

right@home: a national sustained nurse home visiting trial to promote family wellbeing and child development

Submission date 16/04/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 21/08/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 23/04/2025	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Children raised in families affected by economic or social disadvantage have a higher risk of poorer cognitive, emotional and behavioural outcomes in later childhood. The overarching aim of the right@home trial is to improve childrens development and early learning so that school readiness and subsequent academic performance is improved. Specifically, the main objectives are to evaluate, at child age 2 years, the impact of a sustained, nurse home visiting program offered to Australian mothers, on:

Parent care: the parent's ability to provide a consistent, regular and supportive environment for their child e.g. consistent meal times and bedtimes; parent responsivity: the parent's ability to tune in to their child's needs and to respond appropriately; and supportive home environment: building a strong home learning environment through structured developmental promotion activities focusing on language.

Who can participate?

Pregnant Australian women who could benefit from additional support.

What does the study involve?

Enrolled families will be randomly allocated into one of two groups. The Program Group will be offered at least 25 home visits by a maternal and child health nurse to deliver the right@home intervention. The Usual Care group will receive the standard universal Child and Family Health (CFH) service in Victoria and Tasmania. The CFH checks are available to all families from birth until 5 years at no out-of-pocket cost. In the first two years, all families are offered six (Tasmania) or nine checks (Victoria). The first visit occurs in families' homes and successive visits occur at a local centre.

What are the possible benefits and risks of participating?

There will be no immediate direct benefit to those taking part, although participants may feel good about helping with research. Participants are asked questions about themselves and their

families. If participants feel stressed or anxious about any of the questions, they do not have to answer them. Possible inconveniences are the time to do the questionnaires with the researchers.

Where is the study run from?

The study is a collaboration between the Australian Research Alliance for Children and Youth (trial director), the Centre for Community Child Health at the Murdoch Children's Research Institute and The Royal Children's Hospital (responsible for research evaluation) and Western Sydney University (responsible for program implementation).

When is the study starting and how long is it expected to run for?

The expected duration of the trial is 5 years. Recruitment will take place over 16 months (2013-2014) and families will be offered the intervention and followed for 2.5 years (2014-16), with data analysis in 2017.

The second phase aims to investigate if there are long-lasting effects of the right@home intervention on children's early learning and development by the time they start school. We will continue to follow up these families until the study children are six years old, and collect data through annual face-to-face home visits and six monthly telephone contact.

In phase three we plan to use linked data to assess program impacts on children's academic skills at age 8-9 years.

Who is funding the study?

The study is funded by the Victorian and Tasmanian governments, the Ian Potter Foundation, the Sabemo Trust, the Sidney Myer Fund, the Vincent Fairfax Family Foundation, the National Health and Medical Research Council.

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

right@home: a randomised controlled trial of sustained, nurse home visiting measuring the benefit on parenting and the home environment when offered to Australian mothers from the antenatal period to child age 2 years

Acronym

right@home

Study objectives

At child age 2 years, compared with the control group, intervention mothers will demonstrate improved:

1. Parent care, i.e. the parents ability to provide a consistent, regular and supportive environment for their child
2. Parent responsivity, i.e. the parents ability to tune in to their child's needs and to respond appropriately
3. Supportive home environment, i.e. building a strong home learning environment through structured developmental promotion activities focusing on language

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. The Royal Children's Hospital, Victoria, 14/03/2013, HREC 32296
2. Ballarat Health Services, Victoria, 23/04/2013, HREC/13/BHSSJOG/9
3. Peninsula Health, Victoria, 22/04/2013, HREC/13/PH/14
4. Northern Health, Victoria, 07/05/2013, HREC P03/13
5. Southern Health, Victoria, 17/05/2013, HREC 13084X
6. University of Tasmania, Tasmania, 13/05/2013, HREC H0013113

Study design

Longitudinal randomised controlled multi-site evaluation study

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Early learning and development

Interventions

Interventions as of 07/10/2016

Sustained nurse home visiting (SNHV) program compared with usual care.

Intervention group: The MECSH (Miller Early Childhood Sustained Home visiting) program is the foundation for the right@home program. Built onto the MECSH program are a number of evidence-based strategies that are intended to directly impact the three primary outcomes. These evidence-based strategies, termed “focus modules” include infant sleep training; nutrition; safety; regulation; attachment and social support; and video feedback and motivational interviewing techniques.

The intervention group will receive at least 25 home visits (actual number of visits determined by need) primarily by the same SNHV program nurse during the remainder of pregnancy and the first 2 years post birth. The nurse will be provided with clinical supervision and each group of nurses will be supported by a dedicated social care practitioner for them and their families. The SNHV nurses are Child and Family Health (CFH) nurses who have received additional training in the intervention program, operating within a distinct SNHV team. Each nurse will be expected to have Family Partnership Training (see <http://www.fpta.org.au/>).

The home visits are standardised as follows:

1. Antenatal and postnatal care in accordance with the CFH and MECSH guidelines. The content of home visits will focus on the three primary outcome areas listed above, and will be individually tailored to the mother’s needs, skills, strengths and capacity.
2. Postnatal Learning to Communicate program focussing on language promotion
3. Access to early childhood health services, volunteer home visiting services and family support services.
4. Group activities and community links including parenting group and walking group specifically for intervention families, and linking into community activities

The intervention incorporates the standard CFH visits provided through universal care in Victoria and Tasmania.

Original interventions:

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The intervention group will receive at least 25 home visits (actual number of visits determined by need) primarily by the same SNHV program nurse during the remainder of pregnancy and the first 2 years post birth. The nurse will be provided with clinical supervision and each group of nurses (up to 4) will be supported by a dedicated social care practitioner for them and their families. The SNHV nurses are MCH nurses who have received additional training in the intervention program, operating within a distinct SNHV team. Each nurse will be expected to have Family Partnership Training (see <http://www.fpta.org.au/>).

The home visits are standardised as follows:

1. Antenatal and postnatal care in accordance with the MCH and MECOSH guidelines. The content of home visits will focus on the three primary outcomes listed above, and will be individually tailored to the mothers needs, skills, strengths and capacity.
2. Postnatal Learning to Communicate program focussing on language promotion
3. Access to early childhood health services, volunteer home visiting services and family support services.
4. Group activities and community links including parenting group and walking group specifically for intervention families, and linking into community activities

The intervention incorporates the standard Key Age and Stage provided through universal care in Victoria and Tasmania.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

The primary objectives of this study are to evaluate, at child age 2 years old, the impact of a SNHV program offered to Australian mothers, on:

1. Parent care: the parents ability to provide a consistent, regular and supportive environment for their child-promoting child regulation
 - 1.1 Nutrition: e.g. consistent meal times, nutritious food
 - 1.2 Sleep: regular bedtimes and bed routines
 - 1.3 Safety: home safety
2. Parent responsivity: the parents ability to tune in to their child's needs and to respond appropriately; and
3. Home environment: building a strong home learning environment through structured developmental promotion activities focusing on language.

Key secondary outcome(s)

The secondary objectives of this study are to evaluate, across child age 6 weeks to 2 years, the impact of a SNHV program offered to Australian mothers on:

1. Maternal: Pregnancy outcomes, Quality of Life, Mental health, Parent wellbeing, General Health, Parenting self-efficacy, and Health service use
2. Child: General health and functioning
3. Sibling: Mental health/behaviour

Removed 07/10/2016

4. Nurse: Ability to effectively engage with parents and Use and knowledge of evidence-based clinical strategies.

Completion date

31/12/2023

Eligibility

Key inclusion criteria

Pregnant Australian women, who have sufficient English proficiency to answer questions face-to-face. The inclusion criteria, based on the results of our pilot (RCH HREC 32771, Northern Health HREC P 20/12, Peninsula Health HREC 13-PH-13), are any two of the following 10 risk factors:

1. Current smoking
2. Young pregnancy (<23 years old)
3. No support (emotional, financial, practical) during pregnancy
4. Poor/fair/good general health (versus very good/excellent general health)
5. Anxious mood
6. Not finishing high school
7. Not having a household income
8. A long-term illness
9. Living without another adult, and
10. Never had a job

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Total final enrolment

722

Key exclusion criteria

Current exclusion criteria:

Women will be excluded from the trial if:

1. They are enrolled in the Tasmanian Department of Health and Human Services C U @ Home home visiting program
2. Do not comprehend the recruitment invitation (e.g. have an intellectual disability such that they are unable to consent to entering the study, or have insufficient English to complete face-to-face assessments, i.e. require an interpreter)
3. Have no mechanism for contact (landline or mobile telephone, or email address)

Removed 07/10/2016:

Experience a critical event such as miscarriage, late termination of pregnancy, stillbirth and neonatal death

Removed 27/07/2016:

They are enrolled in the Victorian Department of Human Services Cradle to Kinder research program

Date of first enrolment

09/05/2013

Date of final enrolment

31/08/2014

Locations**Countries of recruitment**

Australia

Study participating centre

Centre for Community Child Health

Parkville

Australia

3052

Sponsor information**Organisation**

Australian Research Alliance of Children & Youth (Australia)

ROR

<https://ror.org/05mmh0f86>

Funder(s)**Funder type**

Government

Funder Name

Victorian Department of Education and Training

Funder Name

Tasmanian Department of Health and Human Services (DHHS)

Funder Name

The Ian Potter Foundation

Funder Name
Sabemo Trust

Funder Name
Sidney Myer Fund

Funder Name
Vincent Fairfax Family fund

Funder Name
National Health and Medical Research Council

Alternative Name(s)
National Health and Medical Research Council, Australian Government, NHMRC National Health and Medical Research Council, NHMRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Australia

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from the right@home Research Manager, anna.price@mcri.edu.au

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	2-year outcomes	01/01/2019	23/05/2019	Yes	No
Results article	3-year maternal mental health outcomes	01/02/2021	29/03/2021	Yes	No
Results article	5-year follow-up	28/11/2022	29/11/2022	Yes	No

Results article	6-year follow-up	30/06 /2023	04/07 /2023	Yes	No
Results article	Evaluating the trial using using linked administrative data at school transition	16/05 /2024	23/04 /2025	Yes	No
Protocol article		20/03 /2017		Yes	No
Other publications	brief survey of risk factors	01/06 /2019	23/05 /2019	Yes	No
Other publications	case study in design, testing and implementation	01/05 /2018	23/05 /2019	Yes	No
Other publications	quality of delivery	06/05 /2019	23/05 /2019	Yes	No
Other publications	3-year economic evaluation	06/12 /2021	08/12 /2021	Yes	No
Other publications	findings at school transition using linked administrative data	16/05 /2024	29/01 /2025	Yes	No
Plain English results		01/12 /2023	29/01 /2025	No	Yes
Study website	Study website	11/11 /2025	11/11 /2025	No	Yes