Promoting school climate and health-related outcomes: a cluster randomised controlled trial of the SEHER multi-component secondary school intervention in Bihar, India.

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ABSTRACT

Background: School environments affect health and academic outcomes. With increasing secondary school retention, promoting quality school social environments may offer a scalable opportunity to improve adolescent health and wellbeing.

Methods: We conducted a cluster-randomised trial to assess the effectiveness of a multi-component whole-school health promotion intervention (SEHER) with integrated economic and process evaluations among Grade 9 students of 74 government-run secondary schools in Bihar, India. Schools were randomised (1:1:1) to three arms: the SEHER intervention delivered by a lay counsellor (the SEHER *Mitra* (SM) arm), the SEHER intervention delivered by a teacher (Teacher as SM (TSM) arm), and a control arm in which only the classroom-based life-skills Adolescence Education Program. The primary outcome was "school climate" measured with the Beyond Blue School Climate Questionnaire (BBSCQ).

Findings: Students were assessed at the start and end of the academic year (June 2015-March 2016). We randomised 25 schools to each arm. One school subsequently dropped out of the TSM arm. The baseline survey included 13,035 participants, the end-point survey included 14,414 participants. The coverage of the intervention was high in both arms, but higher for some components in the SM-delivered schools. Participants in the SM-delivered intervention schools had substantially higher school climate scores than those in the control arm (BBSCQ baseline-adjusted mean difference (aMD) 7·57; 95%CI:6·11,9·03; ES=1·88 95%CI:1·44, 2·32; p<0·001) and the TSM-delivered intervention (aMD 7·57; 95%CI:6·06,9·08; ES=1·88 95%CI 1·43, 2·34; p<0·001). There was no effect of the TSM-delivered intervention compared with control (aMD -0·009; 95%CI:-1·53,1·51, ES=0·00; 95%CI:-0·45, 0·44). SM-delivered intervention schools had moderate to large improvements in the secondary outcomes of depression, bullying, violence, attitude towards gender equity, and knowledge of reproductive and sexual health compared with both the TSM and control arms. The additional cost of the SM-led intervention compared to the existing AEP was estimated as $3213 per school for SM ($15·0 per student) and $1390 per school for the TSM-led intervention ($7·4 per student).

Interpretation: The multicomponent whole-school SEHER health promotion intervention had substantial beneficial effects on school climate and health-related outcomes when delivered by lay counsellors, but no effects when delivered by teachers.

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RESEARCH IN CONTEXT

Evidence before this study

Our review included synthesis of international reviews on WHO's Health Promoting Schools and whole school interventions. Evidence indicates that whole-school interventions are more effective in achieving health and educational outcomes than classroom only or single intervention approaches. However, most of the studies contributing to this evidence are from higher income countries, mainly the United States of America and Europe. This raises the questions of feasibility and sustainability of the whole-school interventions in low- and middle-income countries. We supplemented this evidence with a review of evaluation studies on school-based health promotion in India. School-based health promotion interventions have generally been delivered by existing human resources such as teachers and healthcare providers. However, these interventions can compete with teaching duties and other commitments. The evaluation of our whole-school intervention in Goa (India) demonstrated that a lay school counsellor could be an effective delivery agent for such intervention.

Added value of this study

This study is the first report of findings from a low and middle-income country assessing the effectiveness and cost-effectiveness of a whole-school, multi-component intervention in secondary schools targeting school environments, delivered either by a lay counsellor or teacher, compared against government-run life skills classroom intervention alone. The intervention, when delivered by lay counsellors, showed large effects on improving school climate and a range of health-related outcomes including depressive symptoms, bullying, violence, attitude towards gender and knowledge of reproductive and sexual health, compared with both the life skills intervention and the teacher delivered intervention. There was no effect of the teacher-delivered intervention when compared with the life skills intervention.

Implications of all the available evidence

A whole-school, multi-component intervention targeting school environments delivered by lay counsellors in government-run secondary schools is acceptable, feasible, and effective for enhancing school climate and improving health-related outcomes. The findings of such intervention should be replicated in other contexts and the intervention could be scaled up as a relatively low-cost strategy to improve the adolescent health outcomes.

INTRODUCTION

Adolescence is accompanied by the emergence of health risks (e.g. substance misuse, violence, and sexual risk behaviours), many of which have important consequences for physical and mental health.[1] Effective action to reduce adolescent health risks would have profound implications for population health given their health effects both in adolescence and in later life.[2] Schools provide a promising platform for health promotion in adolescents because, as enrolment and retention increase progressively in most countries[3], they present an opportunity to reach the majority of adolescents. Furthermore, schools and peers form a central role in adolescents' social lives, thus influencing multiple health, psychosocial and educational outcomes. Improvements in education and features of the school environment can be associated with improvements in health outcomes.[4-5]

School climate[6] is an indicator of the quality of a school's environment "*…based on patterns of students', parents' and school personnel's experience of school life and reflects norms, goals, values, interpersonal relationships, teaching and learning practices, and organizational structures."* School climate can be considered a proximal determinant for risks associated with health (e.g. emotional wellbeing, violence, bullying and reproductive and sexual health).[7-10] For example, victims of bullying tend to report lower school connectedness and higher school dissatisfaction.[6] The World Health Organization's *Health Promoting Schools* (HPS) framework[11] emphasizes the development of healthy school policies, adaptation of school curricula on health education to promote skills development, and the reorientation of health services toward the prevention of illness and promotion of health. The creation of "a school climate in which trusting relationships, respect and consideration for others flourish and the promotion of opportunities which actively develop pupils' knowledge and skills, enabling them to exercise responsibility for their own and others' health" are inherent in the values of the HPS framework.[12] A recent systematic review of the effectiveness of the HPS framework reports positive effects on a range of outcomes including body mass index, tobacco use, being bullied, sexual health, physical activity, and dietary intake[13]. However, this review was focused on younger children in primary schools and only four studies were conducted with adolescent students in secondary schools. A review of reviews reported positive effects of multi-component school interventions for preventing teenage pregnancy, smoking, and bullying.[14] This review included a great variety of interventions and included less rigorous non-randomised studies. Most evidence is from high-income countries limiting the generalizability of this evidence to diverse global contexts where school ethos and resources differ vastly[13, 14]. Therefore, there is an existing knowledge gap regarding whole school intervention in

adolescents, particularly in low- and middle-income countries, which further enhances the relevance of our findings.[13, 14]

As in most other countries, school-based health promotion interventions in India have generally been delivered by teachers or healthcare providers, who are perceived as the least resource-intensive options. However, these interventions commonly compete with teaching duties and other commitments, compromising their delivery in contexts where teachers already consider themselves to be over-burdened.[15] A review of school health promotion interventions in India suggested that a lay counsellor could be an effective delivery agent for a multicomponent school-based health promotion intervention in low resource settings.[15] The SEHER Project designed a school health promotion intervention which sought to improve school climate and health-promoting behaviours, and to then evaluate its effectiveness and costs when delivered by two different personnel i.e. a new, low-cost, lay counsellor—called as SEHER *Mitra* (SM) and an existing teacher—called as Teacher as SEHER *Mitra* (TSM). The SEHER intervention is inspired by the Health Promoting Schools framework[14], and includes whole- school-, class- and individual-focused components to promote the health and wellbeing of adolescents in secondary schools.[15]

This paper describes the effectiveness of the SEHER intervention, delivered by these two providers, on school climate and a range of health-related outcomes (bullying, violence, depressive symptoms, attitudes towards gender equity and knowledge of reproductive and sexual health). Our hypotheses were that the SEHER intervention delivered by either type of provider would be superior to the currently available intervention (the class-room based life-skills Adolescence Education Program; AEP), and that the intervention delivered by a lay counsellor would be more effective but more expensive than the intervention delivered by a teacher.

METHODS

Trial design*:* A 3-arm cluster-randomised trial in government-run secondary schools that included Grade 9 students (Trial Registration Number NCT02484014; www.clinicaltrials.gov).

Setting: According to the 2011 census, Bihar is the third most populous state of India with a total population of over 103 million, with 22·5% of the population aged 10-19 years.[16] Out of 23 major Indian states in 2014, Bihar is ranked 21 in human development.[17] Nalanda district has a population of over 2·8 million, and a literacy rate of 66% (compared with 74% overall in

India).[16] The state Government's Department of Education (DoE) is the main education provider.

Sample: Of the 136 government-run secondary and higher secondary schools in Nalanda District of Bihar, 112 were eligible for inclusion in the trial based on three criteria: currently implementing AEP (see below); >100 students in Grade 9; and >4 employed teachers. Of the 112 eligible schools, 75 were randomly selected to participate in the trial. To ensure that the selected schools were representative of larger government secondary schools in the district, 68% of co-educational (63/93), 69% of girls-only (9/13), and 50% of boys-only (3/6) schools were selected. The schools were allocated in a 1:1:1 ratio using minimisation[18, 19], balancing on: type of school (only secondary or combined secondary and higher secondary school); school size (101-300, 301-600 or >600 students); and gender composition (co-educational; boys only; or girls only). The random allocation was carried out in April 2014 by an independent statistician at the London School of Hygiene and Tropical Medicine (LSHTM).

Prior to the trial, the intervention was pilot tested in the 50 schools randomly allocated to SM and TSM arms between April 2014 and March 2015.[15] There was one SM or one TSM per school. The pilot was conducted in the same schools as the main trial for two reasons: (1) the secondary schools start from Grade 9 in Bihar, which was our primary target group for the evaluation of the effectiveness, hence the trial participants would not have been exposed to the intervention; and (2) the pilot-testing helped in embedding the intervention into the school systems, which is an important pre-requisite for evaluation of complex interventions[20, 21]. Following the pilot, one school that had been randomly allocated to the TSM arm withdrew as the school administration thought that the content of the intervention was not appropriate for Grade 9 students, leaving a total of 74 schools in the trial (Figure 1). The trial was conducted during the academic year April 2015-March 2016. All the Grade 9 students present on the day of the baseline and/or end-point outcome assessment were eligible to participate in the study.

***Consent procedure*:** The trial was conducted with the Department of Education which provided written instructions to the selected schools to participate in the study. Further assent for participation in the study was obtained from all school principals prior to randomisation. Parents of Grade 9 students were invited to a meeting in each school at which the study was explained and any questions or concerns addressed. An information sheet was sent to each child's parent(s) informing them of the study and asking them to specifically inform the school if they did not wish their child to participate in the research. Thus, 'opt-out' consent[22] was obtained from the parents of all Grade 9 students for their child to participate in the outcome

assessment. All students participating in the outcome assessment were provided with detailed information about the trial prior to inviting them to participate. The student's assent was obtained by the outcome evaluators in a classroom setting in the presence of a School Management Committee member.

Interventions: The government-run Adolescence Education Program (AEP)[23] took place in all three arms. A trained teacher from school conducted classroom-based sessions on the process of growing-up, establishing positive and responsible relationships, gender and sexuality, and prevention of HIV, other sexually transmitted infections and substance use. These topics are delivered through 16 hours of sessions. The program has been implemented in 809 secondary schools of 9 districts in Bihar since July 2010.

The theory and development of the multi-component SEHER intervention has been described elsewhere.[15] This multi-component intervention was designed within the health promoting schools framework[11] and adapted elements from previous work using that framework led by the investigators, including a pilot study in Goa[24] and the Gatehouse Project[25]. The intervention's conceptual framework[15] emphasizes the importance of positive school climate, i.e. supportive relationships among school community members, a sense of belonging to school, a participative school environment, and student commitment to academic values. The intervention identifies four priority areas for action: promoting social skills among adolescents; engaging the school community i.e. adolescents, teachers and parents in school-level decision-making processes; providing access to factual knowledge about health and risk behaviours to the school community; and enhancing problem-solving skills among adolescents. Our intervention theory is based on the premise that school climate is the student's perceptions or experiences of the school's social environment which encompasses safety (i.e. social, emotional, and physical), teaching and learning (academic climate) and relationships (community climate). Physical safety refers to the degree to which violence, aggression and physical bullying are present; emotional safety includes availability of school-based mental health services and support; and social safety refers to the sense of feeling safe with other people. The teaching and learning climate refers to actual methods and instructional practices used by the teachers in the classrooms and how teachers communicate their expectations and give feedback to students. The community aspect of school climate refers to the quality of relationships within a school (i.e. relationships between teachers, students, and administrators) and includes sense of school connectedness, respect for diversity, and partnership with other members of the community. The intervention strategies were organized at three levels: whole school-, group- and individual-levels which are described in Box 1.

The TSMs were nominated by the school principals and were required to have a minimum of 5 years teaching experience in secondary schools, >15 years of service remaining, and not teaching the AEP curriculum. The trainee SMs were required to be aged >/=18 years, to have a Bachelor's degree, and to be fluent in the local language (Hindi). Trainee SMs were recruited by placing advertisements in local newspapers and selected based on their performance in a structured interview. The TSMs and SMs were trained separately in a week-long training, with an identical curriculum. This was followed up with in-service training through separate monthly group meetings for TSMs and SMs. Eight supervisors provided support and supervision to a combination of SMs and TSMs through three planned individual visits per month. The supervisors were required to have a Master's degree in Psychology, Sociology or Social Work and to have >2 years of experience of working with adolescents.

***Outcomes and assessment procedures**:* Baseline and end-point data were collected through a self-completed questionnaire administered at the start of the academic year (July 2015) and towards the end, 8 months later (March 2016), respectively. Supervised by the research team, students who were present on the day of the assessment at school completed the questionnaire in each survey using pen and paper.

The primary outcome was school climate, measured through an adapted version of the 28-item Beyond Blue School Climate Questionnaire (BBSCQ; Supplement 1).[26] The total BBSCQ score can range from 0 to 28, with higher scores indicating a more favourable view of the school climate. The BBSCQ was developed under the aegis of Beyond Blue Schools Research Initiative—a program guided by cognitive behavioural theories to facilitate the development of protective factors for mental health among adolescents in secondary schools in Australia.[27] The Items for the BBSCQ were selected from the following instruments: a) Quality of School Life[28]; b) Patterns of Adaptive Learning[29]; c) Psychological Sense of School Membership[30]; d) Manitoba School Improvement Program – Students' Relationship with their Learning Environment[31]; and e) Youth Participation Survey[32]. The resulting BBSCQ questionnaire was subsequently used in school-based RCTs to measure students' perceptions of the school climate in high income countries such as Australia[33] and the United Kingdom[34]. A factor analysis in a sample of 2049 students (aged 12-18 years) from three school-districts from a mid-western state in the USA supported four subscales relating to a) Supportive Teacher Relationships (labelled Teacher Support: 33·91% variance); b) Student Belonging (labelled Belonging: 8·53% variance); c) Student Participation in School Activities and Decisions (labelled Participative Environment 5·58% variance); and d) Personal Commitment to Academic Values (4·47% variance).[35] The primary rationale for selection of

this measure in SEHER was because it was the only available instrument with robust psychometric properties and prior use in secondary schools to measure the primary outcome which was the key variable in our theory of how the intervention affected health outcomes. The BBSCQ was systematically adapted for use in the study setting through translation and back-translation followed by cognitive testing of items with 60 students. The pilot testing of the SEHER outcome questionnaire (including the BBSCQ) was conducted in 15 purposefully-selected school, with a total of 3104 students (1448 boys and 1656 girls) enrolled in Grade 9. The Cronbach's alpha for the questionnaire total score was very high (α=0·91) suggesting high internal consistency. The Cronbach's alpha for the subscales were in the range of 0·82-0·89.

There is compelling body of evidence which points to the potential influence of the school climate on a range of adolescent health-related outcomes like mental health[36], violence[37], bullying[38] and sexual and reproductive health outcomes[39]. Based on this evidence, these secondary outcomes were selected and measured at baseline and 8-month follow-up:

- Depressive symptoms in the previous two weeks, measured with the Patient Health Questionnaire-9 (PHQ-9).[40] The total score can range from 0 to 27 with higher scores indicating more severe symptoms. It has been applied in previous surveys with school-going adolescents in India[41, 42] and shown acceptable internal consistency (Cronbach's alpha=0·83) among Indian adolescent students (14-18 years old)[41].
- The experience of bullying in the last 30 days was measured through the contextualized version of the Bullying Victimization Questionnaire.[43] The total score can range from 0 to 12, with higher scores indicating higher levels of victimization by peers.
- Violence - participants were classified as a perpetrator of violence if they reported either threatening to injure someone or that they had beaten someone leading to injury in the past six months[43]. Participants were classified as a victim of violence if they reported at least one experience of physical threat or violence within the past six months. Participants responded to close ended responses (Yes/No), which were combined for the two items each for violence victimization and perpetration.
- Attitude towards gender equity, measured with the 10-item adapted version of Gender Equitable Men Survey.[44] The total score can range from 0 to 10, with higher scores indicating a positive attitude towards gender equity.
- Knowledge of reproductive and sexual health measured with an 8-item questionnaire based on WHO's Illustrative Questionnaire for Interview-Surveys with Young People.[45] The total score can range from 0 to 8, with higher scores indicating better knowledge of reproductive and sexual health.

We assessed a range of exploratory behavioural outcomes: current smoking and chewing of tobacco, drinking alcohol, consumption of other substances, and sexual behaviour using a set of questions based on WHO's Illustrative Questionnaire for Interview-Surveys with Young People.[45] In addition, participants were asked to report the number of suicide attempts made. The reporting time-frame for these behavioural outcomes at the end-point was the period after the beginning of Grade 9. The end-point outcome assessments were supervised by field-workers recruited solely for this activity and who were masked to allocation status. All the authors, apart from the trial statistician (HW) and data manager (BP), were masked until the trial arms were unblinded in the presence of both the Trial Steering and Data Safety and Monitoring Committees on October 17, 2016.

***Process evaluation**:* Implementation indicators were obtained from monthly logs and counselling case records maintained by the SMs and TSMs, the field visit reports by supervisors, and students' self-reported coverage of intervention activities at the end-point.

***Sample size estimation**:* In a pilot study in 15 schools in Bihar, we observed that the mean score of the BBSCQ was 20·6 (SD 6·7) with an intra-cluster correlation (ICC) of 0·02. We powered the trial to be able to detect a sex-specific effect size of +/-0·2 (difference in means/SD) with approximately 90% power. Based on these assumptions, we recruited 75 schools (25 per arm) with a minimum cluster size of 115 students, to provide high power for the primary outcome (98% power overall; 88% for boys and 93% for girls). The mean PHQ-9 score observed at the pilot study was 6·3 (SD 5·8) with an ICC of 0·01 and the mean frequency of bullying was 0·86 (1·63) with an ICC of 0·03. Based on these scores, the trial sample was estimated to provide 80% power to estimate an effect size of +/-0·4 for depressive symptom severity, and an effect size of +/-0·2 for frequency of bullying.

***Statistical methods**:* The analysis plan was finalised by the Trial Steering Committee and the Data Safety and Monitoring Committee and uploaded on the National Institute of Health's clinical trials registry in July 2016. Statistical analyses were performed using Stata 14. Analyses were intention-to-treat. Baseline data were summarised by arm. Multiple imputation was used to impute items within a scale which did not have a response, assuming data were missing at random. The trial design was a repeated cross-sectional survey (before and after the intervention/control implementation) allowing us to assess the cluster level changes in outcomes for all students who were present on the day of the survey. All models included a random effect to adjust for within-school clustering, minimisation variables (school type, school size, and school nature), baseline cluster-level score of the outcome, and a-priori fixed effects

to account for age, gender, caste, marital status and parent's education and occupation.[46] For continuous outcomes, the intervention effect was estimated using linear regression and reported as adjusted mean differences (aMD) and effect sizes (standardised mean difference, SMD—standardised using the pooled SD from the whole sample at end-point survey) with 95% confidence intervals (95%CI). For binary outcomes, intervention effects were estimated as adjusted odds ratios (aOR) with 95%CI, using random effects logistic regression. Intervention effects were estimated overall and stratified by gender. For the economic evaluation, the costs associated with the introduction of the two SEHER interventions were estimated by adding the fixed costs of training (venue/per diem), furniture and supplies; recurrent personnel costs for SEHER *Mitra* and supervisors hired specifically for the intervention; and costs related to supervision of the intervention, both for offsite meetings and for onsite visits. All costs reported are in 2015 Indian Rupees and then converted to US dollars at exchange rate of $1 = INR 65 (average exchange rate during the study period). We did not conduct the cost-effectiveness analyses specified in the analysis plan as the SEHER investigators concluded that it would be difficult to interpret the results in the light of our primary outcome being a mediator of health outcomes, rather than a health outcome in itself. This decision was taken before the unblinding of the data.

Role of funding agency: The sponsors of the study (John D. and Catherine T. MacArthur Foundation, USA and the United Nations Population Fund's India Office) had no role in study design, data collection, data analysis, data interpretation, or writing of the paper.

Ethical approval**:** The trial protocol was approved by the Institutional Review Boards at the London School of Hygiene & Tropical Medicine (UK) and Sangath (India).

RESULTS

On average 292 (SD 209; Min-Max: 55-937) students were enrolled in Grade 9 in study schools during 2015-16. The average attendance in Grade 9, when compared to the officially registered number of students, was 50·7% across the trial period. We did not observe any change in attendance rates in the study schools during the academic year. Of the 21,550 students whose names were recorded in the school register at the start of the academic year in Grade 9 in the 74 schools, 13,035 (60·4%) students participated at baseline assessment (52·5% were boys). The difference between the numbers enrolled and who completed the baseline survey is because many students start school later than the enrolment date, were absent on the day of the survey, or were not truly being enrolled in these schools[47]. Altogether,

69 parents (43 from SM; 16 from TSM and 10 from control arm schools) informed the school before the baseline survey that they did not wish their child to participate in the study; a further 17 students declined participation in the baseline survey. A total of 14,414 (66·8%) students participated in the end-point survey (52·9% were boys; Figure 1). Twenty-three students declined participation in this assessment. The higher number of students in the end-point assessment reflects the fact that some students start school after the beginning of the year (and therefore would have missed the baseline survey). In total, 10202 participants (SM:3609; TSM3192 & C:3401) completed both the baseline and end-point assessments.

Baseline school characteristics were similar by arm, except that the schools in the TSM arm tended to be slightly smaller than in the other arms (Table 1). Participant characteristics were generally similar between arms (Table 2), except for caste and marital status. School size, caste and marital status were therefore included as covariates in effectiveness analyses (as specified *a-priori*). There were no differences in baseline measures of primary or secondary outcomes by arm. The mean age of the baseline participants was 13·7 years (SD 0·8) and the mean baseline BBSCQ score was 17·90 (SD 4·1). Supplement 2 shows the school and arm-wise mean BBSCQ score at baseline and end-point. At baseline, the ICC for BBSCQ score in 74 schools was 0·13 (95%CI 0·09, 0·18).

Implementation*:* SMs were younger than the TSMs (mean age (SD) 29·3 (5·1) vs 37·9 (6·0) years; p<0·001), while the TSMs were better educated than the SMs (100% vs 85% with a Master's degree; p=0·004). Based on the SM/TSM and supervisor records, a similar coverage of planned whole-school level intervention activities was observed in both the intervention arms (Table 3). However, the SM arm had received and addressed more speak-out box chits than the TSM arm. For the group-level activities, the SM arm also had higher coverage of peer group meetings. Based on the end-point student survey, 95% of the students in the SM arm, and 88% of the students in the TSM arm reported being aware of the SEHER intervention activities (p=0·38). Similar proportions of students in both arms reported participating in the monthly competitions and being aware about the counselling services. However, the SMs counselled nearly ten times the number of students than the TSMs (Table 3).

Effectiveness analyses: There was strong evidence that school climate scores at end-point were higher in the SM arm than in the control arm (mean BBSCQ=24·13 vs 17·75; aMD=7·57 95%CI:6·11, 9·03; ES=1·88 95%CI:1·44, 2·32; p<0·001). Participants in the SM arm had improved scores for all secondary outcomes compared with those in the control arm, i.e. a lower severity of depressive symptoms (mean PHQ-9=5·24 vs 6·51; p<0·001); lower self-

reported bullying scores (mean bullying=0·63 vs 1·44; p<0·001); lower self-reported violence victimization (11·9% vs 17·2%; p=0·002); improved attitudes towards gender equity (mean Gender Equitable Men's Survey =5·9 vs 5·5; p<0·001); improved knowledge of reproductive and sexual health (mean knowledge of RSH=3·8 vs 2·9; p=0·013); and lower violence perpetration (9·7% vs 13·9%; p=0·030; Table 4). There was no evidence of a difference between the SM arm and the control arm on any of the exploratory outcomes (Table 4). Most findings were consistent for both genders (Supplement 3 & 4) and participants who completed both baseline and end-point assessments (Supplement 5). There was strong evidence of effect modification by gender i.e. the intervention effects were stronger among female participants in the SM arm for school climate (p<0·001); depressive symptoms (p=0·002); attitude towards gender norms (p<0·001); violence victimization (p=0·018) and perpetration (p=0·006).

In contrast, there was no evidence of an intervention effect of the TSM arm versus the control arm on the primary outcome (mean BBSCQ=17·16 vs 17·75; aMD=-0·009 95%CI: -1·53, 1·51; ES=0·0 95%CI (-0·45, 0·44; p=0·99) and most secondary outcomes (Table 4). Participants in the TSM arm had worse outcomes for both self-reported violence victimization (22·8% vs 17·2%; p=0·043) and perpetration (18·2% vs 13·9%; p=0·051; Table 4). There was evidence that the TSM arm had lower incidence of self-reported tobacco chewing than the control arm (3·1% vs 5·5%; p=0·005), but there was no evidence of a difference between the SM and TSM arms on the other exploratory outcomes (Table 4). These findings were consistent for both genders (Supplement 3 & 4) and participants who completed both baseline and end-point assessments (Supplement 5).

There was strong evidence that participants in the SM arm had better school climate scores (aMD=7·57 95%CI:6·06, 9·08; ES=1·88 95%CI 1·43, 2·34; p<0·001) and secondary outcomes at end-point than those in the TSM arm (Table 4). There was weak evidence that the TSM arm had lower incidence of self-tobacco chewing than the SM arm (3·1% vs 4·9%; p=0·023), and there was no evidence of a difference between the SM and TSM arms on the other exploratory outcomes (Table 4). These findings were consistent for both genders (Supplement 3 & 4) and participants who completed both baseline and end-point assessments (Supplement 5). There was strong evidence of effect modification by gender i.e. the intervention effects were stronger among female participants in the SM arm for school climate (p<0·001); attitude towards gender norms (p<0·001); bullying (p=0·012); violence victimization (p<0·001) and violence perpetration (p<0·001) while the effect on depressive symptoms was stronger among male participants in the SM arm (p=0·003).

***Economic evaluation*:** The costs for administrative staff, office space and supplies, on-site supervisory visits, and intervention supplies were similar between the two arms (Table S3). The additional cost for the SM arm was due to salaries, benefits, communication charges and per diems for these counsellors. Offsite supervision costs included per diems provided to teachers for meetings. The additional cost of the SM-led intervention compared to the existing AEP was estimated to be $3213 per school for SM ($15·0 per student) and $1390 per school ($7·4 per student) for TSM (Supplement 6). In the context of the annual per student expenditure of $131·2 in Bihar in the year 2016-17[48], the total cost per student of the SM intervention is about 10% of the current budgetary allocation.

DISCUSSION

The SEHER trial estimated the effectiveness of a multi-component whole-school health promotion intervention on school climate and a range of adolescent health-related outcomes in government-run secondary schools in Bihar, India. We observed that the SEHER intervention delivered by lay counsellors (SM) was associated with large improvements in school climate. The intervention was also associated with evidence of substantial improvements on a range of secondary outcomes such as frequency of reported bullying, violence, depression symptom scores, attitudes towards gender equity and knowledge of reproductive and sexual health. In contrast, when the SEHER intervention was delivered by trained teachers (TSM), there was no evidence of effect on overall school climate nor on secondary outcomes. As hypothesized, the lay counsellor arm out-performed the teacher arm on almost all outcomes. The additional cost of the SM intervention amounted to about 10% of the current per capita expenditure in government schools in Bihar. Moreover, our findings were consistent for both genders, but we observed stronger intervention effects in female students.

Both the Lancet Commission on Adolescent Health and Wellbeing[49] and the Global AA-HA! implementation guidance[50] recommend schools as a setting for promoting health and wellbeing among adolescents. However, most of the evidence in support of these recommendations comes from high income settings[51, 52]. Our results add to this evidence base and are consistent with the literature on school connectedness, ethos, and environment[8, 10, 51-53] and with our hypothesis and intervention theory of change. For example, a systematic review of 10 studies, all from the USA and the UK, found that five evaluations of interventions aiming to develop a stronger sense of community and/or improve relationships between staff and students were associated with potential benefits particularly on violence and aggression; two trials of interventions enabling students to advocate changes in school catering and physical activity reported benefits for physical activity (but not diet); and three evaluations of

improvements to school playgrounds offered weak evidence of effects on physical activity.[51] Notably, our findings are consistent with those of the INCLUSIVE trial in the UK which evaluated a whole- school intervention with a similar theoretical framework aiming to modify the school environment, and reported statistically significant reduced rates of bullying and improvements on a range of secondary outcomes including various measures of substance use and of mental health and wellbeing (Bonell et al, companion paper).

The absence of a comparable effect in the TSM-delivered SEHER intervention requires further explanation. Firstly, the higher coverage of some of the intervention activities by SMs might have partially explained the superior effects of this arm. Secondly, the SM was a full-time staff member dedicated to facilitating the program in the school. On the other hand, the TSM already had a primary responsibility of teaching the regular syllabus, in addition to ancillary academic tasks (e.g. marking tests and exams), non-academic tasks (preparation of electoral rolls, electoral booth operations, etc.), and administrative tasks (preparation and submission of monthly attendance reports and management of incentive schemes for students). Thus, the quality of the SM-delivered interventions may have been superior. Finally, the SM's primary role as a facilitator of the intervention was clear to them as well as to the school community. In contrast, the TSMs were performing the role of the facilitator of the intervention in addition to their primary role of a teacher. This might have led to a less effective intervention if the TSMs were not able to switch between roles effectively (for example, from the orthodox instructional pedagogical stance characteristic of teachers in this context to the collaborative, participatory stance required for the intervention); similarly, students may also have found it difficult to adjust to this switch in roles of the teacher and thus engaged less with the TSM-delivered intervention.

The primary limitations of the study were that we used self-report questionnaires to assess our outcomes. Even though all the measures we used had been previously tested in similar populations or were systematically translated and pilot tested by our team, there is still a potential for measurement bias. We were unable to use any objective tests of adolescent health because there were none which had been validated for the outcomes we hypothesized. A second limitation is that there were a large number of students registered in the schools but who never or rarely attended school; we are unable to determine with certainty why there was such a large gap, or to evaluate the generalizability of our findings to these missing students.

Many health and education problems among school children in India and other low- and middle-income countries are complex and require a well-coordinated plan and actions by multiple stakeholders. This study provides compelling evidence that the delivery agent for a

health promoting intervention matters greatly: thus, while a multi-component intervention delivered by an additional, low-cost, staff member improved school climate and a range of health outcomes, the same intervention when delivered by an existing teacher, with the same intensity of training and supervision, showed no effect. This may be due to the pedagogical culture in government-run education system in Bihar and hence, require further investigation in different education settings across India as well as in other low- and middle-income countries. Importantly, another intervention—Girls First Resilience Curriculum, aimed at building resilience and sharing health information among rural adolescent girls in government schools, also used an external human resource (local women as group facilitators) in Bihar, and was effective in improving emotional resilience, self-efficacy, social-emotional assets, psychological wellbeing, and social wellbeing.[54, 55]

This study provides evidence that lay counsellors can implement whole school health promotion interventions with impressive results. We have nested a qualitative study (conducted before the trial was unblinded) to explore the processes of and challenges in the intervention delivery, and to examine the intervention components and school-level factors that facilitated or impeded the intervention delivery. We expect that the findings of the qualitative study will help illuminate the processes that might explain the differences between two intervention arms and the greater intervention effects observed in girls. We have continued the SEHER intervention for a second year and will administer the outcome survey to the existing cohort as well as to a new cohort of Grade 9 students to test the dose-response effects in the first cohort and to test the consistency of effects in the second cohort. We will also assess the mediating effects of school climate at the end of one year on outcomes at the end of a second year of exposure. These analyses may enhance our confidence in the findings we report in this paper.

Future research should focus on the evaluation of the scaling up of the SEHER intervention in different settings (e.g. in states with a stronger educational infrastructure) or delivery of the intervention by existing human resources such as Adolescent Friendly Health Centre counsellors, Auxiliary Nurse Midwives and Accredited Social Health Activists linked to school health services under India's national adolescent health program (the Rashtriya Kishor Swasthya Karyakram). As school retention increases with ever increasing proportions of students in secondary schools, the SEHER intervention delivered by a lay counsellor offers a relatively low-cost model to improve school climate and promote a range of health outcomes in adolescents in low resource settings.

Contributors

SS drafted the manuscript and all authors reviewed and approved it. SS,HAW, BV, DR, GP, and VP were responsible for the design of the trial; SS, PK, RG, DR, GP, and VP were responsible for intervention delivery and data gathering instruments; SS, HAW, BP,AS, RG, GP, and VP were responsible for trial conduct; AS, BP, and SS were responsible for database design and management; and SS, HAW, BV, GP, DR, and VP were responsible for analyses and interpretation of the results.

Declaration of interests

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