

The virtual infant parenting program

Submission date 01/07/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 07/07/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 30/08/2016	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

The virtual infant parenting program: a randomised controlled trial

Study objectives

Principal hypotheses:

Relative to the non-intervention arm, participants in the experimental arm of the study will have:

1. A reduction in rates of teenage motherhood
2. A reduction in teenage termination rates
3. Higher self-efficacy to make informed decisions relating to pregnancy by understanding the responsibilities associated with having a child through the virtual parenting experience
4. An increased knowledge and/or use of services and resources related to having a child, in the areas of: nutrition, exercise, immunisation, contraception, body image, sexual and mental health, prevention of injury, smoking, alcohol and illicit drugs, sudden infant death syndrome (SIDS), post-natal depression (PND), breastfeeding, sexually transmitted infections (STIs), economic implications, support network, and brain development

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. The Ethics Committee of the Womens and Childrens Health Service (Australia), 20/02/2003, ref: EC06-108
2. The Department of Health Western Australia - Human Research Ethics Committee, 13/04/2005, ref: 200437

Study design

An intervention trial using a school-based cluster-randomised design

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

School

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Pre-conception health promotion

Interventions

The intervention group received the Virtual Infant Parenting (VIP) Program. The VIP Program is an innovative six-day health promotion program delivered in schools where teenage participants learn about pre-conceptual health, pregnancy, childbirth and the practical realities of caring for an infant. One component of the Program is care of an infant simulator over a weekend.

Each student received one VIP intervention held over 6 consecutive days comprised of four education sessions of 60 minutes duration and two-day care of the infant simulator over the weekend. School health nurses implemented the program with groups of five students at a time. The total intervention period within schools was from August 2003 to May 2006.

The control group received no intervention beyond existing school health curriculum.

The duration of follow-up in the intervention and control arms is up to the age of 20 (5 - 7 years follow-up).

Intervention Type

Behavioural

Primary outcome measure

1. Rates of teenage live births up to the age of 20 as identified by state medical records and tracked through the Western Australian Data Linkage System (WADLS)
2. Rates of teenage termination up to the age of 20 as identified by linkage with state abortion clinics

Measurement of the primary outcome for both arms commenced in December 2006 with the first linkage to the WADLS and will continue to be measured quarterly until December 2011.

Secondary outcome measures

1. Pre-conceptual health and risk behaviours:
 - 1.1. Preconceptual health risk behaviours
 - 1.2. Folate supplementation
 - 1.3. Injury prevention awareness
 - 1.4. Immunisation awareness for teenagers
2. Birth and early child health outcomes (after birth of first child):
 - 2.1. Planned pregnancy
 - 2.2. Birthweight
 - 2.3. Percentage expected birth weight (PEBW)
 - 2.4. Apgar Test
 - 2.5. Perinatal health status
3. Maternal health and wellbeing:
 - 3.1. PND (Edinburgh Scale)
 - 3.2. Kessler Psychological Distress Scale
 - 3.3. SIDS risk factor awareness
 - 3.4. Immunisation status
 - 3.5. Breastfeeding
 - 3.6. Awareness and uptake of health and other community supports
 - 3.7. Perceived level of support
 - 3.8. Recall of specific VIP Program elements

Measurement of the secondary outcomes takes place at 6-months post a live-birth in either of the study arms. The method of measurement for the secondary outcomes is face-to-face interview.

Overall study start date

20/02/2003

Completion date

31/12/2010

Eligibility

Key inclusion criteria

All government and independent schools within the Perth metropolitan area and with a funded school health nurse who had the capacity to conduct health promotion programs were recruited to the study. Individual participants were females aged 13 - 15 years of age (in Year 9 or 10) at the time of recruitment.

Participant type(s)

Other

Age group

Child

Lower age limit

13 Years

Upper age limit

15 Years

Sex

Female

Target number of participants

67 schools and 2,600 students (1,300 per arm of the study)

Key exclusion criteria

1. Catholic schools due to a potential conflict of interest in regards to the teaching material
2. Male students were excluded from the study follow-up design
3. Female students who did not consent, or whose parents or guardians did not consent to participate in the study follow-up design

Date of first enrolment

20/02/2003

Date of final enrolment

31/12/2010

Locations

Countries of recruitment

Australia

Study participating centre

Telethon Institute for Child Health Research

Perth

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6008

Sponsor information**Organisation**

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Sponsor type

Research organisation

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ROR

<https://ror.org/01dbmzx78>

Funder(s)**Funder type**

Government

Funder Name

Healthway Western Australia (Australia) (ref: 11842)

Funder Name

Lotterywest (Australia)

Funder Name

Department of Health in Western Australia (Australia)

Funder Name

Department of Education in Western Australia (Australia)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	05/11/2016		Yes	No