior to randomization as the intervention was delivered at classroom-level, and the consent process itself was likely to influence the students’ help-seeking directly. However, steps were taken to ensure that no personally identifiable data were collected before obtaining informed consent.

Outcomes

Primary outcome: ‘Referral proportion’ was the proportion of adolescents in the participating classes that were referred, representing the unmet need for psychological help among the students

Secondary outcomes: 1) ‘Case level proportion’ was defined in two ways: the proportion of who met the criteria for mental health ‘caseness’ (defining the student’s eligibility to participate in the host trial) either as a fraction of all students in the participating classes (added to the original protocol, before commencing data analysis), or as a fraction of referred students only. The counselling intervention in the host trial was designed as an early intervention for adolescents with elevated symptoms and associated distress/impairment. Adolescents were assessed eligible to participate in the host trial if they reported a Total Difficulties score on the self-reported Strengths and Difficulties Questionnaire (SDQ) above the locally validated cut-offs of >/= 19 and >/= 20 for borderline difficulties among boys and girls respectively, representing the top 15% of scores obtained from a normative reference sample in Indian youth; and score of 2 or more on the SDQ Impact Supplement, indicating clinically significant distress and functional impairment; and duration of mental health problems lasting for more than 1 month, assessed on the chronicity item on the SDQ Impact Supplement. These eligibility criteria also recognise that psychopathology in young people can present in the form of heterogenous symptoms with help-seeking driven by a desire to address associated stressors and functional impairment. The SDQ has been widely used as a measure of psychopathology among children and adolescents globally, including in India. 2) ‘Self-referral proportion’ was defined as the proportion of referred adolescents who were self-referred.
We also assessed the effect of the IC on the following exploratory outcomes: 1) Severity of adolescent-reported mental health symptoms on the SDQ Total Difficulties scale; 2) severity of adolescent-reported symptoms on the SDQ Internalizing and Externalising problem sub-scales. These sub-scale scores (range 0-20) were derived from summing scores for Emotional/Peer relationship problems and Conduct/Hyperactivity-inattention problems, respectively.

**Analysis**

A power calculation was based on a within-period comparison for a SW-CRCT, using Stata package “clustersampsi” and parameters based on pilot data. Using referral proportions of 5% for CC and 15% for IC, an intra-cluster correlation coefficient (ICC) of 0.124, a pragmatic sample size of 70 classes (average class size of 50 students) provided 92% power to detect a difference of 10 percentage points (treating the outcome as a binomial variable), at a significance level of 0.05.

While data for the primary outcome of referral proportion and the secondary outcome of self-referral proportion were available for all of the 835 referred adolescents, assessments for eligibility to participate in the host trial was completed for 610 participating adolescents. Data for individual items on the SDQ were lost for one of these 610 students due to a technical malfunction. Thus, exploratory outcomes – requiring the scores of individual items on the SDQ - were available for 609 adolescents only.

We used multiple imputations with a chained equations framework to impute missing data for the 225 referred adolescents who did not participate in the host trial (updated in the statistical methods outlined in the original protocol, before commencing data analysis). We first imputed the missing data for the underlying variables of the Internalising and Externalising SDQ sub-scale scores, Impact score, and, chronicity of mental health problems. The SDQ Total Difficulties score and eligibility for the host trial were then computed passively from the imputed data for the underlying variables. We used univariate methods with logit for categorical variables, and predictive mean matching (k-nearest-neighbour option=5) for continuous variables. The imputation model included period, allocation sequence, school, and grade, as they were associated with trial participation (Table 2). The number of imputations was set to 50, to account for the high proportion of missing data.

We used Generalized Estimating Equations (GEE) with robust standard errors (measured using the sandwich estimator method) for analysis of the outcomes, a recommended method for analysis of the SW-CRCTs. The analysis model for calculating the marginal probability of the outcomes included parameters for the effect of the classroom sensitisation session for the time periods when the intervention was introduced and for the subsequent time period, and parameters for the second and the third time period (added to the initial analysis model before commencing data analysis) to account for secular trend. We specified the ‘exchangeable’ correlation structure, later changed to ‘independent’ when the model did not converge for the outcomes of referral proportion, eligible proportions, and, self-referral
proportion. Sensitivity analysis was conducted using GEE for a ‘within-period comparison’ of data from the second period only.²⁶

**Patient & Public Involvement**

Formative research activities, including literature reviews and intervention design workshops with local and international experts, were triangulated with qualitative data from 280 stakeholders, including adolescents, parents, school staff, and mental health practitioners.¹⁷ Structured school-based sensitisation were endorsed by the various stakeholder groups to overcome demand-side barriers to engagement in mental health services.¹⁹ These activities were subsequently tested and refined in pilot work prior to the current trial.¹⁷ Key modifications included: (i) re-designed content of classroom sessions which stronger emphasis placed on normalisation of adolescent mental health problems and assurances about confidentiality to address concerns about stigma; (ii) use of an animated video and group discussion (rather than didactic verbal instructions) to increase student engagement with the classroom session; (iii) increased variety of referral methods to facilitate discreet self-referral processes; and (iv) use of structured/scripted briefings to standardise information provided to school staff.

**RESULTS**

**Trial flow indicators**

The trial began on 20ᵗʰ August 2018, and was completed on 9ᵗʰ December 2018, after accommodating two short breaks – one for exams between the first and the second period and one for a major Indian festival (Diwali) between the second and third period (figure 2). The total student population in the 70 randomly selected classes was 3,587 with a mean class size of 51.2 (95%CI=47.3 to 55.2); 2036 (56.8%) were boys. Across the two sequences of IC delivery, there was a balanced distribution with respect to grades (i.e., across years 9-12). However, the numbers of adolescents included in each of the six schools and the gender distribution differed significantly (Table 1), owing to the varying class sizes across the schools.

Table 1: Characteristics of students in participating classes (clusters) by the allocation sequences.

<table>
<thead>
<tr>
<th></th>
<th>Total (N=3587)</th>
<th>Sequence 1=35 classes (n=1857)</th>
<th>Sequence 2=35 classes (n=1730)</th>
<th>Test statistic, p value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>2036</td>
<td>1106</td>
<td>930</td>
<td>12.3, p&lt;0.001</td>
</tr>
<tr>
<td>Female</td>
<td>1551</td>
<td>751</td>
<td>800</td>
<td>4.7, p=0.031</td>
</tr>
<tr>
<td><strong>Grade:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9ᵗʰ</td>
<td>1614</td>
<td>831</td>
<td>783</td>
<td></td>
</tr>
</tbody>
</table>
Overall, there were 835 referrals (23.3% of all the 3587 students) from the 70 classes included in this trial (mean referrals per class=12, SD=1.55, primary outcome). From these 835 referrals, 610 (73.1%) consented to participate in the sensitisation trial and completed eligibility assessments for the host trial (secondary outcome of ‘case level proportion’ and exploratory outcomes). The participation rate was significantly lower in the CC (n=32 of 55 referred in CC, 58.2%) as compared to the IC (n=578 of 780 referred in IC, 74.1%; Pearson chi2(1)=6.62, p<0.001). Non-participation was associated with grade and school, but not with the age or gender of the student (Table 2). Reported reasons for non-participation included “no current problem/ problem resolved/ not interested otherwise” (n=8, 34.8% in CC and n=112, 55.4% in IC), “inability to read/comprehend the language of the intervention” (n=8, 34.8% in CC and n=19, 9.4% in IC), “referred by another party but not interested” (n=4, 17.4% in CC and n=15, 7.4% in IC), and, “lack of time” (n=1, 0.5% in IC). Another 35 (17.3%) adolescents, all from the IC, were not contacted as the recruitment target of the host trial was achieved. Additionally, n=3 (13.0%) in CC and n=20, (9.9%) in IC were not contactable.

Table 2: Characteristics of the participants and non-participants for mental health threshold eligibility assessment
<table>
<thead>
<tr>
<th></th>
<th>Total Referred</th>
<th>Trial participant</th>
<th>Non-participant</th>
<th>Test statistic, p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N=835</td>
<td>N=610</td>
<td>N=225</td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>244</td>
<td>179</td>
<td>65</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>591</td>
<td>431</td>
<td>160</td>
<td></td>
</tr>
<tr>
<td>Grade</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9th</td>
<td>396</td>
<td>298</td>
<td>98</td>
<td>Pearson chi squared(1)= 0.02, p=0.90</td>
</tr>
<tr>
<td>10th</td>
<td>190</td>
<td>155</td>
<td>35</td>
<td>Pearson chi squared(3)= 20.8, p=0.001</td>
</tr>
<tr>
<td>11th</td>
<td>42</td>
<td>26</td>
<td>16</td>
<td></td>
</tr>
<tr>
<td>12th</td>
<td>207</td>
<td>131</td>
<td>76</td>
<td></td>
</tr>
<tr>
<td>School</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GBSSS, Mahipalpur</td>
<td>209</td>
<td>177</td>
<td>32</td>
<td>Pearson chi squared(5)= 66.1, p&lt;0.001</td>
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<tr>
<td>GBSSS, Molarband</td>
<td>135</td>
<td>103</td>
<td>32</td>
<td></td>
</tr>
<tr>
<td>SBV, Molarband</td>
<td>202</td>
<td>122</td>
<td>80</td>
<td></td>
</tr>
<tr>
<td>GGS, Molarband</td>
<td>87</td>
<td>68</td>
<td>19</td>
<td></td>
</tr>
<tr>
<td>ASMS-SKV, Mahipalpur</td>
<td>80</td>
<td>38</td>
<td>42</td>
<td></td>
</tr>
<tr>
<td>SBV Co-Ed, Vasant Vihar</td>
<td>122</td>
<td>102</td>
<td>20</td>
<td></td>
</tr>
</tbody>
</table>

**Intervention delivery**

The CC activities were conducted as per-protocol in most schools. The intervention supervisors met with the principals of five schools. The lay counsellors and researchers convened a total of 12 meetings with teachers (2 per school in 4 schools, 1 and 3 respectively in the remaining 2 schools; average duration=15 minutes). A total of 278 teachers (66.0% of the total teacher body) participated. Six drop-boxes (one per school) were installed outside the counsellors’ rooms, and 30 posters (five per school) were displayed in prominent locations.

The IC classroom sensitisation sessions were scheduled in two steps. The first was conducted in 35 classes at the beginning of the second time period with a mean duration of 23 minutes (SD=0.81 minutes; fidelity score=1.88, SD=0.04); 1136 students (61.2% of the relevant student population) attended these sessions. The remaining 35 classes received the classroom sensitisation sessions at the beginning of the third time period, mean duration was 22.3 minutes (SD=0.81 minutes; fidelity score=1.98, SD=0.02; t-test(15)=2.17, p=0.05, when compared with fidelity of the first step); 1211 students (70.0% of relevant student population) attended the sessions. Regular school attendance was, however, not recorded for each of 3587 students during the trial.
Effectiveness of the intervention (Table 3)

The intervention was associated with a large effect on the primary outcome: out of the 835 referrals, 55 (6.6%) were generated from the CC, and 780 (93.4%) from the IC. During the time periods when the classroom sensitisation sessions were delivered, the referral proportion rose with an odds ratio (OR) of 111.36 (95%CI = 35.56 to 348.77, p<0.001) (figure 3). In the subsequent time period, the referrals dropped but continued to be significantly higher than in the CC (OR=5.80, 95%CI = 1.33 to 25.29; p=0.02). Sensitivity analysis was conducted for the primary outcome of referral proportion from the second period in line with the model used in the power calculation; the result (OR = 134.67, 95%CI = 41.37 to 438.34, p<0.001) was similar to the main analysis. We were not able to report the ICC for this study as the GEE analysis model for the primary outcome did not converge with an exchangeable correlation structure. School-based researchers and counsellors monitored for adverse events such as death, life-threatening events, clinical deterioration requiring hospitalization or other specialist treatment, victimization, sexual abuse, and chronic absenteeism as per the trial protocol.21 There were no adverse events recorded during the trial.
Table 3: Primary, secondary, and exploratory outcomes of the trial

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Denominator or used for analysis</th>
<th>Control Condition (number, percentages, or mean score)</th>
<th>Intervention Condition (number, percentages, or mean score)</th>
<th>Immediate effect of classroom sensitisation (intervention)</th>
<th>Continued effect of classroom sensitisation (intervention)</th>
<th>Effect of time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Denominator</td>
<td>Control Condition</td>
<td>Intervention Condition</td>
<td>OR = 111.36*** (95% CI = 35.56 to 348.77; p&lt;0.001)</td>
<td>OR = 5.80** (95% CI = 1.33 to 25.29; p=0.02)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3587 students</td>
<td>55 (1.5%)</td>
<td>780 (21.7%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary outcome</td>
<td></td>
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<tr>
<td>Referral proportion</td>
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<tr>
<td>Eligible-proportion of referred adolescents</td>
<td></td>
<td>835 referred students</td>
<td>9 (28.1% of 32 trial participants)</td>
<td>185 (32.0% of 578 trial participants)</td>
<td>OR = 0.27 (95% CI = 0.02 to 3.11, p=0.29)</td>
<td>OR = 0.16 (95% CI = 0.01 to 2.30, p=0.18)</td>
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<tr>
<td>Eligible-proportion of all students</td>
<td></td>
<td>3587 students</td>
<td>9 (0.3%)</td>
<td>185 (5.2%)</td>
<td>OR = 52.39*** (95% CI = 12.49 to 219.66, p&lt;0.001)</td>
<td>OR = 2.25 (95% CI = 0.34 to 14.96, p=0.40)</td>
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<tr>
<td>Exploratory outcomes</td>
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<tr>
<td>Severity of mental health symptoms</td>
<td></td>
<td>835 referred students</td>
<td>Mean score = 17.81 (95% CI = 15.64 to 19.98)**</td>
<td>Mean score = 17.63 (95% CI = 17.18 to 18.08)**</td>
<td>β = -1.89* (95% CI = -3.78 to 0.01, p=0.05)</td>
<td>β = -2.45 (95% CI = -5.69 to 0.79, p=0.14)</td>
</tr>
<tr>
<td>Outcome</td>
<td>Denominator used for analysis</td>
<td>Control Condition (number, percentages, or mean score)</td>
<td>Intervention Condition (number, percentages, or mean score)</td>
<td>Immediate effect of classroom sensitisation (intervention)</td>
<td>Continued effect of classroom sensitisation (intervention)</td>
<td>Effect of time</td>
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<td>Continued effect of classroom sensitisation (intervention)</td>
<td>Effect of time</td>
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<td></td>
<td>Mean score = 10.31 (95%CI = 9.12 to 11.50)**</td>
<td>Mean score = 9.06 (95%CI = 8.78 to 9.33)**</td>
<td>β = -2.70*** (95%CI = -3.33 to -2.08, p&lt;0.001)</td>
<td>β = -3.68*** (95%CI = -5.24 to -2.11, p&lt;0.001)</td>
<td>β = 1.81*** (95%CI= 0.73 to 2.89, p=0.001); β = 1.42** (95%CI= 0.2-2.64, p=0.02)</td>
</tr>
<tr>
<td>Internalising symptoms sub-scale of SDQ$^\text{v}$</td>
<td>835 referred students$^{\text{††}}$</td>
<td>Mean score = 7.50 (95%CI = 6.28 to 8.74)**</td>
<td>Mean score = 8.57 (95%CI = 8.31 to 8.83)**</td>
<td>β = 0.82 (95%CI = -0.79 to 2.43, p=0.32)</td>
<td>β = 1.28 (95%CI = -0.91 to 3.48, p=0.25)</td>
<td>β = 0.68 (95%CI = -1.06 to 2.42, p=0.44)</td>
</tr>
<tr>
<td>Externalising symptoms sub-scale of SDQ$^\text{v}$</td>
<td>835 referred students$^{\text{††}}$</td>
<td>Mean score = 7.50 (95%CI = 6.28 to 8.74)**</td>
<td>Mean score = 8.57 (95%CI = 8.31 to 8.83)**</td>
<td>β = 0.82 (95%CI = -0.79 to 2.43, p=0.32)</td>
<td>β = 1.28 (95%CI = -0.91 to 3.48, p=0.25)</td>
<td>β = 0.68 (95%CI = -1.06 to 2.42, p=0.44)</td>
</tr>
</tbody>
</table>

Notes:

***=results significant with p<0.0001, **=results significant at p<0.05, *=results trending to be statistically significant;

# = Binary outcome, GEE model specified Binomial family distribution of the response variable, logit link function and independent correlation structure as the GEE model did not converge with exchangeable correlation structure with robust standard error type;

$^\text{v}$ = Continuous outcome, GEE model specified Gaussian family distribution of the response variable, identity link function and exchangeable correlation structure with robust standard error type;

OR = Odds Ratio;

$\beta$ = population averaged regression coefficients describing the mean change in the response variable for every 1-unit of change in the predictor variable.
The secondary outcome pertaining to self-referral proportion was not analysed using GEE owing to very few cases of non-self-referrals (21 referrals by teachers);

† = Analysed after multiple imputations using chained equations were done for the missing data of 225 students related to mental health assessments;

^ = Denominator = 610 trial participants for whom complete data for the outcome were available;

‡‡ = Analysed after multiple imputations using chained equations were done for the missing data of 226 students related to mental health assessments;

^^ = Denominator = 609 trial participants for whom complete data for the outcome were available.
With regards to the secondary outcomes, out of the 610 referred adolescents for whom the data were available, 194 (31.8%) fulfilled the criteria for mental health caseness. The proportion of cases of all students was higher in the IC (n=185, 5.2%) as compared with the CC (n=9, 0.3%), with OR=52.39, 95%CI = 12.49 to 219.66, p<0.001. However, there was no significant difference in the proportion of cases among the referred students in the two conditions: 28.1% (n=9 of 32) in the CC vs 32.0% (n=185 of 578) of IC.

Overall, 814 adolescents (97.5% of all referrals) had self-referred and 21 (2.5% of all referrals) were referred by teachers. The proportion of self-referrals was significantly higher in the IC (IC=98.1%, CC=89.1%, Pearson chi2(1)=16.9213, p<0.001). We did not analyse this outcome any further, since the GEE model was unlikely to provide robust estimates considering the low number of teacher-referred adolescents.

Considering exploratory outcomes, adolescents referred from the IC were characterised by lower SDQ Total Difficulties score by 1.89 points (95%CI = -3.78 to 0.01, p=0.05, adjusted for effects of time) and lower Internalizing problem sub-scale scores by 2.70 points; 95%CI = -3.33 to -2.08, p<0.001, adjusted for effects of time). There was no evidence that Externalising problem sub-scale scores were different between the two conditions.

**DISCUSSION**

This study evaluated the added impact of a classroom sensitisation session over and above whole-school sensitisation activities on demand for a school counselling service for adolescents in low-income secondary schools in New Delhi, India. The sensitisation trial was embedded in a host trial which evaluated the effectiveness of a problem-solving intervention delivered by lay counsellors.21 22 Thus, while the host trial sought to address supply side barriers (i.e., lack of specialist mental health providers and contextually-appropriate brief interventions), the sensitisation trial aimed to contribute to the scarce evidence on interventions that stimulate demand for mental health care in low-resourced contexts.

We observed that a single classroom sensitisation session covering common stressors and ways of coping, overseen by a lay counsellor, and consisting of a video presentation followed by a moderated class discussion, greatly increased referrals for mental health care compared with whole-school sensitisation activities alone. While the proportion of self-referrals was high in both conditions, it was significantly higher in the intervention condition. The proportion of referrals who met mental health case criteria was similar in both conditions, but the fact that many more adolescents were referred from the intervention condition meant that overall, it accounted for majority of the eligible referrals into the host trial.

Our findings are contrary to most previous studies which have found no effect of mental health literacy interventions targeted directly at young people on their subsequent help-seeking, despite changes in knowledge and attitudes around mental health care in school settings.11-14 One exception was a recent US study by Lindow and colleagues, which
demonstrated positive effects of the Youth Aware of Mental Health Intervention in schools on help-seeking from peers and school staff (but not mental health professionals) for depression and suicidal thoughts, through an uncontrolled pretest/post-test design. Thus, our findings are unique in that they are based on a randomized controlled trial conducted in a low-resource context, where the intervention allowed for direct engagement of the service providers (counsellors) with the adolescents through a structured classroom sensitisation session.

The intervention was developed through multiple iterations and specifically designed to address the barriers to help-seeking that we had identified in earlier formative research. The intervention not only aimed to facilitate a better understanding regarding mental health problems and the nature of available support in the participating schools, but also offered an opportunity for adolescents to discuss potential concerns such as confidentiality and familiarise themselves with counsellors in the process. It is notable that the most common reasons for non-participation differed between the two trial conditions, such that a greater proportion of non-participants in the intervention condition reported an absence of mental health problems as the main reason for non-participation, as compared to those in the control condition, who were more commonly either not interested after being referred by another party (such as teachers), or were unable to read or comprehend the language of the intervention (which was the same as the medium of instruction in all the selected schools). These suggest that the classroom sensitisation activities might have impacted directly on the awareness of symptoms of mental health problems and the counselling interventions, as well as improved acceptability of help-seeking.

A rapid referral/assessment system allowed adolescents to self-nominate immediately following the classroom sensitisation session, or shortly thereafter for students who preferred more discreet methods. Students who met the mental health case criteria were in turn provided with one of the formats for the low-intensity problem solving intervention (of the host trial) within the subsequent week. These features established an efficient link between the sensitisation session, referral process and on-site treatment provision. Thus, a key characteristic of our study design which may explain our findings is that the sensitisation program was fully integrated with the counselling services in the school, in contrast to the other studies where the latter were often located in a separate setting.

The effects of the classroom intervention could have also been enhanced by context-specific factors. As there was no existing counselling service available in the schools, the unmet need for psychological support among these adolescents was high. The teacher-engagement component appeared to be low, despite the fact that two-thirds of teachers participated in the awareness meetings. This would help to explain the very small fraction of teacher-directed referrals. It is possible that a single meeting was not sufficient to identify and address potential barriers such as unfavourable attitudes of the teachers towards the school counselling programme or logistical reasons pertaining to lack of time and opportunities to know more about their students’ mental health. It is notable that an overwhelming majority
of the adolescents were self-referred across both the intervention and control conditions, as this indicates that the adolescents demonstrated personal agency in seeking psychological help. Potentially, cascading of information that was shared during the classroom session, with students who were absent, and also with students from the control condition (cluster contamination) may have also influenced the self-referral process. Similarly the role of peer behaviour within the classroom sessions and subsequently may have also influenced this process, and warrants further investigation. However, it cannot be ruled out that some students in need of psychological help may not have been referred at all, especially if they were unable to attend schools regularly.

About two-thirds of all the referrals in both conditions did not meet the mental health case criteria, reflecting pre-defined clinical thresholds for symptom severity, functional impact, and chronicity. In other words, while the addition of classroom sensitisation increased the total number of referrals and the total number of adolescents with mental health problems being referred, it was not more efficient than the whole-school sensitisation activities alone in increasing the proportion of referrals who needed mental health care. For a school-based programme, the implications of this finding on the resources involved, are two-fold. Firstly, the screening and assessment of large numbers of false positives may overwhelm the human resources allocated to the programme. Secondly, to ensure that school-based mental health services remain acceptable, the felt need of false positives will need to be addressed by incorporating appropriate early interventions. For example, pilot work prior to the current trial suggested that adolescents expected school counsellors to provide practical guidance for mitigating their life problems (commonly related to academic performance, romantic relationships and conflicts with peers and family). In this context, offering low-cost ‘bibliotherapy’ or a brief single-session psychoeducation intervention containing practical tips for coping with common problems may be considered. Additionally, the use of digital technology to promote self-screening among adolescents and providing guidance may be considered. Adolescents referred for counselling from the intervention condition of the sensitisation trial reported less severe internalising symptoms. Given that most referrals were self-referrals, this may be indicative of increased awareness of internalising symptoms in oneself, and an attitudinal shift towards a greater acceptability of formal help-seeking for symptoms. This contrasts with the likelihood that referrals for externalising problems are more likely to be made by other persons. However, this should be interpreted with caution considering the trial may not be powered enough to detect these differences.

This trial is among the largest evaluations of any demand-side intervention for adolescent mental health care globally. It is also among the few trials to evaluate actual help-seeking behaviour. Among its other strengths are the inclusion of a sufficient number of clusters that provide adequate power to detect the effects of the intervention. The study used an active control condition similar to many of the interventions tested in previous studies and employed minimal exclusion criteria for selecting the classes or referred adolescents for analysis. As the study was implemented in six government-run schools in low-income
localities of New Delhi, India, the results are generalizable to similar settings in the real world.

We also acknowledge several study limitations. Because of the short duration of the trial, we are unable to make inferences about the sustained effects of the intervention. That said, the declining secular trend for referrals following the intervention indicates the need for refresher sensitisation, perhaps once a semester/term. Although we did not assess economic costs, the brevity of the classroom sensitisation session and the fact that it was delivered by the same counsellor who subsequently treated eligible referrals (i.e., requiring no additional human resources) would imply a strong likelihood of cost-effectiveness.

CONCLUSION

In conclusion, our study shows that demand for mental health care can be increased substantially in low-resource secondary schools through a single classroom sensitisation session, delivered by a lay counsellor, employing contextually relevant content and format, in comparison to whole-school sensitisation activities alone. Such interventions should be twinned with school counselling services to enhance the effective coverage of mental health care for adolescents. Further research is needed to determine how school staff can be engaged more effectively to ensure wider and more efficient referral routes. Suitable interventions for adolescents who do not meet clinical thresholds also requires further investigation, particularly in settings where mental health sensitisation generates demand that exceeds capacity for individual face-to-face interventions.

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Contributors

RP drafted the report, which all authors reviewed and approved. AH, DM, PC and VP critically revised the content of the report. RP, AH, JR, PC, DM, and VP designed the trial. DM, RSh, KM, BB, and VP devised the intervention content and data collection instruments. RP, DM, RSa, and RSh were responsible for trial conduct. BB and RP were responsible for database design and management. RP and AH did the statistical analyses.

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Competing interests

We declare no competing interests.
 Patient and public involvement: Patients and/or the public were involved in the design, or conduct, or reporting or dissemination plans of this research. Refer to methods section for further information.

Patient consent for publication: Not required.

Ethics Approval: Ethics approval was obtained from the Institutional Review Boards of Sangath and Harvard Medical School.

Trial registration: The trial was pre-registered on ClinicalTrials.gov (NCT03633916) available at: https://clinicaltrials.gov/ct2/show/NCT03633916.

Data availability statement: Anonymised participant data, data dictionary and CRFs will be made available by 12 months after trial completion at: https://datacompass.lshtm.ac.uk/

Data will be shared after approval by the PI, following a reasonable request submitted through the above site.

The study protocol and statistical analysis plan are publicly available at:
https://clinicaltrials.gov/ct2/show/NCT03633916
https://clinicaltrials.gov/ProvidedDocs/16/NCT03633916/SAP_000.pdf


REFERENCES


