

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

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

Dr Anna Price  
anna.price@mcri.edu.au

### **Study website**

<http://www.aracy.org.au/projects/righthome>

## **Contact information**

### **Type(s)**

Scientific

### **Contact name**

Dr Anna Price

### **Contact details**

Centre for Community Child Health  
The Royal Children's Hospital  
Flemington Road  
Parkville  
Australia  
3052  
+61 (0) 3 9345 6355  
anna.price@mcri.edu.au

# Additional identifiers

## EudraCT/CTIS number

Nil known

## IRAS number

## ClinicalTrials.gov number

Nil known

## Secondary identifying numbers

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

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Other

## **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**

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:

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

Intervention group: The MECOSH (Miller Early Childhood Sustained Home visiting) program is the foundation for the right@home program. Built onto the MECOSH 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 (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 measure**

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.

### **Secondary outcome measures**

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.

**Overall study start date**

01/04/2013

**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

**Age group**

Adult

**Sex**

Female

**Target number of participants**

Target sample size N = 714

**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)

**Sponsor details**

PO Box 5070

Braddon ACT

Canberra

Australia

2612

+61 (0) 2 6248 2403

diana.harris@aracy.org.au

**Sponsor type**

Charity

**Website**

<http://www.aracy.org.au/>

**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)**



NHMRC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

Australia

**Results and Publications**

**Publication and dissemination plan**

Findings will be disseminated via a planned publication in a high-impact, peer-reviewed journal in the year following the final 2 year data collection; presentations (conferences, stakeholder seminars); and to families via reports and regular updates.

**Intention to publish date**

31/12/2018

**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](mailto: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? |
|------------------------------------|--|--------------|------------|----------------|-----------------|
| <a href="#">Protocol article</a>   |  | 20/03/2017   |            | Yes            | No              |
| <a href="#">Other publications</a> | brief survey of risk factors                                   | 01/06/2019   | 23/05/2019 | Yes            | No              |
| <a href="#">Other publications</a> | case study in design, testing and implementation               | 01/05/2018   | 23/05/2019 | Yes            | No              |
| <a href="#">Other publications</a> | quality of delivery  | 06/05/2019   | 23/05/2019 | Yes            | No              |
| <a href="#">Results article</a>    | 2-year outcomes  | 01/01/2019   | 23/05/2019 | Yes            | No              |
| <a href="#">Results article</a>    | 3-year maternal mental health outcomes                         | 01/02/2021   | 29/03/2021 | Yes            | No              |
| <a href="#">Other publications</a> | 3-year economic evaluation                                     | 06/12/2021   | 08/12/2021 | Yes            | No              |
| <a href="#">Results article</a>    | 5-year follow-up   | 28/11/2022   | 29/11/2022 | Yes            | No              |
| <a href="#">Results article</a>    | 6-year follow-up   | 30/06/2023   | 04/07/2023 | Yes            | No              |
| <a href="#">Other publications</a> | findings at school transition using linked administrative data | 16/05/2024   | 29/01/2025 | Yes            | No              |

|                                       |  |            |            |     |     |
|---------------------------------------|--|------------|------------|-----|-----|
| <a href="#">Plain English results</a> | Evaluating the trial using using linked administrative data at school transition | 01/12/2023 | 29/01/2025 | No  | Yes |
| <a href="#">Results article</a>       |  | 16/05/2024 | 23/04/2025 | Yes | No  |