2016

Efficacy of infant simulator programmes to prevent teenage pregnancy: a school-based cluster randomised trial in Western Australia

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This article was originally published as:
Brinkman, S. A., Johnson, S. E., Codde, J., Hart, M. B., Straton, J., Mittinty, M. N., & Silburn, S. R. (2016). Efficacy of infant simulator programmes to prevent teenage pregnancy: a school-based cluster randomised trial in Western Australia. *Lancet, 388* (10057), 2264-2271.
http://doi.org/10.1016/S0140-6736(16)30384-1
Original article available here:
http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)30384-1/abstract

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Abstract

Background: Infant simulator-based programmes seek to prevent teenage pregnancy. They are utilised in western and developing countries but, despite growing popularity, there is no published evidence of their long-term impact. The aim of this trial was to investigate the effect of such a programme, the Virtual Infant Parenting (VIP) Programme, on the pregnancy outcomes of birth and induced abortion.

Methods: Fifty-seven of 66 eligible schools (86%) in Perth, Western Australia enrolled in the pragmatic clustered (by school) randomised trial (ISRCTN24952438) with even randomisation to the intervention and control groups. Between 2003 and 2006, the VIP programme was administered to 1,267 girls in the intervention schools, while 1,567 girls in the control schools received the standard health education curriculum. Participants were aged 13-15 years and were followed until age 20 via data linkage to hospital medical and abortion clinic records. Log binomial and Cox proportional hazards regression was used to test for differences in pregnancy rates between study groups.

Findings: Compared to girls in the control group, a higher proportion of girls in the intervention group recorded at least one birth (7.6%, n=97; 4·3%, n=67) or at least one abortion as the first pregnancy event (8.9%, n=113; 6.4%, n=101). After adjustment for potential confounding, the intervention group had a higher overall pregnancy risk (RR = 1·36, 95% CI 1.10–1·67, p=0.003) compared to the control group. Similar results were obtained using proportional hazard models (HR = 1.35, 95% CI 1.10–1·67, p=0·016).

Interpretation: The infant-simulator based VIP Programme did not achieve its aim of reducing teenage pregnancy. Girls in the intervention group were more likely to experience a birth or an induced abortion than those in the control group before turning 20 years of age.

Funding: The Health Promotion Research Foundation of Western Australia (Healthway), Lotteries WA, the Western Australian Department of Education and Training and the Western Australian Department of Health.

Research in context

Evidence before this study

There is limited and contradictory evidence as to whether health promotion or education programmes are able to reduce teenage pregnancy rates. A 2016 Cochrane review of 53 randomised controlled trials concluded that programmes with a combined educational and contraceptive component appear to reduce unintended pregnancy but that evidence on measures such as initiation of sexual intercourse, use of birth control, abortion, childbirth, and sexually transmitted disease is not conclusive. Major electronic databases (including, but not limited to, PubMed, ERIC, PsychINFO and Web of Science) were searched at regular occurrences throughout the study and most recently in February, 2016. These searches were complemented by manual searching of reference lists and interrogation of grey literature including automated searches for “infant simulators”, “baby think it over” and “teenage pregnancy prevention” throughout the study period. No additional randomised trials were identified which were not included in the Cochrane review.

Added value of this study

This study presents the first randomized controlled trial evaluating the efficacy of infant simulator programs on teen pregnancy. The results of this trial indicate that this is likely to be an ineffective use of public resources aimed at teenage pregnancy prevention.

Implications of all the available evidence

Over 89 countries are utilising infant simulators in schools. The results of this trial indicate that this is likely to be an ineffective use of public resources aimed at teenage pregnancy prevention.

Introduction

The social and financial cost to the individual and to society of unintended pregnancy in teenagers is substantial.[1,2] There is limited and contradictory evidence as to whether health promotion or education programmes are able to reduce teenage pregnancy rates. Reviews limited to the United States describe multifaceted programmes that have been successful in changing sexual behaviour, highlighting the importance of addressing the non-sexual antecedents of teenage pregnancy but also the diversity of programs in varying contexts that have demonstrated effectiveness [3, 4, 5] A 2016 Cochrane review of 53 randomised controlled trials concluded that programmes with a combined educational and contraceptive component appear to reduce unintended pregnancy but that evidence on measures such as initiation of sexual intercourse, use of birth control, abortion, childbirth, and sexually transmitted disease is not conclusive.[6] The review highlighted methodological issues, such as self-report bias, short term follow-up and analyses neglecting randomisation. Notably, randomised trials of evidence-based programmes, especially in schools, rarely measure pregnancy as an outcome. [3,4,5,6]

A comparison of teenage pregnancy rates (combined births and induced abortions) within countries of the OECD shows Australia to be sixth highest in a list of 21 countries[1] Like those in other countries, many Australian health services, education systems, and non-government agencies have turned to infant simulator-based programmes in a bid to reduce teen pregnancy rates. Such programmes typically include a series of education sessions in combination with 'care' for an infant simulator—a life-like model that is programmed to replicate the sleeping and feeding patterns of an infant. The infant simulator is an example of an approach used in persuasion technology or captology.[7] The use of infant simulator-based programmes is widespread in developed countries [8] and are expanding into low- and middle-income countries.[9] Despite their popularity there is limited evidence to suggest that such programmes are effective. In addition the simulators are costly- approximately AU$1,200 each when this trial began in 2003.

Previous evaluations of infant simulator-based programmes have been limited to measuring short-term change in knowledge, attitudes, beliefs, and self-reported behaviours. A recent comprehensive literature review found 20 studies on infant simulators with a mean sample size of 365 (range 48–1,829).[10] Most studies reviewed found that the infant simulators had no effect on knowledge levels, and those studies that did show improvements concluded that the infant simulator was only effective in raising knowledge levels if coupled with a strong educational

component. Studies investigating the impact of infant simulators on attitudes and beliefs about teenage pregnancy also report mixed results. Herrman and colleagues found some evidence that infant simulators changed teen attitudes about the costs of teen parenting, impacts on social life, personal freedom, and commitment required for parenting.[10] However, they also reported five studies that showed no change in attitudes or beliefs about teenage pregnancy. Studies on behaviour change were based on self-reported outcomes and almost exclusively asked teens about their intentions to become pregnant or have children, rather than measuring actual behavioural outcomes (such as sexual activity or pregnancy). The majority of studies reviewed showed that the infant simulators produced no change in behavioural intention. Herrman and colleagues concluded that there was inconclusive support for infant simulators and that there was a substantial need for a randomised, controlled trial to evaluate their efficacy.[10]

The aim of this trial was to investigate the impact of a pregnancy prevention programme (with an infant simulator as a component of the programme), the Virtual Infant Parenting (VIP) Programme, on objectively measured births and induced abortions throughout the teenage years.

Methods

Virtual Infant Parenting (VIP) Programme

The Virtual Infant Parenting (VIP) Programme is a school-based pre-conception programme. It is a Western Australian adaptation of the US programme created by 'Realityworks' and often referred to as 'Baby Think It Over'. In 1997 the VIP Programme was piloted in Western Australia with 300 'high-risk' female participants aged 14–15 years. The findings from the pilot study showed the programme to be effective in establishing a positive partnership between health care providers and adolescents.[11,12] Post intervention follow-up questionnaires at one week and three months showed participants to be enthusiastic about the programme, to have good levels of programme recall and attitudes inclined towards delaying pregnancy. Following the original pilot, the programme continued to be implemented by various Area Health Services and area-based general practice networks, with high level support reported from parents, teachers, and general practitioners.[13]

The VIP Programme sought not only to delay pregnancy in the teenage years but to improve knowledge and awareness of pre-conceptual health issues. It was implemented by school health

nurses over six consecutive days with four main components to the curriculum: four educational sessions in small groups of four to five girls, a comprehensive reference workbook, a video documentary of teenage mothers talking about their own experiences, and caring for the infant simulator from the last school period on Friday afternoon through to the first school period on Monday morning.

Evaluation design

The study design for the VIP evaluation involved a pragmatic, school-based, cluster randomised controlled trial with longitudinal objective assessment of pregnancy outcomes for all trial participants up to the age of 20, by means of data linkage to the birth register, hospitalisation, and abortion clinic records. Although the VIP intervention was targeted at an individual level, a clustered design was considered necessary as the programme was delivered at a school level, and in order to limit contamination. Control students received standard school curriculum. This manuscript follows the guidelines for the reporting of randomised controlled trials, and the extension of the CONSORT statement for cluster randomised trials and for pragmatic randomised controlled trials.[14,15] Full details are described in our study protocol.[16]

Recruitment

Recruitment commenced in February 2003 and was completed in May 2006. All government and non-government high schools in the Perth metropolitan area (excluding Catholic schools) were invited to participate in the study. Overall, 57 of the 66 invited schools enrolled in the programme (86%). The government school participation rate was higher (52 of 55 or 95%) than that for non-government schools (6 of 12 or 50%) due to the limited availability of school health nurses for programme delivery in non-government schools. Twenty-nine schools were randomly allocated to the control group, and 28 to the intervention arm of the study.

Randomisation and masking

Randomisation using a table of random numbers without blocking, stratification, or matching was performed by a researcher blinded to the identity of the schools. After initial recruitment one government school was excluded from the intervention group due to non-adherence to the study's student recruitment protocol.

Individual participants were females aged 13–15 years of age (Year 9 or 10) at the time of recruitment. All eligible students were invited to participate in a prospective study of teenage pre-conceptual health, knowledge, and behaviour. Informed, written consent was obtained from both participants and their parents/guardians to access individual medical records to detect any births or induced abortions until the participants reached the age of 20 years. For the intervention group, only five students per school per week could participate in the programme due to the availability of both school health nurses and infant simulators. The program was implemented independently from the school curriculum. After consent was received, participants were randomly assigned into groups of five, and allocated to a week of the school year in which the intervention was conducted. Recruitment and administration of the programme thus continued over three years, with the study active for two years in most schools. Despite best practice recruitment procedures, incentives, and significant time and resources, the participation rates at the student level remained relatively low due to the consent requirements and the nature of the follow-up (Figure 1).

Insert Figure 1 about here

Sample size

Sample size calculations accounted for the intra-cluster correlation coefficient, the anticipated effect size, the desired power, and the expected number of events.[17] We assumed an average of 50 participants per school, a conservative intra-class correlation (ICC) of 0.02, and sought to detect a 25% reduction in pregnancy rate with 80% power with $\alpha=0{\cdot}05$. It was expected that over the follow-up period the magnitude of clustering effects would decline as the students left school and the prevalence of risk behaviours such as unprotected sexual activity would be less influenced by school peers. The expected birth rate, induced abortion rate and pregnancy rate in the control group were estimated from WA Department of Health figures specific to the age and postcode of residence that matched the study sample (6·0% expected to have a birth, 10·8% induced abortion, and thus estimated 16·8% known pregnancy). The required number of participants was estimated to be 1,300 per study group.

Outcome measures

A pregnancy outcome (live birth, stillbirth and induced abortion) was determined through tracking participants via the Western Australian Data Linkage System (WADLS). The WADLS maintains a linked database of administrative health records including births and deaths, hospitalisations in private and public hospitals, and the midwives data collection, which records information on all births. The system uses a multi-stage probability method of matching based on key identifiers such as name, date of birth, and address.[18] For the purposes of this analysis, ascertainment of pregnancy outcomes was complete to 31st August, 2010. It was not possible to measure miscarriage in this study, as no reliable or comprehensive records about miscarriage were available.

The WADLS could only link participants' induced abortion records when the abortion was performed in a hospital or a facility accredited for day surgery. In Perth, approximately one-third of all abortions are performed in clinics, so relevant data was therefore sought and gained directly from clinic databases.

Statistical analysis

All analyses were consistent with accounting for the cluster RCT design. Analysis conducted in this study was threefold. First, differences in pregnancy outcomes between the two study groups by age 20 years were assessed using log binomial regression with robust standard errors. Second, we analysed time to occurrence of a pregnancy event using proportional hazard regression for ages 18 and 20. Third, since the ordinary Cox proportional hazard models can accommodate only one cause of failure we also utilised competing risk models to examine the alternative causes of failure (induced abortion, or birth) independently. Competing risks models minimise the bias related to left truncation that is usually created in the single cause of failure models. For births, the birth date of the baby was used as the outcome date. For induced abortions, the recorded admission date for induced abortion was used. For overall pregnancies, we estimated the due date of a pregnancy for abortion cases by adding six months to the abortion date, as the majority of induced abortions take place in the first trimester. Where more than one pregnancy outcome was detected, the date of the first event was used (i.e. subsequent births and/or abortions were not included in the analyses).

To account for baseline residual differences between the study groups the following variables were included in the model: socio-economic disadvantage (measured by the Australian Bureau of Statistics SEIFA Index of Relative Disadvantage of the census collection district of residence [19]), family type, whether the girl had ever had sexual intercourse, had ever had responsibility for caring for a baby, level of psychological distress (as measured by the Kessler 10 scale[20]), current smoking status, and whether she ever drank alcohol. In addition, educational attainment at Year 12 was obtained through linkage to educational records. These data recorded the highest year of school completed; Year 12 is the final year of high school in Australia. At the time of this study there were two streams of Year 12 subjects— Tertiary Entrance Examination (TEE) and non-TEE — with TEE subjects being on the pathway to University admission. TEE subjects are moderated across the state, and scored on a 0-100 scale. Non-TEE subjects are not moderated and are graded from A to E. Girls going to Year 12 who did at least one TEE subject were classified according to their average scaled TEE score. Girls who did no TEE subjects were classified according to their average grade. Aboriginality was excluded from the regression model because there were too few Aboriginal participants in the study.

There is no missing data on the outcomes, however missing values on covariates ranged from 0.5% (14/2836) to 9% (276/2836). In the context of this study we were unable to collect auxiliary information (such as maternal education) that may have been useful in predicting missing values. The association between treatment status and the outcome was the same for those with and without missing data. For these reasons we undertook complete case analyses. All analyses were undertaken using Stata Version 14.

Role of the funding source

Funding for the recruitment and implementation of the study was originally provided by Healthway, the Western Australian Health Promotion Foundation. The Lotteries Commission of Western Australia provided funds for the purchase of the Infant Simulators. Significant in-kind contributions from the North, East, and South Metropolitan Health Services in the delivery of the VIP Programme and recruitment in the non-intervention schools by their School Health Nurses needs to be acknowledged. MovieTix provided movie vouchers as incentives for recruitment. The follow-up stage of this trial was funded by the Western Australian Department of Health and the Western Australian Department of Education and Training. The authors wish to advise that RealityWorks kindly donated baby slings to the study once they became aware of the research trial. However the company and its suppliers have had no involvement in the study governance,

design, or implementation, and have had no influence in any way. Corresponding author SB had full access to all data in this study and had final responsibility for the decision to submit for publication.

Results

Table 1 summarises the baseline characteristics of participants by study group. The control group had a higher proportion of girls from areas of higher socio-economic status, with 39% of control group girls living in census collection districts in the least disadvantaged quartile, compared with 23% of girls in the intervention group. Some 63% of girls from the control group lived with both their original parents, compared with 58% from the intervention group. Girls from the intervention group were somewhat more likely to have had responsibility for caring for a baby (59% compared with 52%). Other variables showed similar proportions across both groups.

Insert Table 1 about here

Table 2 shows, for the intervention and control groups, the number of participants among whom the first pregnancy outcome was a registered birth and the number in whom the first pregnancy outcome was an induced abortion. There were 2,834 girls included in the study (1,567 in the control group and 1,267 in the intervention group) after excluding one girl who was pregnant at the time of enrolment.

In total, 378 participants had one or more recorded pregnancies (either birth or induced abortion): 168 in the control group, and 210 in the intervention group. Overall, 285 girls had just one event, leaving 93 with more than one event; 19 had 2 or more births; 26 had 2 or more induced abortions. The remaining 48 participants had a "mixed pattern" of pregnancy events, with 24 having a birth as first event and 24 having an abortion as first event. The analysis reported in this paper is limited to their first pregnancy event. Based on this, the proportion of girls having any pregnancy events (induced abortion or birth) was higher in the intervention group (16.6% compared with 10.7% in the control group; $\chi^2 = 20.8$, p=0.000). Similarly, the proportion of girls in the intervention group giving birth was higher than the controls (7.6% compared with 4.3%; $\chi^2 = 14.7$, p=0.000), as was the case for abortion (8.9% compared with 6.4%; $\chi^2 = 6.1$, p=0.013).

Insert Table 2 about here

Table 2 reports the proportion of known pregnancies ending in an induced abortion, which is equal to the number of induced abortions divided by the number of induced abortions and births combined. Overall, 57% of first pregnancies ended in an induced abortion. Pregnancies among girls in the control group were slightly more likely to end in induced abortion (60%) than those in the intervention group (54%) but this was not statistically significant.

Table 3 displays unadjusted and adjusted results from the log binomial and proportional hazards modelling to estimate the relative risk and hazard ratio for overall pregnancies by the age of 20 years.

Insert Table 3

After adjusting for covariates the log binomial regression showed elevated relative risk for any pregnancy as the outcome (RR = 1.36, 95% CI 1.10-1.67, p=0.003) (Table 3). These results were similar to the hazard ratios estimated using the Hazard model (HR = 1.35, 95% CI 1.06-1.73, p=0.016).

Figure 2 shows the proportional hazard curves for time to first pregnancy outcome before the age of 20 years by study group.

Insert Figure 2 about here

The analysis was repeated to examine risk of pregnancy by 18 years as part of testing the proportional hazards assumptions, and to examine if the intervention was more effective in preventing earlier teenage pregnancies. Observed effects from adjusted models remained higher in the intervention group (HR = 1.51, 95% CI 1.02-2.25, p=0.040, pregnancies = 136).

To determine whether the study groups differed in their pregnancy outcomes, analysis of births and induced abortions by the age 20 years were investigated using competing risk analysis (Table 4). In the unadjusted model, where induced abortion was treated as a competing event, the risk of births was higher in the intervention group (HR = 1.89, 95% CI 1.36 – 2.64, p=0.00). A similar effect was observed for the risk of induced abortion in the intervention group when treating births as the competing event (HR = 1.33, 95% CI 1.00 – 1.78, p=0.049).

When the models were run to adjust for confounders, the specific Hazard Ratios were lower in magnitude but still elevated (Births with abortions as the competing event: (HR = 1.36, 95% CI 0.94 – 1.98, p=0.102); Abortions with births as the competing event: HR = 1.23, 95% CI 0.89 – 1.69, p=0.206).

Discussion

This study shows that the infant simulator based Virtual Infant Parenting programme did not reduce the risk of pregnancy in teenage girls, as measured by births and induced abortions. Point estimates for the effect of the intervention were elevated suggesting higher pregnancy risk among those experiencing the VIP program.

These results need to be considered in light of the study's limitations. A potential limitation of the study is the relatively low participation rate at the individual level (45% in the control schools and 58% in the intervention schools) and we have no information about eligible students who did not consent to participate. Girls in the control group had on average higher socio-economic status of residence and higher educational attainment. While we have controlled for observed baseline differences between the two groups, it is possible that there were other differences between the two groups that were not measured and may have had an impact on the study's findings. Another limitation of the study is the inability to measure miscarriage (spontaneous abortion) as a pregnancy outcome. Many miscarriages are undetected, and few women seek medical attention. Furthermore, the WADLS does not include information from primary care visits.

Our estimates of the required sample size to account for the intra-cluster coefficient, the anticipated effect size and expected number of outcome events was based on examining pregnancy outcomes combining births and induced abortions. Therefore, the analysis of these pregnancy outcomes separately using the competing risk model may have lacked the power to statistically determine whether the intervention group was more likely to choose to go to full-term

or have an induced abortion compared to the control group, despite us showing that the intervention group had a higher risk of pregnancy. Nonetheless, the VIP programme was not designed to inform choices once pregnant, but rather to prevent pregnancy occurring in the first place, and there was no a priori hypothesis about whether the programme would influence such a choice.

Due to the sensitive nature of the topic, the age of the girls and the ethical requirements for informed consent from both the participants and their parents, it is unlikely that a similar study could achieve a markedly higher participation rate. Traditionally in Australian schools participation in such infant simulator-based programmes is voluntary, and it is likely that study participants in our intervention group would be similar to those choosing to undertake the programme in a real world setting.

The average abortion proportion in Western Australia for girls aged 15–19 years during the study period was 51.7% [21,22] which is similar to the overall 57% in this study. The abortion proportion was higher in the control group (60%) compared to the intervention group (54%), although not statistically significant. Due to the potential for selection bias, related to the low participation rates, it is not possible for us to rule out the likelihood that participants in the intervention group may have had a higher propensity to have a baby as a teenager upon enrolment into the trial, a difference that may not have been fully captured in our adjusted models.

Other studies have found limited positive value in infant simulator-based programmes. Kralewski and Stevens-Simon found that caring for a baby simulator led to a small increase in the percentage of teenage girls who planned to be a teen parent (12–15%), although this study was limited by its small sample size (n=109).[23] They also noted that very few girls (29%) believed that caring for their own infant would be like caring for the infant simulator and that those girls who found it difficult to look after the infant simulator tended to believe that caring for their own baby would be much easier. Additionally, Chavaudra suggests that girls who are at risk of becoming teenage parents tend to enjoy the attention they receive while caring for the infant simulator, which may reinforce their desire to have a baby.[24]

This is the most rigorous evaluation undertaken to date to determine the long-term impact of an infant simulator-based programme and one of very few studies to examine objective pregnancy outcomes. The strengths of this trial include its pragmatic nature, large sample size, long duration of follow-up, and relatively complete follow-up via data linkage or record review for both

abortion and birth outcomes. It is estimated that the study achieved over 98% coverage of births and induced abortion outcomes in the State via data linkage together with abortion clinic records. While it is not possible to determine the number of cases lost to follow-up on the primary outcome, average migration rates from the State on an annual basis are low, around 2% of the population per year in the age group 15-19 years.[25]

Despite the popularity and widespread use of infant simulator-based programmes, the results of this trial show that the VIP Programme was not effective in reducing pregnancy rates among teenagers. This finding is consistent with the limited available evidence of infant simulator-based programmes on student attitudes and behaviour even in the short-term.
Over the past 20 years the promoters of infant simulators have broadened their associated school curriculum to include not only courses on pregnancy prevention, but also courses in parenting and child development, and courses for students interested in child care careers. The company claims that 67 percent of U.S. school districts are using the simulators and that their worldwide coverage expands to more than 89 countries[26]. Despite the theoretical rationale for possible effectiveness, the claims of the company, and benefits cited in descriptive studies, our results indicate that the use of infant simulators in schools does not have the desired long-term effect of reducing teenage pregnancy, and is likely to be an ineffective use of public resources aimed at pregnancy prevention.

Author contributions

SS was the principal investigator of this research trial. SS, SB, JC, and BH conceived the original study design. SB project managed the study, supervised research staff, enrolment and the follow-up of study participants. JS aided data access to the abortion clinics. MM undertook the statistical analyses. All authors assisted with the interpretation of the data and have been involved with the ongoing steering and management of the research trial. All authors participated in the writing of this article and approved the final version.

Conflicts of interest

We declare that we have no conflicts of interest.

Ethics

Ethical approval to approach students to participate in the trial and to be tracked via data linkage up to the age of 20 years was obtained from the Princess Margaret Hospital (PMH) Ethics Committee. Ethics approval was given by the WA Department of Health's Confidentiality of Health Information Committee (CHIC) to undertake the data linkage.

Acknowledgements

We would like to sincerely thank our resilient trial co-ordinators, Sarah Baxendale and Heidi Hutton, our research assistants, the school health nurses, teachers, school support staff, the schools that participated in the study and the study participants. Thanks also go to the staff of the Data Linkage Unit in the Department of Health WA, staff at the abortion clinics for extraction of relevant data and all the custodians of the various data sets that contributed to this study.

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Table 1: Baseline characteristics

	Intervention group	Control group
Schools—		
Number	27	29
Average number of participating students (%)	46·9	54·0
Individual factors at baseline—		
Number of participating students	1,268	1,568
Mean age (years)	14·8	14·9
Index of relative socioeconomic disadvantage of census collection district of residence[1]—		
Bottom 10%	158 (12.5%)	85 (5.4%)
10%-25%	159 (12.5%)	144 (9.2%)
25%-50%	208 (16.4%)	190 (12.1%)
50%-75%	436 (34.4%)	511 (32.9%)
Top 25%	289 (22.8%)	610 (38.9%)
Missing	18 (1.4%)	28 (1.8%)
Family type[1]—		
Both original parents	728 (57·5 %)	992 (63·3 %)
Step/blended	216 (17·1 %)	224 (14·3 %)
Sole parent	256 (20·2 %)	265 (16·9 %)
Other	67 (5·3 %)	86 (5·5 %)
Ever had sex[1]—		
No	1067 (84·2 %)	1272 (81·2 %)
Yes	190 (15·0 %)	280 (17·9 %)
Not stated	10 (0·8 %)	15 (1·0 %)
Ever responsible for caring for a baby[1]—		
No	520 (41·0 %)	739 (47·2 %)
Yes	743 (58·6 %)	819 (52·3 %)
Not stated	4 (0·3 %)	9 (0·6 %)

Educational attainment—		
Year 10	197 (15·5%)	136 (8·7%)
Year 11	206 (16·3%)	192 (12·2%)
Year 12 - non-TEE average grade C or below	246 (19·4%)	243 (15·5%)
Year 12 - non-TEE average grade A or B	228 (18·0%)	325 (20·7%)
Year 12 - TEE - average score below 60	279 (22·0%)	374 (23·8%)
Year 12 - TEE - average score 60 or higher	111 (8·8%)	297 (19·0%)
Level of psychological distress[1]—		
Low	490 (38·5%)	524 (33·5 %)
Moderate	705 (55·4%)	838 (53·6 %)
High	69 (5·4%)	196 (12·6 %)
Missing	9 (0.7%)	3 (0.1%)
Current smoker[1]		
No	1178 (92.9%)	1428 (91.1%)
Yes	84 (6·7 %)	129 (8·3 %)
Not stated	6 (0.4%)	11(0.6%)
Ever drank alcohol[1]		
No	736 (58.1%)	474 (30.2%)
Yes	498 (39·3 %)	850 (54·2 %)
Not stated	33 (2.6%)	243 (15.6%)

1 at time of enrolment into the trial

Table 2: Births, abortions and pregnancies in the intervention and control groups[1]

	Intervention (n=1267)	Control (n=1567)	Both groups (n=2834)
Births—			
Total number	97	67	164
%	7.6%	4.3%	5.8%
Abortions—			
Total number	113	101	214
%	8.9%	6.4%	7.5%
Pregnancies—			
Total number	210	168	378
%	16.6%	10.7%	13.3%
Abortion proportion[2]	53.8%	60.1%	56.7%

[1] Data only shows the first pregnancy outcome for each subject who become pregnant

[2] Abortion proportion is the proportion of pregnancies (births and abortions) that end in abortion

Table 3: Relative risk estimates for any pregnancy before aged 20 years

Model	Estimated RR	95% CI	p value
Log binomial			
Unadjusted (N=2519)	1·61	(1.14–2.30)	0.007
Adjusted[1] (N=2519[2])	1·36	(1.10–1·67)	0.003
Cox proportional Hazards			
Unadjusted (N=2515[3]) (n[4]=334)	1·57	(1.26–1.95)	0·000
Adjusted1 (N=2515) (n=334)	1·35	(1.06–1·72)	0·016

Note: Ratios > 1·0 indicate the intervention group has a higher hazard of pregnancy than the control group.

1. Model adjusted for socioeconomic status, family type, whether the participant had ever had sex, whether she had ever had responsibility for caring for a baby, educational attainment, her level of psychological distress and whether she ever drank alcohol or was a current smoker.
2. N =Total Sample size
3. Four observations not used in the proportional hazard analysis as they were on or before entry period
4. n = number of pregnancies

Table 4: Competing risks model for a birth or induced abortion before the age of 20

Unadjusted model	Hazard Ratio	95% CI	p value
Births with abortions as a competing event (N=2515)	1.89	(1.36–2.64)	0·000
Abortions with births as a competing event (N=2515)	1.33	(0.97–1.67)	0·05
Adjusted model[1]			
Births with abortions as a competing event (N=2515)	1.36	(0.94–1.97)	0·102
Abortions with births as a competing event (N=2515)	1.23	(0.89–1.69)	0·206

Note: Hazard ratios > 1·0 indicate the intervention group has a higher hazard of pregnancy than the control group.

1. Model adjusted for socioeconomic status, family type, whether the participant had ever had sex, whether she had ever had responsibility for caring for a baby, educational attainment, her level of psychological distress and whether she ever drank alcohol or was a current smoker.

Figure 1: Participant Flow

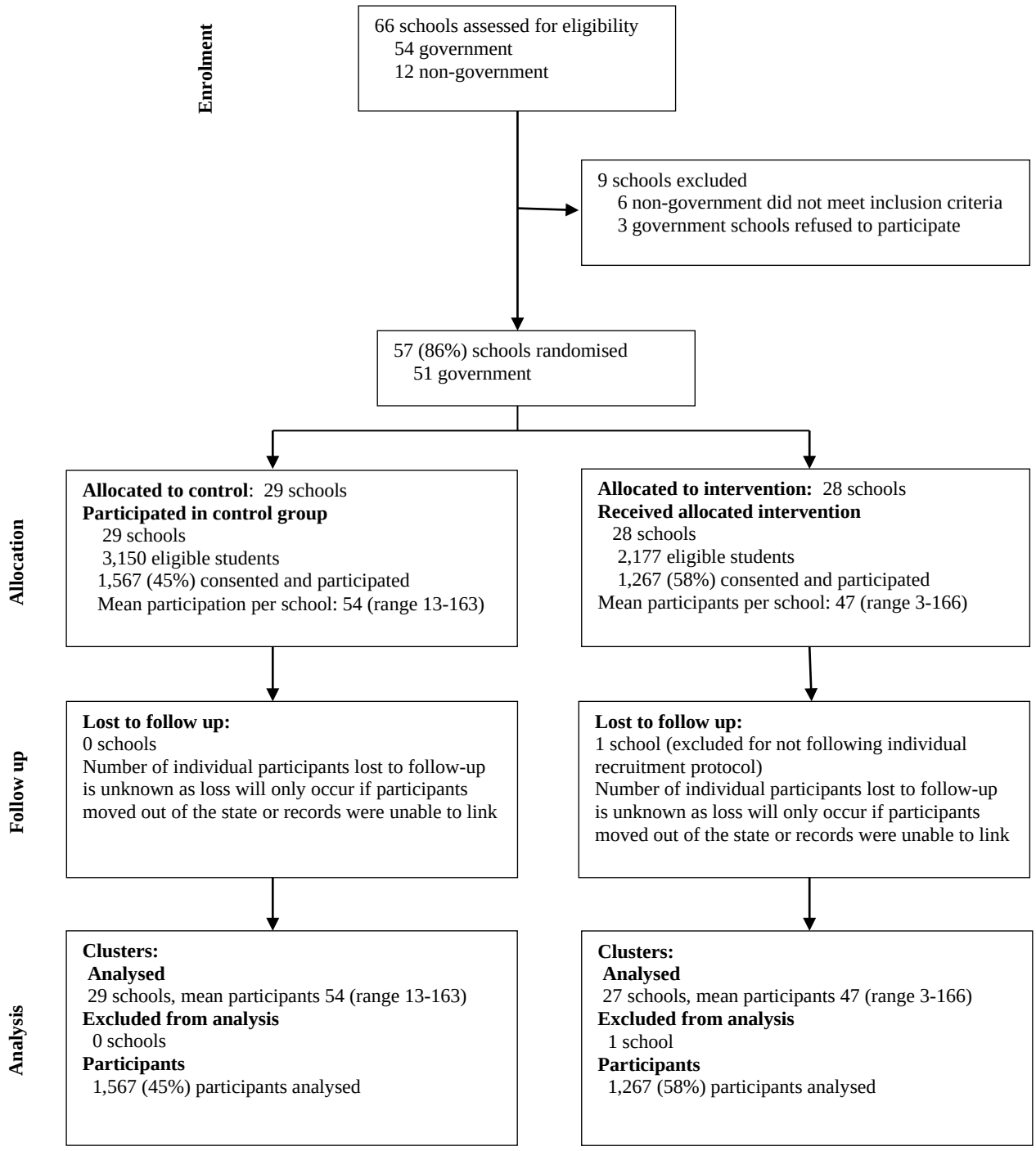
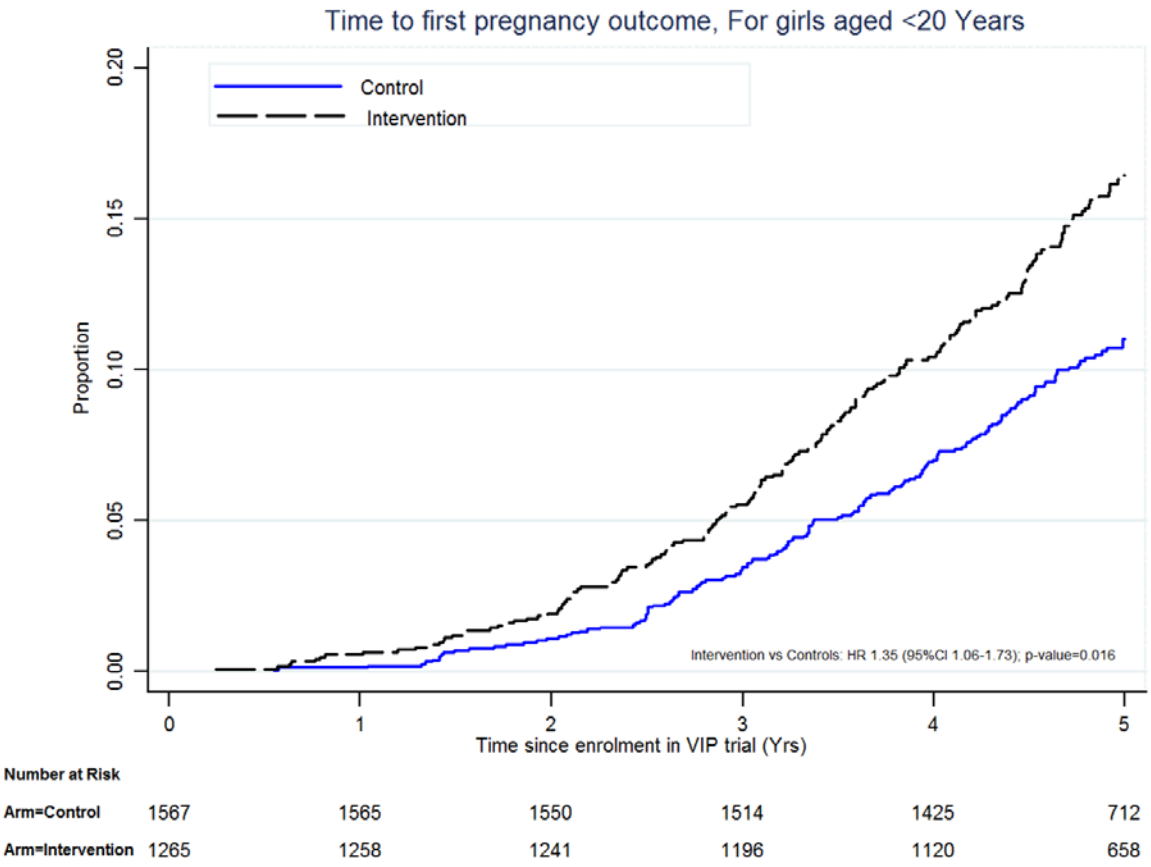


Figure 2: Survival analysis – time to first pregnancy outcome (birth or abortion), by study group



Note: Sample drops after 4 years as the participants age past 20 years of age.