

Impact of a theoretically based sex education programme (SHARE) delivered by teachers on NHS registered conceptions and terminations: final results of cluster randomised trial

M Henderson¹, D Wight¹, G M Raab², C Abraham³, A Parkes¹, S Scott⁴, G Hart⁵

EDITORIAL by Stammers

¹Medical Research Council Social and Public Health Sciences Unit, Glasgow G12 8RZ

²School of Nursing Midwifery and Social Care, Napier University, Edinburgh EH4 2LD

³School of Social Sciences, University of Sussex, Brighton BN1 9SN

⁴Faculty of Humanities and Social Sciences, University of Keele, Keele ST5 5BG

⁵Centre for Sexual Health and HIV Research, University College London, London WC1E 6AU

Correspondence to: M Henderson marion@msoc.mrc.gla.ac.uk

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ABSTRACT

Objective To assess the impact of a theoretically based sex education programme (SHARE) delivered by teachers compared with conventional education in terms of conceptions and terminations registered by the NHS.

Design Follow-up of cluster randomised trial 4.5 years after intervention.

Setting NHS records of women who had attended 25 secondary schools in east Scotland.

Participants 4196 women (99.5% of those eligible)

Intervention SHARE programme (intervention group) v existing sex education (control group).

Main outcome measure NHS recorded conceptions and terminations for the achieved sample linked at age 20.

Results In an "intention to treat" analysis there were no significant differences between the groups in registered conceptions per 1000 pupils (300 SHARE v 274 control; difference 26, 95% confidence interval -33 to 86) and terminations per 1000 pupils (127 v 112; difference 15, -13 to 42) between ages 16 and 20.

Conclusions This specially designed sex education programme did not reduce conceptions or terminations by age 20 compared with conventional provision. The lack of effect was not due to quality of delivery. Enhancing teacher led school sex education beyond conventional provision in eastern Scotland is unlikely to reduce terminations in teenagers.

Trial registration ISRCTN48719575.

INTRODUCTION

Several overviews have concluded that sex education can have beneficial effects on sexual behaviour,¹⁻³ although earlier reviews relied almost entirely on quasi-experimental studies. More rigorous evaluations of school sex education have been less likely to find positive outcomes.^{4,5} Experimental evaluations often have considerable attrition from the intended target group or rely on self reported behavioural outcomes, or both, which has potential for presentational bias.⁵ We are aware of only one published randomised trial of school sex education that uses anything other than self reported data to evaluate effectiveness.⁶

Between 1993 and 1996 a sex education programme delivered by teachers (SHARE) was

developed for 13-15 year olds in Scotland; this was evaluated between 1996 and 1999 in a cluster randomised trial. Interim outcomes at six months after the intervention (average age 16 years 1 month) showed that, compared with those receiving conventional sex education, SHARE improved knowledge and the quality of sexual relationships but had no impact on reported sexual or contraceptive behaviour.^{7,8} At this age, however, only a third of the sample reported having sexual intercourse and follow-up data were obtained from only 70% of the original sample.

We report on the impact of the intervention on conceptions and terminations by age 20 (4.5 years after the intervention) as recorded by the NHS. By linking to NHS data for the whole cohort of young women we have outcomes that are not subject to reporting biases and much less affected by sample attrition than outcomes from self reported data.

METHODS

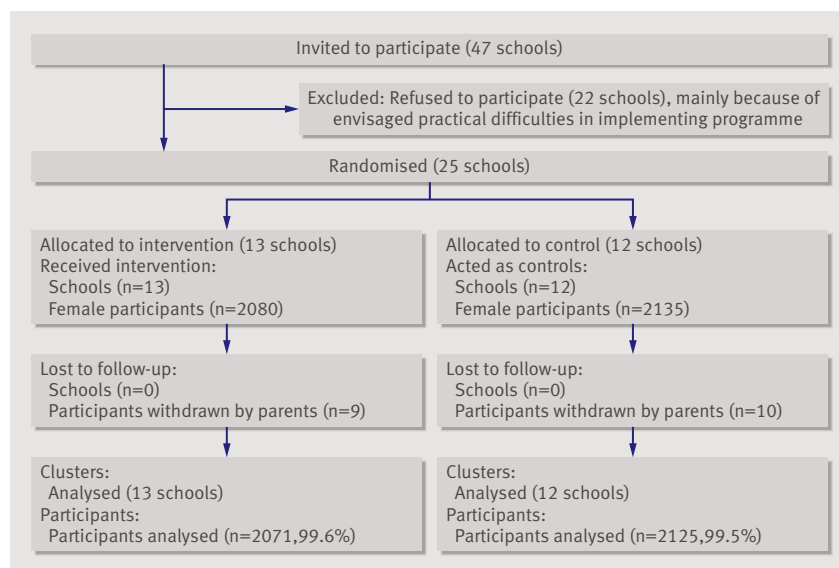
The intervention programme

The SHARE (sexual health and relationships) programme is a five day training programme for teachers plus a 20 session pack: 10 sessions in the third year of secondary school (at ages 13-14) and 10 in the fourth year (at ages 14-15).⁹ It is intended to reduce unwanted pregnancies, reduce unsafe sex, and improve the quality of sexual relationships. The total cost of training each teacher was about £900 (€1343, \$1684), including a copy of the package.

The programme combines active learning, information leaflets, and the development of skills to negotiate sexual encounters, handle condoms, and access services, primarily through the use of interactive video but also role playing.¹⁰

Conventional education

In the 12 control schools sex education for third and fourth years varied from seven to 12 lessons in total, primarily devoted to provision of information and discussion. Only two control schools routinely demonstrated how to handle condoms, and none



Flow of clusters and female participants through the trial

systematically developed negotiation skills for sexual encounters. The cost of conventional education varied, starting from about £20. Few teachers had more than one day's training, costing about £180 a day. Some received none or only a few hours' training.

Recruitment and randomisation of schools

We invited all non-Roman Catholic state schools within 15 miles of the main cities in Tayside and Lothian regions to participate (figure).

Incentives offered were the full cost of the teacher training or, for schools allocated to the control arm, the equivalent (£2000-£2500) to spend on personal and social education (PSE) but not on sex education. A balanced randomisation took into account socioeconomic characteristics of the school populations, the proportion of pupils staying at school beyond the age of 16, school size, and local sexual health services, among other factors. One of these was the quality of school sex education before the trial.

We calculated the sample size to have 80% power to detect a 33% decrease in the cumulative termination rate (identified as the main outcome) from after the delivery of the programme in intervention schools to age 20 with a two sided *t* test. A design effect of 1.5 was assumed.

Follow-up data and statistical analysis

The information services division of the NHS in Scotland holds data on all births, stillbirths, miscarriages, and terminations in Scotland.¹¹ We submitted records for the women in the trial for linkage to the NHS data. The division provided results aggregated by school, cohort, status as early or late school leaver, and parents' socioeconomic status only for those who stayed on at school. Confidentiality constraints did not allow further disaggregation. The division also provided aggregated data on the ages at conception for all linked events.

We submitted records for 4196 women (2109 from the first cohort and 2087 from the second) to the division, and 922 (22%) linked to one or more conceptions with an estimated date between the pupils' 15th and 20th birthdays. By their 15th birthday, most pupils had received the first year of the programme and at least a proportion had received the second year.

To be able to assess the impact of deprivation at school level and to adjust for it in the analysis, we developed a school level socioeconomic measure based on several of the school level indicators used to balance the randomisation at baseline (see bmj.com).

Rates of conceptions and terminations were calculated from the events identified at linkage. We used a restricted randomisation test¹² that allows for the balance imposed by the design to compare the rates between the programme and control arms of the trial. Analyses were adjusted for the individual factors (school leaver status and social class) and the socioeconomic factor at school level. Further model based analyses were carried out of the two binary outcomes (any conception and any abortion) to compute design effects and intracluster correlations.

RESULTS

Schools were well balanced on characteristics of individual pupils at baseline.⁷ At age 14, the sample was representative of young people in Scotland in terms of socioeconomic status and family structure according to the 1991 census. The overall observed rates of 287 per 1000 for conceptions and 119 per 1000 for terminations compare with figures for all Scotland of 319 per 1000 for conceptions and 127 per 1000 for terminations for the same age group over the same time span.

There were large differences in rates of conceptions and terminations between the schools. The termination rate did not follow the same pattern as the conception rate: the proportion of conceptions terminated was higher for those schools with low overall conception rates. The conception rate was strongly related to socioeconomic factors, whereas the relation between socioeconomic factors and terminations was somewhat weaker.

SHARE pupils had slightly higher rates of conceptions and terminations than the control pupils, but differences were not significant (table). The model based analyses for the binary outcomes confirmed the lack of evidence of differences by treatment arm. Approximate intracluster correlations¹³ were 0.04 for any conception and 0.005 for any abortion, corresponding to design effects of 8 and 2, respectively. After adjustment for covariates the correlations were reduced to 0.003 and 0.002, both yielding design effects under 1.5.

DISCUSSION

This rigorous evaluation of a sex education programme delivered by teachers did not find any benefit on rates for conception or termination compared with normal

Rates of terminations and conceptions in teenagers per 1000 pupils and rates of any termination and conception per 1000 pupils* according to allocation to teacher delivered sex education (SHARE) or existing sex education (control).† Figures are differences between SHARE minus control with 95% confidence intervals and P values‡

	Termination rate/1000	Conception rate/1000	Any termination/1000 women	Any conception/1000 women
SHARE schools (n=2125)	126.6	300.2	108.9	222.6
Control schools (n=2071)	112.0	273.8	104.3	216.8
Unadjusted	14.6 (-13.1 to 42.2), P=0.32	26.4 (-33.3 to 86.2), P=0.40	4.5 (-18.0 to 27.0), P=0.71	5.7 (-34.2 to 45.0), P=0.87
Adjusted for school socioeconomic measure	15.3 (-11.5 to 42.2), P=0.28	30.4 (-12.8 to 73.6), P=0.18	5.1 (-17.1 to 27.3), P=0.67	15.3 (-20.5 to 37.2), P=0.57
Adjusted for school socioeconomic measure and leaver/social class measure	15.7 (-10.7 to 42.1), P=0.26	31.9 (-16.1 to 79.9), P=0.22	5.6 (-16.0 to 27.2), P=0.67	9.7 (-21.8 to 41.2), P=0.54

*Includes live births, stillbirths, therapeutic terminations, and miscarriages.

†Some pupils have ≥1 termination/conception. "Termination rate per 1000" and "conception rate per 1000" show rates for terminations and conceptions even when some of these events belong to same woman. "Any termination per 1000 women" and "any conceptions per 1000 woman" show rates for "any" women experiencing these events.

‡Restricted randomisation test, two sided.

sex education. A balanced randomisation ensured optimal matching of control and intervention arms, and linkage to NHS data on conceptions and terminations ensured no reporting bias and only minimal attrition from the original eligible sample. There may have been a small level of attrition across both arms because of women attending private health care (less than 2% of terminations), moving from Scotland during the study period (1% average annual migration out of Scotland), or having their terminations in England or Wales (2.7% of all the terminations performed on Scottish residents). The comparison between this study and national rates suggests that the linkage was broadly effective.

We followed up all the girls in the sample to the age of 20 and found no significant differences between the two groups in levels of conceptions and terminations. By the age of 20 some of the conceptions may have been planned; we assume these would be balanced across both arms of the trial. Further analysis indicated that our results cannot be explained by differential quality of delivery of the programme.

WHAT IS ALREADY KNOWN ON THIS TOPIC

Overviews have suggested that sex education delivered by teachers can delay age at first sexual intercourse and reduce unsafe or unprotected intercourse

More rigorous evaluations, however, generally have less positive outcomes and, to date, few evaluations have used objective measures of sexual risk taking

WHAT THIS STUDY ADDS

Enhanced sex education (SHARE) improved knowledge and reduced regret but did not reduce conceptions or terminations compared with conventional sex education. High quality sex education should be continued, but to reduce unwanted pregnancies complementary, longer term interventions that address socioeconomic inequalities and the influence of parents should be developed and rigorously evaluated

The lack of impact on the primary sexual outcomes is in keeping with results of other rigorous evaluations⁵ but not all.¹⁴ The strong relation between conceptions and social deprivation, and the inverse relation between rate of conceptions and proportion of those conceptions that were terminated, mirror findings for the United Kingdom as a whole.¹¹

We have previously published interim outcomes from this study, based on self reported data from both boys and girls at median age 16 years 1 month (six months after the intervention).⁷ At this age, pupils and teachers preferred the SHARE programme compared with conventional sex education. It also increased pupils' practical knowledge of sexual health, reduced regret of first sexual intercourse with most recent partner (all significant), and had small but significant beneficial effects on beliefs about alternatives to sexual intercourse and intentions to resist unwanted sexual activities and to discuss condoms with partners.^{7,8} These results contributed to the Scottish Executive's decision to continue to use the SHARE programme in Scottish schools.¹⁵ The programme did not, however, affect reported sexual experience or use of contraception.⁷

A cluster randomised trial in England of pupil led sex education compared with conventional teacher led sex education (RIPPLE study) collected similar, but only self reported, outcomes. It found that by the age of 16, significantly fewer girls in the peer led group reported having intercourse compared with the conventional education group (35% *v* 41%), but proportions were similar for boys (33% *v* 31%). The proportions of pupils reporting unprotected first sexual intercourse did not differ for girls or boys.¹⁶

The potential for whole class sex education delivered by teachers to influence young people's behaviour might have already been reached by conventional provision. Effective programmes may have to address fundamental socioeconomic divisions in society, and strategies involving parents.^{17,18} To date, the most promising programmes have greater scope and duration than school sex education and aim to change future life opportunities for young people.^{2,19}

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Effect of isoniazid prophylaxis on mortality and incidence of tuberculosis in children with HIV: randomised controlled trial

Heather J Zar¹, Mark F Cotton², Stanzi Strauss¹, Janine Karpakis², Gregory Hussey¹, Simon Schaaaf², Helena Rabie², Carl J Lombard³

EDITORIAL by Colebunders

¹School of Child and Adolescent Health, Red Cross Children's Hospital, University of Cape Town, South Africa

²Department of Paediatrics and Child Health, Tygerberg Children's Hospital, Stellenbosch University, South Africa

³BioStatistics Unit, Medical Research Council, South Africa

Correspondence to: H Zar hzar@ich.uct.ac.za

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ABSTRACT

Objectives To investigate the impact of isoniazid prophylaxis on mortality and incidence of tuberculosis in children with HIV.

Design Two centre prospective double blind placebo controlled trial.

Participants Children aged ≥ 8 weeks with HIV.

Interventions Isoniazid or placebo given with co-trimoxazole either daily or three times a week.

Setting Two tertiary healthcare centres in South Africa.

Main outcome measures Mortality, incidence of tuberculosis, and adverse events.

Results Data on 263 children (median age 24.7 months) were available when the data safety monitoring board recommended discontinuing the placebo arm; 132 (50%) were taking isoniazid. Median follow-up was 5.7 (interquartile range 2.0-9.7) months. Mortality was lower in the isoniazid group than in the placebo group (11 (8%) v 21 (16%), hazard ratio 0.46, 95% confidence interval 0.22 to 0.95, $P=0.015$) by intention to treat analysis. The benefit applied across Centers for Disease Control clinical categories and in all ages. The reduction in mortality was similar in children on three times a week or daily isoniazid. The incidence of tuberculosis was lower in the isoniazid group (5 cases, 3.8%) than in the placebo group (13 cases, 9.9%) (hazard ratio 0.28, 0.10 to 0.78, $P=0.005$). All cases of tuberculosis confirmed by culture were in children in the placebo group.

Conclusions Prophylaxis with isoniazid has an early survival benefit and reduces incidence of tuberculosis in children

with HIV. Prophylaxis may offer an effective public health intervention to reduce mortality in such children in settings with a high prevalence of tuberculosis.

Trial registration Clinical Trials NCT00330304.

INTRODUCTION

Tuberculosis and HIV are dual pandemics in children in sub-Saharan Africa. Tuberculosis accelerates the course of HIV, increasing morbidity, mortality, and the frequency of opportunistic infections,¹⁻⁴ and is responsible for a major proportion of mortality.⁵ Prevention of tuberculosis in children with HIV through prophylaxis with isoniazid may be effective in reducing mortality in areas with a high prevalence of tuberculosis. In studies of adults with HIV prophylaxis with isoniazid significantly reduced the incidence of tuberculosis.⁶⁻⁸ The effect of such prophylaxis in children is unknown. We investigated the effect of isoniazid prophylaxis on mortality in children with HIV living in an area with high tuberculosis prevalence.

METHODS

We carried out a prospective double blind placebo controlled trial of isoniazid versus placebo given with co-trimoxazole either daily or three times a week in children with HIV in two centres in Cape Town, South Africa. The study started in January 2003; the placebo arm of the study was ended on 17 May 2004 on the recommendation of the data safety monitoring board.