

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



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## Summary

**Background** Infant simulator-based programmes, which aim to prevent teenage pregnancy, are used in high-income as well as low-income and middle-income countries but, despite growing popularity, no published evidence exists of their long-term effect. The aim of this trial was to investigate the effect of such a programme, the Virtual Infant Parenting (VIP) programme, on pregnancy outcomes of birth and induced abortion in Australia.

**Methods** In this school-based pragmatic cluster randomised controlled trial, eligible schools in Perth, Western Australia, were enrolled and randomised 1:1 to the intervention and control groups. Randomisation using a table of random numbers without blocking, stratification, or matching was done by a researcher who was masked to the identity of the schools. Between 2003 and 2006, the VIP programme was administered to girls aged 13–15 years in the intervention schools, while girls of the same age in the control schools received the standard health education curriculum. Participants were followed until they reached 20 years of age via data linkage to hospital medical and abortion clinic records. The primary endpoint was the occurrence of pregnancy during the teenage years. Binomial and Cox proportional hazards regression was used to test for differences in pregnancy rates between study groups. This study is registered as an international randomised controlled trial, number ISRCTN24952438.

**Findings** 57 (86%) of 66 eligible schools were enrolled into the trial and randomly assigned 1:1 to the intervention (28 schools) or the control group (29 schools). Then, between Feb 1, 2003, and May 31, 2006, 1267 girls in the intervention schools received the VIP programme while 1567 girls in the control schools received the standard health education curriculum. Compared with girls in the control group, a higher proportion of girls in the intervention group recorded at least one birth (97 [8%] of 1267 in the intervention group vs 67 [4%] of 1567 in the control group) or at least one abortion as the first pregnancy event (113 [9%] vs 101 [6%]). After adjustment for potential confounders, the intervention group had a higher overall pregnancy risk than the control group (relative risk 1.36 [95% CI 1.10–1.67],  $p=0.003$ ). Similar results were obtained with the use of proportional hazard models (hazard ratio 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 they reached 20 years of age.

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## Introduction

The social and financial cost to the individual and to society of unintended pregnancy in teenagers is substantial.<sup>1,2</sup> The evidence as to whether health promotion or education programmes are able to reduce teenage pregnancy rates is sparse and contradictory. Reviews limited to the USA describe a range of multifaceted programmes delivered in varying contexts that have been successful in changing sexual behaviour; however, these reviews all highlight the importance of addressing the non-sexual antecedents of teenage pregnancy.<sup>3–5</sup> A 2016 Cochrane review of 53 randomised controlled trials concluded that programmes with a combined educational and contraceptive component seem to reduce unintended pregnancy.<sup>6</sup> However, the review also suggested that evidence about measures such as initiation of sexual intercourse, use of birth control, abortion, childbirth, and

sexually transmitted disease remains inconclusive.<sup>6</sup> The review drew attention to 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.<sup>3–6</sup>

A comparison of teenage pregnancy rates (combined births and induced abortions) within countries of the Organisation for Economic Co-operation and Development (OECD) shows Australia to be sixth highest in a list of 21 countries.<sup>1</sup> 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 pregnancy rates in teenagers. Such programmes typically include a series of education sessions in combination with “care” for an infant simulator—a lifelike model that

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### Research in context

#### Evidence before this study

Sparse and contradictory evidence exists 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 seem to reduce unintended teenage 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. We searched major electronic databases (including, but not limited to, PubMed, ERIC, PsycINFO, and Web of Science) at regular occurrences throughout the study, from Nov 1, 2002, to March 18, 2016, using the search terms “teenage pregnancy prevention” and “infant simulator” for articles published in English. These searches were complemented by manual searches of reference lists and interrogation of the 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 that were not included in the Cochrane review.

#### Added value of this study

To the best of our knowledge, this study presents the first randomised controlled trial assessing the efficacy of infant simulator programmes on teenage pregnancy. The results of this trial suggest that such programmes are likely to be an ineffective use of public resources aimed at teenage pregnancy prevention.

#### Implications of all the available evidence

Schools in more than 89 countries currently use simulators. The results of this trial indicate that this intervention is likely to be an ineffective use of public resources aimed at teenage pregnancy prevention.

is programmed to replicate the sleeping and feeding patterns of a baby. The infant simulator is an example of an approach used in persuasion technology or captology.<sup>7</sup> The use of infant simulator-based programmes is widespread in developed countries<sup>8</sup> and is expanding into low-income and middle-income countries.<sup>9</sup> Despite their popularity, little evidence is available to suggest that such programmes are effective. Additionally, the simulators are expensive, costing around AUS\$1200 each when this trial began in 2003. At present, in Australia, a standard pack of ten infant simulators along with the required equipment costs \$18 245.<sup>10</sup>

Previous assessments 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 identified 20 studies on infant simulators with a mean sample size of 365 participants (range 48–1829).<sup>11</sup> Most studies reviewed reported 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 increasing knowledge levels if it was combined with a strong educational component. Studies investigating the effect of infant simulators on attitudes and beliefs about teenage pregnancy also report mixed results. Herrman and colleagues<sup>11</sup> found some evidence that infant simulators changed teen attitudes about the costs of teen parenting, effects on social life and personal freedom, and the commitment needed for parenting. However, they also reported five studies that showed no change in attitudes or beliefs about teenage pregnancy. Studies of behaviour change were based on self-reported outcomes and almost exclusively asked teenagers about their intentions to become pregnant or have children, rather than measuring actual behavioural outcomes (eg, sexual activity or pregnancy). Most of the studies reviewed showed that the infant simulators produced no change

in behavioural intention. Herrman and colleagues<sup>11</sup> concluded that there was inconclusive support for the efficacy of infant simulators and that there was a substantial need for a randomised controlled trial.

The **Virtual Infant Parenting (VIP) Programme** is a school-based preconception pregnancy prevention programme, a component of which is an infant simulator. It is a Western Australian adaptation of the US programme created by **Realityworks** (Eau Claire, WI, USA) and often referred to as “Baby Think It Over”. The programme seeks not only to delay pregnancy in the teenage years but also to improve knowledge and awareness of preconception health issues. Although “Baby Think It Over” is often implemented by teachers, nurses, or doctors, the VIP programme was implemented by school health nurses over 6 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 lesson on Friday afternoon through to the first class on Monday morning.

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.<sup>12,13</sup> Post-intervention follow-up questionnaires at 1 week and 3 months showed participants to be enthusiastic about the programme, to have good levels of programme recall, and to display 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.<sup>14</sup>

The aim of this trial was to investigate the effect of the VIP programme on objectively measured births and induced abortions throughout the teenage years in Perth, Western Australia.

## Methods

### Study design and participants

The study design for the VIP evaluation was 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 years, by means of data linkage to the birth register, admission to hospital, and abortion clinic records. Additionally by implementing the programme at a school level, the risk of control participant's exposure (or contamination) to the infant simulators was minimised.

All 66 government and non-government high schools (excluding Catholic schools) in the Perth metropolitan area of Western Australia were invited to participate in the study. All eligible students in these schools were invited to participate in this prospective study of teenage preconceptual health, knowledge, and behaviour. Individual participants were girls aged 13–15 years (in school year 9 or 10) at the time of recruitment. Incentives to participate included a chocolate frog for returned consent forms, and the opportunity to win cinema tickets. Parent or guardian consent forms had a tea bag stapled to the top of the form to enhance uptake.

This report 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.<sup>15,16</sup> Full details are in the study protocol.<sup>17</sup>

Written, informed consent was obtained from both participants and their parents or guardians to access individual medical records to detect any births or induced abortions until the participants reached the age of 20 years. Ethics 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 Ethics Committee. Ethics approval was given by the Western Australia Department of Health's Confidentiality of Health Information Committee to undertake the data linkage.

This study is registered as an international randomised controlled trial, number ISRCTN24952438.

### Randomisation and masking

Participating schools were randomly allocated 1:1 to the control group or the intervention group of the study. Randomisation using a table of random numbers without blocking, stratification, or matching was done by a researcher who was masked to the identity of the schools. In the schools randomly assigned to the intervention group, only five students per school per week could participate in the programme because of the availability of

both school health nurses and infant simulators. After consent was received, school health nurses randomly assigned participants into groups of five. Each group was then allocated to a different week in the school year to complete the programme.

### Procedures

In the schools allocated to receive the intervention, because we had only 54 infant simulators and one school health nurse per school, and because only five participants per school could go through the programme for each week of the school year, recruitment and administration of the programme continued for 3 years, with the study active for 2 years in most schools. Control students received the standard school curriculum.

Each pregnancy outcome (livebirth, stillbirth, and induced abortion) was determined by tracking participants via the Western Australian Data Linkage System (WADLS). The WADLS maintains a linked database of administrative health records including births and deaths, hospital admissions in private and public hospitals, and the midwives' data collection, which records information about all births in Western Australia. The system uses a multi-stage probability method of matching based on key identifiers such as name, date of birth, and address.<sup>18</sup> For the purposes of this analysis, ascertainment of pregnancy outcomes was complete as of Aug 31, 2010. We could not gather data about miscarriage in this study because no reliable or comprehensive records about miscarriage were available.

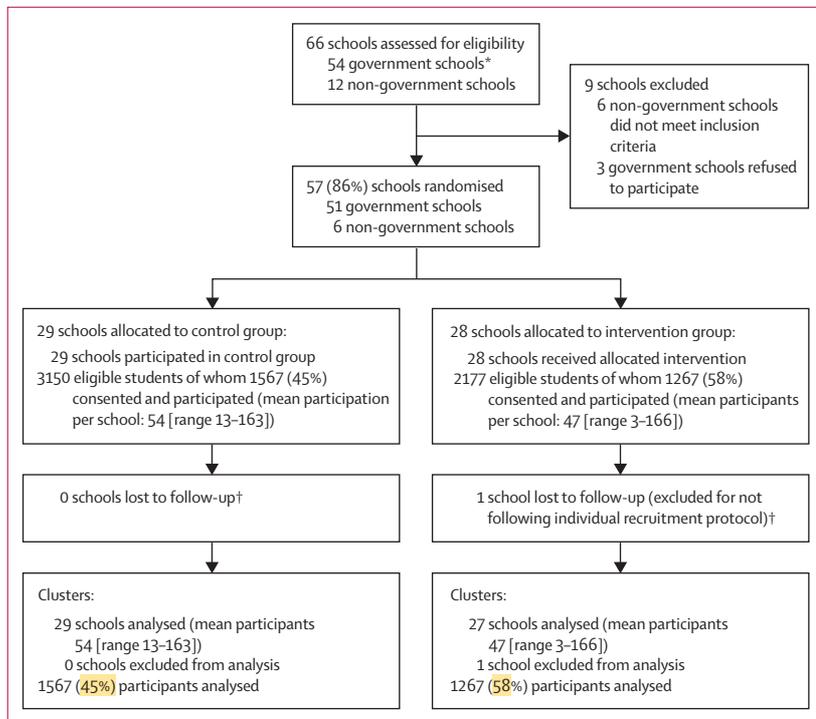
The WADLS could only link participants' induced abortion records when the abortion was performed in a hospital or a facility accredited for day surgery. In Perth, around a third of all abortions are performed in clinics, so relevant data was sought and gained directly from clinic databases.

### Outcomes

The primary outcome was pregnancy, as deduced by a livebirth, stillbirth, or induced abortion. For those participants who recorded more than one pregnancy the time to the first pregnancy was used in our analyses. Secondary outcomes were the result of the pregnancy (either livebirth, stillbirth, or abortion).

### Statistical analysis

Sample size calculations accounted for the intra-cluster correlation coefficient, the anticipated effect size, the desired power, and the expected number of events.<sup>19</sup> We assumed an average of 50 participants per school, a conservative intra-class correlation of 0·02, and sought to detect a 25% reduction in pregnancy rate with 80% power with an  $\alpha$  value of 0·05. We expected that during the follow-up period the magnitude of clustering effects would decrease as the students left school and the prevalence of risk behaviours such as unprotected sexual activity would be influenced less by school peers.



**Figure 1: Trial profile**

\*One school had two campuses. †Number of individual participants lost to follow-up is unknown because loss will only occur if participants moved out of the state or records were unable to be linked.

The expected birth rate, induced abortion rate, and pregnancy rate in the control group were estimated from Western Australia 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). We calculated the required number of participants to be 1300 per study group.

We did complete case analyses in this study. All analyses were consistent with accounting for the cluster randomised controlled trial design. We did three different analyses in this study. First, we assessed differences in pregnancy outcomes between the two study groups by age 20 years 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 years. Third, since the ordinary Cox proportional hazard models can accommodate only one cause of failure, we also used 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 6 months to the

abortion date, since most induced abortions take place in the first trimester. Where more than one pregnancy outcome was detected, the date of the first event was used (ie, 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: socioeconomic disadvantage (measured by the Australian Bureau of Statistics Socio-Economic Indexes for Areas Index of Relative Disadvantage of the census collection district of residence<sup>20</sup>); family type; whether the girl had ever had sexual intercourse; whether or not the girl had ever had responsibility for caring for a baby; level of psychological distress (as measured on the Kessler 10 scale<sup>21</sup>); current smoking status; and whether the girl ever drank alcohol. Additionally, educational attainment at year 12 (ie, at 17 years of age) 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 when this study was done, there were two streams of year 12 subjects—Tertiary Entrance Examination (TEE) subjects, which are on the pathway to University admission, and non-TEE subjects. 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 into 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.

All analyses were done using Stata version 14.1.

### 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. Substantial 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 need to be acknowledged. MovieTix provided cinema 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; however, these departments had no role in study design, data collection, data analysis, data interpretation, or writing of the report. 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. The corresponding author had full access to all

the data in this study and had final responsibility for the decision to submit for publication.

## Results

Recruitment began on Feb 1, 2003, and was completed on May 31, 2006. Overall, 57 (86%) of the 66 invited schools enrolled in the programme. The government school participation rate was higher (51 [95%] of 54) than that for non-government schools (six [50%] of 12) because of the low availability of school health nurses for programme delivery in non-government schools. Of the 57 participating schools, 29 were randomly allocated to the control group and 28 to the intervention group. After initial recruitment, one government school was excluded from the intervention group because of non-adherence to the study's student recruitment protocol (instead of recruiting all students in years 9 and 10, they only recruited students attending non-academic streams, thus potentially biasing the sample). Therefore, because of this exclusion, there were 27 schools in the intervention group. Despite best practice recruitment procedures, incentives, and investment of substantial time and resources, the participation rates at the student level remained low because of consent requirements and the nature of the follow-up (figure 1).

2834 girls were included in the study (1567 in the control group and 1267 in the intervention group) after excluding one girl from the intervention group who was pregnant at the time of enrolment. Table 1 summarises the baseline characteristics of participants by study group. Compared with the intervention group, the control group had a higher proportion of girls from areas of higher socioeconomic status than the intervention group, and a higher proportion of girls who lived with both their original parents than in the intervention group (table 1). Girls from the intervention group were slightly more likely to have had responsibility for caring for a baby. Other variables were similar across both groups (table 1).

Table 2 shows, for the intervention and control groups, the number of participants in whom the first pregnancy outcome was a registered birth and the number of participants in whom the first pregnancy outcome was an induced abortion. In total, 378 (13%) of 2834 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 of these girls had just one event, leaving 93 girls with more than one event; of these, 19 had two or more births and 26 had two 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 analysis, the proportion of girls having any pregnancy events (induced abortion or birth) was higher in the intervention group than in the control group (210 [17%] of 1267 in the intervention group vs 168 [11%] of 1567 in the control

	Intervention group (n=27 schools)	Control group (n=29 schools)
Participating students	1267 (47%)	1567 (54%)
Mean age of students, years	14.8 (13.2-16.7)	15.0 (13.4-16.5)
Index of relative socioeconomic disadvantage of census collection district of residence*		
Bottom 10%	158 (13%)	85 (5%)
10-25%	159 (13%)	144 (9%)
25-50%	208 (16%)	190 (12%)
50-75%	436 (34%)	511 (33%)
Top 25%	289 (23%)	610 (39%)
Missing	17 (1%)	27 (2%)
Family type*		
Both original parents	728 (58%)	992 (63%)
Step-parents/blended	216 (17%)	224 (14%)
Sole parent	256 (20%)	265 (17%)
Other	67 (5%)	86 (6%)
Ever had sex*		
No	1067 (84%)	1272 (81%)
Yes	190 (15%)	280 (18%)
Not stated	10 (1%)	15 (1%)
Ever been responsible for caring for a baby*		
No	520 (41%)	739 (47%)
Yes	743 (59%)	819 (52%)
Not stated	4 (<1%)	9 (1%)
Educational attainment		
Year 10 (15-16 years of age)	197 (16%)	136 (9%)
Year 11 (16-17 years of age)	206 (16%)	192 (12%)
Year 12 (17-18 years of age): non-TEE, average grade C or below	246 (19%)	243 (16%)
Year 12: non-TEE, average grade A or B	228 (18%)	325 (21%)
Year 12: TEE, average score <60	279 (22%)	374 (24%)
Year 12: TEE, average score ≥60	111 (9%)	297 (19%)
Level of psychological distress*		
Low	490 (39%)	524 (34%)
Moderate	705 (55%)	838 (54%)
High	69 (5%)	196 (13%)
Missing	3 (<1%)	9 (1%)
Current smoker*		
No	1178 (93%)	1428 (91%)
Yes	84 (7%)	129 (8%)
Not stated	5 (<1%)	10 (1%)
Ever drunk alcohol*		
No	736 (58%)	474 (30%)
Yes	498 (39%)	850 (54%)
Not stated	33 (3%)	243 (16%)

Data are n (%) or median (IQR). TEE=Tertiary Entrance Examination. \*At time of enrolment into the trial.

**Table 1: Baseline characteristics**

group;  $\chi^2=20.8$ ,  $p=0.000044$ ). Similarly, the proportion of girls in the intervention group giving birth was higher than in the control group (97 [8%] of 1267 in the intervention group compared with 67 [4%] of 1567 in the control group;  $\chi^2=14.7$ ,  $p=0.000044$ ), as was the case for abortion (113 [9%] vs 101 [6%];  $\chi^2=6.1$ ,  $p=0.013$ ).

	Intervention group (n=1267)	Control group (n=1567)	Both groups (n=2834)
Births	97 (8%)	67 (4%)	164 (6%)
Abortions	113 (9%)	101 (6%)	214 (8%)
Pregnancies	210 (17%)	168 (11%)	378 (13%)
Proportion of abortions†	54%	60%	57%

\*Data show only the first pregnancy outcome for each participant who became pregnant. †The proportion of pregnancies (births and abortions) that end in abortion.

**Table 2: Births, abortions, and pregnancies in the intervention and control groups\***

	Estimated RR (95% CI)	p value
<b>Log binomial model</b>		
Unadjusted (n=2519 participants)	1.61 (1.14–2.30)	0.0071
Adjusted* (n=2519 participants)	1.36 (1.10–1.67)	0.0031
<b>Cox proportional hazards model</b>		
Unadjusted (n=2515 participants‡; n=334 pregnancies)	1.57 (1.26–1.95)	0.000044
Adjusted* (n=2515 participants‡; n=334 pregnancies)	1.35 (1.06–1.73)	0.016

RR=relative risk. RRs >1.0 indicate the intervention group has a higher hazard of pregnancy than the control group. \*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. ‡Four observations were not used in the proportional hazard analysis because they were made on or before the study entry period.

**Table 3: Relative risk estimates for any pregnancy before the age of 20 years**

Table 2 shows 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, 214 (57%) of 378 first pregnancies ended in an induced abortion. Pregnancies in girls in the control group were slightly more likely to end in induced abortion (101 [60%] of 168) than those in the intervention group (113 [54%] of 210) but this difference was not statistically significant ( $\chi^2=0.35$ ,  $p=0.55$ ).

Table 3 shows the 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. After adjusting for covariates, the log binomial regression model showed increased relative risk (RR) for any pregnancy as the outcome (table 3). These results were similar to the hazard ratios (HRs) estimated using the hazard model (table 3). The proportion hazard curves for time to first pregnancy outcome before the age of 20 years are shown in figure 2. The analysis was repeated to examine risk of pregnancy by 18 years as part of testing the proportional hazards assumptions (which held true), and to examine whether the intervention was more effective in preventing earlier

teenage pregnancies. Observed effects from adjusted models remained higher in the intervention group than in the control group (HR 1.51 [95% CI 1.02–2.25],  $p=0.040$ , in 136 pregnancies).

There were no missing data on the outcomes; however, the proportion of missing values on covariates ranged from 0.5% (14/2834) to 9% (276/2834). Covariates with missing data were smoking status, alcohol consumption history, socioeconomic status, and level of psychological distress. In the context of this study, we were unable to collect auxiliary information (eg, maternal education) that might 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 did complete case analyses.

To ascertain whether or not the study groups differed in their pregnancy outcomes, we investigated our analysis of births and induced abortions by the age 20 years using a competing risk analysis (table 4). In the unadjusted model, in which induced abortion was treated as a competing event, the risk of births was higher in the intervention group than in the control group (table 4). A similar effect was noted for the risk of induced abortion in the intervention group when births were regarded 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 HRs were smaller but still increased in the intervention group compared with the control group (table 4).

## Discussion

This study shows that the infant simulator-based VIP programme did not reduce the risk of pregnancy in teenage girls in Australia, as measured by births and induced abortions. Point estimates for the effect of the intervention were increased, suggesting a higher pregnancy risk in girls who experienced the VIP programme than in those who did not.

These results need to be considered in light of the study's limitations. One such potential limitation is the quite 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 agree to participate. Girls in the control group had on average higher socioeconomic status of residence and higher educational attainment. Further analyses investigating the residual covariate imbalances suggest that this discrepancy had no effect on our findings (appendix); however, although we have controlled for observed baseline differences between the two groups, there might have been other differences between the two groups that were not measured, which could have affected the study's findings. Another limitation of the study is the inability to measure miscarriage (spontaneous abortion) as a pregnancy outcome. Many

See Online for appendix

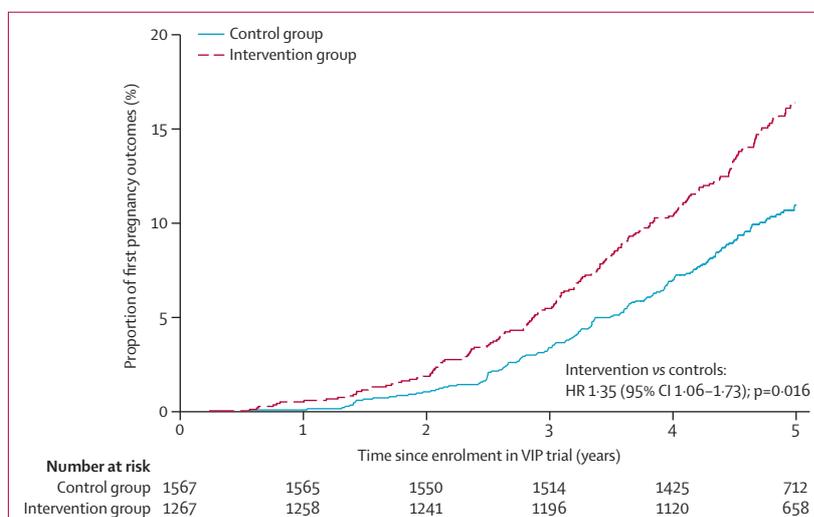
miscarriages are undetected, and few women seek medical attention. Furthermore, the WADLS does not include information from primary care visits.

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 an assessment of pregnancy outcomes combining births and induced abortions. Therefore, the analysis of these pregnancy outcomes separately using the competing risk model might have lacked the power to statistically ascertain whether or not girls who became pregnant in the intervention group were more likely to choose to go to full term or have an induced abortion compared with the control group, despite the intervention group having higher risk of pregnancy. Nonetheless, the VIP programme was not designed to inform teenagers' 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.

Because of the sensitive nature of the topic, the age of the girls, and the ethics requirements for informed consent from both the participants and their parents, a similar study is unlikely to have been able to achieve a substantially higher participation rate. Traditionally in Australian schools, participation in such infant simulator-based programmes is voluntary, and study participants in our intervention group are likely to 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%<sup>22,23</sup> which is similar to the overall 57% recorded in this study. The abortion proportion was higher in the control group than in the intervention group, although this difference was not statistically significant. Because of the potential for selection bias, related to the low participation rates, we cannot rule out the likelihood that participants in the intervention group might have had a higher propensity to have a baby as a teenager upon enrolment into the trial—a difference that might not have been fully captured in our adjusted models.

Other studies have found little positive value in infant simulator-based programmes. Kralewski and Stevens-Simon<sup>24</sup> reported 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). 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<sup>25</sup> 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 might reinforce their desire to have a baby.



**Figure 2: Survival analysis**

The graph shows time to first pregnancy outcome (birth or abortion), by study group. The sample size drops after 4 years as the participants age past 20 years of age. HR=hazard ratio. VIP=Virtual Infant Parenting.

	HR (95% CI)	p value
<b>Unadjusted model</b>		
Births with abortions as a competing event (n=2515)	1.89 (1.36–2.64)	0.00015
Abortions with births as a competing event (n=2515)	1.33 (1.00–1.78)	0.049
<b>Adjusted model*</b>		
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

HR=hazard ratio. HRs >1.0 indicate the intervention group has a higher hazard of pregnancy than the control group. \*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.

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

This study is the most rigorous evaluation undertaken so far to ascertain 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 through data linkage or record review for both abortion and birth outcomes. The study attained more than 98% coverage of births and induced abortion outcomes in Western Australia via data linkage together with abortion clinic records. Although it is not possible to determine the number of cases lost to follow-up on the primary outcome, average migration rates from Western Australia on an annual basis are low, at around 2% of the population per year in the age group 15–19 years.<sup>26</sup>

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 in teenagers. This finding is consistent with the scarce available evidence of the effect of infant simulator-based programmes on student attitudes and behaviour even in the short term.

During 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 careers in childcare. Realityworks (WI, USA) claims that 67% of US school districts are using the simulators and that their worldwide coverage expands to more than 89 countries.<sup>27</sup> Despite the theoretical rationale for possible effectiveness, the claims of the company, and benefits cited in descriptive studies, our results suggest 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.

#### Contributors

SRS was the principal investigator of this research trial. SRS, SAB, JPC, and MBH conceived the original study design. SAB project-managed the study, and supervised research staff and enrolment and follow-up of study participants. JAS helped to obtain data access from the abortion clinics. MNM did 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.

#### Declaration of interests

We declare no competing interests.

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