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'right@home': a randomised controlled trial of sustained nurse home visiting from pregnancy to child age 2 years, versus usual care, to improve parent care, parent responsivity and the home learning environment at 2 years

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ABSTRACT

Introduction: By the time children start school, inequities in learning, development and health outcomes are already evident. Sustained nurse home visiting (SNHV) offers a potential platform for families experiencing adversity, who often have limited access to services. While SNHV programmes have been growing in popularity in Australia and internationally, it is not known whether they can improve children's learning and development when offered via the Australian service system. The right@home trial aims to investigate the effectiveness of an SNHV programme, offered to women from pregnancy to child age 2 years, in improving parent care of and responsivity to the child, and the home learning environment.

Methods and analysis: Pregnant Australian women (n=722) are identified after completing a screening survey of 10 factors known to predict children's learning and development (eg, young pregnancy, poor mental or physical health, lack of support). Consenting women—surveyed while attending clinics at 10 hospitals in Victoria and Tasmania—are enrolled if they report having 2 or more risk factors. The intervention comprises 25 home visits from pregnancy to 2 years, focusing on parent care of the child, responsivity to the child and providing a good quality home learning environment. The standard, universal, Australian child and family health service provides the comparator (control). Primary outcome measures include a combination of parent-reported and objective assessments of children's sleep, safety, nutrition, parenting styles and the home learning environment, including the Home Observation of the Environment Inventory and items adapted from the Longitudinal Study of Australian Children.

Ethics and dissemination: This study is approved by the Royal Children's Hospital Human Research Ethics Committees (HREC 32296) and site-specific HRECs. The investigators and sponsor will communicate the trial results to stakeholders, participants, healthcare professionals, the public and other relevant groups via presentations and publications.

Trial registration number: ISRCTN89962120, pre-results.

Strengths and limitations of this study

- First multisite, multijurisdictional randomised controlled trial to test the effectiveness of sustained nurse home visiting in Australia.
- Evaluation will inform the ongoing provision and delivery of the universal child and family health services in Victoria and Tasmania.
- This study is crucial for generating Australian evidence of an effective intervention to reduce the impact of social and environmental factors predisposing children to inequitable outcomes.
- The exclusion criteria mean the findings may not generalise to non-English-speaking women or women with severe intellectual disability.
- While we use a population-based sampling strategy for recruitment, women stop receiving the intervention if they move out of a study region. This could be avoided if the service is delivered across the participating states (ie, following the intention of the real-life design).

BACKGROUND

By the time children start school, inequities in learning, development and health outcomes are already evident, due to the failure of health, education and welfare systems to

adequately ameliorate the impacts of early adversity. The clear social gradient associated with children's vocabulary, emerging literacy, well-being and behaviour is evident from birth to school entry.[1] These trajectories track into adolescence and correspond to poorer educational attainment, income and health across the life course.[2–10] Neuroimaging research extends the evidence for these suboptimal trajectories, showing that children raised in poverty from infancy are more likely to have delayed brain growth with smaller volumetric size of the regions particularly responsible for executive functioning and language.[11] This evidence supports the need for further effort to redress inequities that arise from the impact of adversity during the potential developmental window of opportunity in early childhood.

The Australian Early Development Census is a population-level measure of early childhood development collected on every student by teachers at school entry (N>260 000) every 3 years.[12] It measures five domains of early childhood development (physical health and well-being; social competence; emotional maturity; language and cognitive skills; and communication skills and general knowledge). Results show that 17.4% of children who live in areas subject to the greatest socioeconomic disadvantage are developmentally vulnerable on two or more of these domains. In other words, they are not equipped with the developmental abilities they need to flourish at school. This proportion is almost triple the 6.5% of children living in the most advantaged areas.[12]

Families experiencing the most adversity are often the least able to access health resources and support services.[13] To address the need for better reach, sustained nurse home visiting (SNHV) has become increasingly popular as a model of service delivery to improve outcomes for these families.[14] Internationally, the best known SNHV programme is the US Nurse-Family Partnership (NFP), also known as Family Nurse Partnership (FNP) in the UK. Designed and led by Professor David Olds, NFP/FNP has grown in popularity as multiple trials have concluded effectiveness for a variety of outcomes for young, first-time mothers and their children. This includes improved birth, health and child development outcomes, and reductions in child maltreatment.[15] A number of SNHV programmes have also shown favourable effects on healthcare usage, including rates of well-child healthcare visits.[15]

In Australia, SNHV-type programmes are becoming more widespread, with a number of states offering an array of outreach and home visiting programmes to parents via universal (predominantly nursing) healthcare platforms.[16] However, only the Maternal (formerly Miller) Early Childhood Sustained Home-visiting (MECSH)[17] programme has been rigorously evaluated when delivered in this 'real-life' setting. Conducted by Kemp *et al*,[18] MECSH recruited 208 participants from Miller, a Sydney suburb known for experiencing significant socioeconomic disadvantage. Pregnant women of any age or parity were eligible if they reported one or more risk factors on the antenatal psychosocial screening interview, which is a standard clinical tool collected in New South Wales' birthing hospitals. The SNHV programme aimed to improve family, maternal, and child health and developmental outcomes measured when children turned 2 years old.

Compared with 'usual care' mothers who received the universally available and free programme of nurse-delivered well-child checks, MECSH 'intervention' mothers were more responsive to children's needs (effect size (d)=0.26, p=0.02). Effects at child age 2 years were most pronounced for women who were first-time mothers, had more than one antenatal risk factor or had poorer mental health.[18] Intervention mothers who were born overseas (n=62) also breast fed for longer (d=0.87, p<0.001) and reported an improved experience of being a mother (d=0.54, p=0.003) than the equivalent usual care subgroup. There were no differences between groups in child development, immunisation rates, maternal health or smoking rates.[18]

Despite the international interest and considerable financial investment required to implement SNHV programmes, the literature shows variable results. Even the most successful SNHV programmes have moderate effects in the short term, and mixed benefits in the longer term.[19] One reason for this may be that the measures assessed by these trials cover a broad range of child and parent outcomes that are not always explicitly targeted by the intervention. A review by Segal *et al*[20] of SNHV programmes designed to reduce child maltreatment found that programme logic helped target explicit outcomes and was related to effectiveness. They noted the use of programme logic to be a key feature missing from many trials including those targeting developmental and behavioural outcomes.

The context and design of the evaluation of programmes may also be a key factor to evidence of effectiveness. Benefits observed in one system (eg, USA) may not translate in different service systems with different populations and reach. For example, a recent evaluation of the effectiveness of FNP delivered in England's broadly based, publicly funded, healthcare setting, concluded no evidence of benefit for the primary outcomes versus usual care, that is, smoking in pregnancy, birth weight, emergency hospital attendance and admission for the child, and subsequent pregnancy.[21] That said, some secondary outcomes (eg, language development concern, child safety) did show some benefit even within a trial where the control group received high levels of routine care. This suggests that outcomes for SNHV need to be carefully considered with thoughtful programme logic, rigorous study design and an understanding of the likely, specific healthcare system benefits.[21]

In the Australian context, the results from the MECSH trial suggest that SNHV holds promise for improving children's learning and development outcomes.

However, with more SNHV programmes in Australia gaining traction without evaluation in randomised controlled trials (RCTs), and evidence for only moderate effects from international research, it is important to empirically determine whether an Australian SNHV programme can help families overcome the effects of adversity by improving the learning and development of their children. In response to this need, the state governments of Victoria and Tasmania and philanthropic organisations have funded a new partnership committed to the development and evaluation of the first multisite, multijurisdictional, randomised trial of SNHV delivered via the universal nurse-delivered child and family health (CFH) service. This is the largest SNHV trial in Australia. The programme is known as 'right@home'.

This paper reports the research protocol for the right@home RCT. The primary hypotheses are that at child age 2 years, when compared with those in usual care, the intervention mothers will demonstrate improved: (1) parental care of the child; (2) parent responsivity and (3) a supportive home learning environment. Secondary hypotheses are that (1) *mothers* will have improved pregnancy outcomes, quality of life, mental health, general health and well-being, parenting self-efficacy and health service use; (2) *children* will demonstrate improved general health and functioning; and (3) *siblings* will have improved mental health and behaviour. In developing this trial, we found a relative absence of detail in the international home visiting literature on process details for intervention and evaluation. This protocol therefore provides detailed description of the intervention, study design and research methods employed.

METHODS AND DESIGN

Study design

The right@home trial is an RCT of SNHV from pregnancy to child age 2 years, compared with usual care. It is conducted as a superiority trial with two parallel groups and a primary end point at child age 2 years. Parental care of the child, parental responsivity to the child and the home learning environment are evaluated at 2 years by researchers who are blinded to intervention status.

Setting

This is a multisite trial conducted in the states of Victoria and Tasmania in Australia where each state is responsible for the delivery of their local healthcare system. Participants are recruited from the public maternity hospitals servicing four local government areas (councils) in Victoria (Ballarat, Dandenong, Frankston, Whittlesea) and three regions in Tasmania (South, North, North West). The trial regions are selected for their high prevalence of families experiencing socioeconomic and psychosocial adversity, a mix of metropolitan and regional areas, and interest from the universal CFH services in participating in the trial.

Participants

Eligible participants are pregnant women attending the antenatal clinics from May 2013 to August 2014:

- With expected due dates before 1 October 2014,
- Are <37 weeks gestation,
- Have sufficient English proficiency to verbally answer interview questions,
- Have 2 or more of 10 risk factors identified by risk factor screening (see Recruitment and eligibility section and table 2), and
- Have home addresses within the travel boundaries specified by the local councils/regions managing the intervention nurses.

Women are excluded if they:

- Are enrolled in the Tasmanian Department of Health and Human Services CU@Home visiting programme (for first-time mothers aged 15–19 years),
- Do not comprehend the recruitment invitation (eg, 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), or
- Have no mechanism for contact (landline or mobile telephone, or email address).

Recruitment and eligibility

Trained researchers are provided with scripts and approach all women in the waiting rooms of antenatal clinics, inviting them to complete the hardcopy risk factor survey (table 1). Women with insufficient English proficiency for participation are most frequently identified before completing the screening survey, although a proportion is identified afterwards. The majority of women who are ineligible due to other exclusion criteria are most often identified after completing the screening survey (eg, after reporting their local postcode). When the antenatal clinics are extremely busy, the researchers cannot invite all women to complete the survey. Researchers then verbally assess eligibility regarding gestation and address before offering the survey. To accommodate low literacy, researchers ask women if they would like the survey read to them or to complete it alone. Researchers check all surveys for completeness. Surveys were collected until the necessary sample size for the RCT was reached and the recruitment period ended. Eligibility based on risk is defined as 2 or more of 10 risk factors as identified by a pilot study of the recruitment processes conducted in February to March 2013. The risk factor measures are summarised in table 2.

Eligible women are invited into the RCT and the initial baseline visit is booked immediately where possible. Interested women are visited in their homes by trained researchers who collect informed consent and conduct a comprehensive baseline questionnaire including questions about their mental and physical health, psychosocial circumstances and pregnancy (table 3). The questionnaire is conducted face-to-face to minimise participant burden and the potential impact of low literacy.

Table 1 Graphical depiction (Perera diagram) of the trial components shared and unique to the trial arms

Time point relative to randomisation	Intervention	Control
Screening (face-to-face)	A	
Informed consent (face-to-face)	B	
Enrolment & Baseline Data Collection (face-to-face)	C	
Randomisation		
SNHV	D	
6 week phone assessment	E	E
SNHV	D	
6 month phone assessment	F	F
SNHV	D	
1 year face-to-face assessment	G	G
SNHV	D	
18 month phone assessment	H	H
SNHV	D	
2 year face-to-face assessment	I	I

A	Screening survey for pregnant women in antenatal clinics
B	Women who meet the eligibility criteria and are interested in the RCT are visited in their home to obtain formal consent
C	After obtaining formal consent, eligible women complete a baseline questionnaire
D	Sustained nurse home visiting intervention
E	Study 6 week follow-up to collect new contact details and assess pregnancy, health care access and health literacy
F	Study 6 month follow-up to collect new contact details, health literacy and health service use data
G	Study 1 year follow-up to assess primary and secondary outcomes
H	Study 18 month follow-up to collect new contact details, health literacy and health service use data
I	Study 2 year follow-up to assess primary and secondary outcomes

RCT, randomised controlled trial; SNHV, sustained nurse home visiting.

Table 2 Description of measures

Item	Description
Screening criteria to establish eligibility at waiting room survey*	
Young pregnancy	Calculated from year of birth and dichotomised into '<23' vs '≥23 years'[22]
Living with another adult	'Yes' vs 'no'
Support in pregnancy	Anyone supporting participant through pregnancy, for example, financially, emotionally or practically? (This could be a partner/husband, relative or friend) (yes/no)
Smoking	'Yes' vs 'no'
Global health	Single 5-point item ('poor' to 'excellent') from the self-reported SF6,[23] dichotomised into 'poor/fair/good' vs 'very good/excellent'[24]
Long-term illness	Health problem or disability that limits daily activities (yes/no), drawn from the UK 2001 Census[25]
Anxious mood	Matthey 2-item Generic Mood Question, which has shown good correlation with longer, validated anxiety measures including the EPDS and the Hospital Anxiety Depression Scale[26]
Education	Highest level of school completed, dichotomised into '<year 12' vs 'completed year 12' reflecting completion of secondary level education in Australia
Income	Person in household who currently has paid work/earns an income (yes/no)
Ever worked	Participant has ever had a job before (yes/no)
Primary outcomes collected at 2 years	
Regular meal times	Single 5-point item ('never' to 'always)'. Study designed based on Sleep Well Be Well Regular Bedtime item[27]
Food choices	12-item measure of food choices over past 24 hours, rated on a 3-point scale (not at all/once/more than once), drawn from LSAC[28]
Regular bedtime	Single 5-point item ('never' to 'always'), adapted from the 'Sleep Well Be Well' study[27]
Regular bed routine	Single 5-point item ('never' to 'always'), drawn from the 'Sleep Well Be Well' study[27]
Safety of the environment	Items assessing aspects of home safety, which are dichotomised into 'safe' vs 'not safe'. Study designed based on Royal Children's Hospital Safety Centre and KidSafe checklists[30 31]
Warm parenting	6-item measure assessing parental warmth. Items rated on a 5-point scale ('never/almost never' to 'always/almost always'), drawn from LSAC[29]
Hostile parenting	5-item measure assessing parental hostility. Items rated on a 10-point scale ('not at all' to 'all of the time'), drawn from LSAC[29]
Parent responsivity and the home learning environment	HOME:[32] 45-item measure comprised of observation and parent report, assessing the quality and quantity of stimulation and support available to a child in the home environment. Items dichotomised ('not observed or reported' vs 'observed and/or reported') and summed. Continuous total score ranging 0–45, with higher scores indicating a better home environment. 6 subscale scores: parental responsivity (11 items), acceptance of the child (8 items), organisation of the environment (6 items), learning materials (9 items), parental involvement (6 items), variety in experience (5 items)
Secondary outcomes at 2 years	
Child ever breast fed	Single item 'yes' vs 'no'
Duration of breast feeding	Age in months at which breast feeding stopped
Age started solids	Age in months
Drink choices apart from milk/formula	Child regularly has drinks other than milk or formula 'yes' vs 'no'; if yes, list of regular drink choices[28]
Feeding problem	Single 4-point item report of child feeding problems, dichotomised into yes (moderate/severe) vs no (none/mild), study designed based on LSAC sleep problem item[28]
Child ate breakfast today	Single item 'yes' vs 'no', drawn from LSAC[28]
Sleep problems	Single 4-point item report of child sleep problems, dichotomised into yes (moderate/severe) vs no (none/mild), drawn from LSAC[28]
Child–parent relationship	Single 5-point item ('poor' to 'excellent'), study designed based on the single global health item drawn from the self-reported SF6

Continued

Table 2 Continued

Item	Description
Parenting efficacy	4-item parenting efficacy scale. Items rated on a 10-point scale ('not at all how I feel' to 'exactly how I feel') drawn from LSAC, and a single 5-point parenting efficacy item assessing mother's feelings about herself as a parent ('not very good' to 'very good') drawn from LSAC[29]
Global health	See description in Screening measures above
Maternal mental health	DASS:[33] 21-item measure, rated on a 4-point scale ('not at all' to 'most of the time') assessing the negative emotional states of depression, anxiety and tension/stress. Three subscales (7 items each): depression, anxiety and stress scales
Life satisfaction	Personal Well-being Index (International Well-being Group, 2013):[34] single item assessing general life satisfaction, and 8 items assessing satisfaction with specific life domains, rated a 10-point scale ('no satisfaction at all' to 'completely satisfied')
Locus of control	3 items assessing mother's self-efficacy or locus of control, drawn from the UK Millennium Cohort[35]
Maternal quality of life	AQoL-8D:[36 37] 35-item measure assessing health-related quality of life. Provides a single overall utility-based quality of life measure, and 8 separately scored scales: independent living, happiness, mental health, coping, relationships, self-worth, pain, senses, which can be totalled into 2 super dimension scales: physical and psychosocial
Smoking	'yes' vs 'no'
Current education	Mother currently undertaking study or training 'yes' vs 'no'; if yes, type of qualification, drawn from LSAC.[28]
Current employment	Mother currently employed 'yes' vs 'no'; if yes, type of employment and age of child when mother returned to work.
Maternal stress	Hair cortisol as a measure of maternal stress response over the past 3 months. The hair sample is a minimum length of 3 cm, with the total density of the sample equating to approximately half a pencil's width (30–50 mg). Cortisol concentrations to be reported as a continuous measure[38]
Child global health	See description in Screening measures above, collected for child and parent
Child stress	Hair cortisol, see description for maternal stress above
Communication and symbolic behaviour	CSBS:[39] 6 items from the CSBS Developmental Profile Infant/Toddler Checklist (item numbers 7, 8, 11, 13, 18, 24) selected to assess child communication, which have not shown a ceiling effect when assessed at child age 2 years in a population cohort of child language.[40] Items rated on a 3-point scale (not yet/sometimes/often)
Maternal–child interactions	Drawn from fine analysis of maternal–child video, identifying maternal responsive behaviours (eg, expansions, imitations, questions, labels, directives) that are associated with child language outcomes, adapted from the work by Levickis *et al*[40]
Sibling mental health and behaviour	25-item Strengths and Difficulties Questionnaire (4–10 years old version):[41 42] assesses emotional and conduct behaviour, and total difficulties scores (higher scores indicate greater problem)
Parental enablement	Modified Parent Enablement Index:[43] 6-item measure assessing parent enablement as a result of services provided by the child health nurse, rated on a 3-point scale (much better/better/same or less)
Parent satisfaction	Modified Parent Satisfaction Questionnaire:[44 45] 10-item measure assessing parent satisfaction with services provided by the child health nurse, rated on a 5-point scale ('strongly agree' to 'strongly disagree')

*Eligible participants report 2 or more of the 10 risk factors identified by risk factor screening.
AQoL-8D, Assessment of Quality of Life-8D; CSBS, Communication and Behaviour Scales; DASS, Depression Anxiety and Stress Scales; EPDS, Edinburgh Postnatal Depression Scale; HOME, Home Observation for Measurement of the Environment; LSAC, Longitudinal Study of Australian Children; SF6, Short Form-6.

Randomisation

Sequence generation: Participants are randomly assigned to either usual care (control) or programme (intervention) arm with a 1:1 allocation following a computer-generated randomisation schedule stratified by site (Ballarat Hospital, Dandenong Hospital, Frankston Hospital, Northern Health, Launceston General Hospital, Hobart Royal Hospital, Northwest Regional Hospital) and parity (first time parent vs those with children already) using permuted blocks of sizes 2, 4 or 6.

Allocation concealment mechanism and implementation: Participants are randomised using a study-designed,

Table 3 Data collection schedule

	Antenatal		Postnatal				
Measures	**Screening**	**Base**	**6-week**	**6-month**	**12-month**	**18-month**	**24-month**
Screening							
Young pregnancy	●						
Gestation	●						
Postcode/zip code	●	●	●	●	●	●	●
First child	●						
Living with another adult	●	●	●	●	●	●	●
Support in pregnancy	●						
Global health	●	●	●	●	●	●	●
Smoking	●				●		●
Long-term illness	●						
Anxious mood	●		●	●	●	●	●
Education	●	●			●		●
Income	●	●	●	●	●	●	●
Ever worked	●						
Primary outcomes							
Care outcomes							
Regular meal times					●	●	●
Food choices						●	●
Regular bedtime				●	●	●	●
Regular bed routine						●	●
Safety of the environment					●		●
Responsivity outcomes							
Warm parenting					●		●
Hostile parenting					●		●
Parent responsivity, acceptance, and involvement					▲●		▲●
Home learning environment outcomes							
Home organisation of the environment, learning materials and variety					▲●		▲●
Secondary outcomes							
Care outcomes							
Child ever breast fed			●	●			
Duration of breast feeding			●	●			
Age started solids			●	●			
Drink choices apart from milk/formula					●		
Feeding problem				●	●		
Child ate breakfast today							
Sleep problem				●	●	●	●
Responsivity outcomes							
Child–parent relationship				●	●	●	●
Maternal outcomes							
Parenting efficacy					●		●
Global health	●	●	●	●	●	●	●
Anxious mood	●		●	●	●	●	●
Maternal mental health		●	●	●	●	●	●
Life satisfaction		●			●		●
Locus of control		●			●		●
Maternal quality of life		●			●		●
Maternal stress					+		+
Smoking	●				●		●
Current employment		●					●
Current education							●
Child outcomes							
Child global health				●	●	●	●
Child stress							+
Communication and symbolic behaviour							●
Maternal–child interactions					▲		▲
Impact							
Parental enablement					●		●
Parent satisfaction					●		●
Sibling outcomes							
Sibling mental health and behaviour		●			●		●

●Collected by parent report; ▲collected by observation; +collected by hair sample.

online, central randomisation service. To ensure baseline allocation concealment, the project coordinator does not randomise until the participant is recruited into the trial; that is, after the participant provides informed consent, all the inclusion and exclusion criteria are addressed, the eligibility of the participant is confirmed and all baseline measurements are completed. At the end of each baseline assessment, the researcher checks in with project coordinator who attempts to contact each participant to conduct randomisation allocation almost immediately.

Usual care

Families in participating sites are provided with well-child checks which are delivered by community-based nurses. These checks are available to all families from birth until 5 years at no out-of-pocket cost. In the first 2 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. Nurses also provide a needs-based 'enhanced' service, which involves additional home and/or centre visits. Eligibility for the enhanced model of care is decided by the local area's CFH service. This 'usual service' provides the comparator for the right@home intervention.

Intervention

The right@home SNHV programme is designed as an integral element of the universal CFH services in Victoria and Tasmania. This approach reflects the concept of proportionate universalism, where action to address social gradients in child health and development 'must be universal, but with a scale and intensity that is proportionate to the level of disadvantage'[46] (ie, higher dose and intensity for higher need).

Development of the intervention: The intervention programme was developed based on a series of three literature reviews conducted to inform the trial,[19 47 48] which addressed the overarching question: *What features of an SNHV programme are likely to bring about improved learning and development outcomes for young children whose families could benefit from greater support?* The original intention was not to undertake three literature reviews (only the first); however, the findings of each highlighted the need to undertake a subsequent review with a different focus. The first literature review concluded that there is limited knowledge about what makes SNHV programmes effective. Factors that did emerge as important for impact were programmes being delivered by a more professionally skilled workforce, visits starting in the antenatal period, being offered over a longer period of time and being offered to the families experiencing greatest adversity or complexity.[49] The most effective SNHV programmes are those targeted to populations identified as most likely to benefit from additional support.[49]

The second literature review then investigated factors associated with successfully working with families experiencing adversity. From a range of disciplines the review determined that, to be successful, programmes must involve a partnership between the family and nurse, focus on goals that parents prioritise, build competencies, be non-stigmatising and maintain continuity of care.[48] The third review went on to investigate specific evidence-based interventions that focused on this trial's primary outcome areas and had the potential to enhance the effectiveness of SNHV programmes. The outcome areas were derived from reviewing the early childhood evidence which highlighted the importance of the home learning environment,[50] parent responsivity and language development[40] and the differential effect of adversity on executive functioning and therefore self-regulation.[51] All of these areas are considered necessary precursors for optimising children's learning and development trajectories.

Intervention overview: The right@home intervention is structured around the core MECSH framework and programme.[17 18] This core is bolstered by five evidence-based strategies for content and two for the process of delivery, termed 'focus modules' (see description of content below).[47] Taking heed of Segal *et al*'s[20] review demonstrating the importance of programme logic for effective home visiting programs, the intervention content is selected to align with evidence of impact on the primary objectives.

The intervention schedule includes a minimum of 25 home visits offered to the woman, primarily by the same specially trained right@home nurse. Three visits are scheduled antenatally, with the remainder during the first two years postbirth. The actual number of antenatal home visits that a woman receives is determined by gestation and may vary. For example, a woman recruited at 20 weeks gestation should receive the three visits. If a woman is recruited later, more frequent visits may be offered to catch up. After 36 weeks gestation, one antenatal visit is scheduled if possible, unless it is appropriate to delay until the very early postnatal period. Postnatal visits are scheduled to occur within 1 week of birth; at least weekly until 6 weeks; fortnightly until 12 weeks; 3-weekly to 6 months; 6-weekly to 12 months and bi-monthly until 2 years. In preparation for discharge from right@home, families are assisted to re-enter the usual care service, which is available until child age 5. Within the right@home intervention, the nurses incorporate the well-child checks that are delivered via usual care (described above) into the home visits, ensuring right@home builds on the universal platform.

Intervention staffing: Nurses are recruited from the usual care service and trained to deliver the right@home programme. The right@home nurses must be qualified CFH nurses; that is, Baccalaureate-registered nurses (or equivalent) with postgraduate qualifications in CFH, who have also completed Family Partnership Model Training, online and face-to-face training in the core MECSH programme, and additional training in the right@home focus modules. Line managers provide nurses with clinical supervision. Each nurse is expected

to receive a minimum of 1 hour per month of reflective practice supervision—this may be in a group or individually—and is ideally facilitated by someone other than the line manager. In addition to reflective practice supervision, there is case review, where each family is reviewed by the right@home clinical team, and additionally any other clinical professionals relevant to the cases being reviewed, at least once every 6 months. This occurs through scheduled monthly case conference meetings.

Each site has a dedicated social care practitioner, who is a member of the programme team. There is one full-time social care practitioner per 100 families in the programme. The role of the social care practitioner is to provide support for the nursing team and psychosocial support for the families, such as brief counselling interventions, and instrumental support, including advocating for and assisting families with housing, service access and financial issues.

Intervention content: The following evidence-based strategies contribute to the 'focus modules' that are aligned with the primary outcomes:

1. Parental care of the child: keeping children safe within a less chaotic and more structured environment (eg, feeding and sleeping routines) promotes self-regulation, decreases rates of injury and is importantly related to executive functioning and school success.[52] The nurse goes through the following with families at scheduled time points, and reinforces the content as necessary during the course of the intervention.
   A. *Safety*: nurse-led KidSafe audit[30] of the internal and external safety of the child's home;
   B. *Sleep*: from 0 to 6 months: anticipatory guidance on normal infant sleep and positive bedtime routines; from 6 months onwards: a behavioural sleep intervention;[53 54]
   C. *Nutrition*: 'Get up and Grow' healthy eating guidelines.[55]
2. Parent responsivity: the construct of responsivity incorporates both bonding with the child and promoting language (ie, is also related to the home learning environment (the third primary outcome)). Neuroscience suggests that infant brain development related to emotional attachment is most rapid in the first 12 months of life and predictive of infants' ongoing social and emotional development.[51] Parental verbal responsivity is also strongly predictive of child's vocabulary and language.[40]
   D. 'Promoting First Relationships'[56] programme of materials and activities for parents promoting secure and healthy relationships with their children.
3. Home learning environment: research has shown that the home learning environment (including aspects like the number of books in the home, and activities like reading stories and recognising numbers and shapes) independently predicts school outcomes. Importantly this research demonstrated that the home environment promoted children's learning and development regardless of socioeconomic status.[50]
   E. 'Learning to Communicate' programme,[57] from 0 to 12 months and a modified version of the 'smalltalk' programme,[58] from 13 to 24 months, to enhance the ability of parents to provide appropriate stimulation for their babies, which will facilitate their development.

While some of the above content (eg, sleep, safety, nutrition) and supports are provided in the usual care system, they are not provided systematically as in right@home. In this programme, although the focus modules are designed to be implemented at specific developmental points, nurses still structure each home visit flexibly to best address each mother's needs, skills, strengths and capacity. They are guided by a strengths-based approach and joint goal setting, an integral part of the Family Partnership Training and aligned with our literature review findings.[48] The nurse supports and enables the mother and the family to:

- Enhance their coping and problem-solving skills, and ability to mobilise resources;
- Foster positive parenting skills;
- Support the family to establish supportive relationships in their community;
- Mentor maternal–infant bonding and attachment; and
- Provide proactive primary healthcare and anticipatory health education, including but not limited to evidence-based information regarding immunisation, Sudden Infant Death Syndrome (SIDS) risk reduction, infant nutrition and child safety.

Nurses use an additional two 'process' focus modules —video feedback and motivational interviewing strategies—to help parents instigate behavioural change.[47] Nurses and the social care practitioners also help parents access early childhood health services, volunteer home visiting services and family support services; hold group activities specifically for intervention families; and link women into community activities, as needed.

The *key differences* between the right@home intervention and the usual care are:

- Home visiting starting antenatally;
- Continuity of care by the same nurse throughout the 2½-year programme;
- Care by nurses with additional training in the programme model;
- Postnatal home visiting programme to the child's second birthday including: the MECSH structured programme; well-child checks; proactive (rather than needs-based) preventive and anticipatory primary healthcare and health education; and standardised focus modules aligned with primary outcomes;
- Dedicated social care practitioner in the team;
- Group activities specifically tailored for the right@home families.

Intervention fidelity: For the purpose of this study, dose refers to the number of visits from a nurse for each intervention participant. For the delivery of scheduled programme content, nurses and/or social care practitioners enter data into the research database following each visit via 'checklists', indicating the occasion, duration and content delivered in the session. The quality of the intervention, including dose, client retention and delivery of programme content is systematically monitored by the MECSH Support Service at the Western Sydney University through quarterly review of programme delivery and feedback on performance to the participating sites.

Blinding: The research managerial staff, the participants and nurse teams delivering the intervention are aware of the allocation to treatment arm. Control clients will be on the caseload of usual care nurses. Intervention clients may also, on occasion, access the usual care service. Great care is taken to prevent usual care nurses knowing which specific clients are in the study; however, they will be aware that the study is underway and some of their clients may be in the study. At each site a nominated 'special contact', usually the nurse unit manager is informed of all research participants and their intervention or control allocation. The special contact is the only person who knows all of the participants.

Research staff that are responsible for conducting outcome assessments are blinded to treatment allocation. Families are asked not to disclose their randomisation status at assessments. If the research staff are unblinded at face-to-face assessments (see below), then the unblinding is recorded in the study database and attempts are made to organise the next annual assessment with another researcher. Researchers complete phone assessments with participants from different sites, that is, the ones they do not complete face-to-face assessments with, to minimise the opportunities for unblinding. Any data cleaning, coding and/or analysis undertaken by the data managers and statisticians excludes randomisation variables to maintain blinding until all 2-year data are collected. Emergency unblinding should not be necessary as intervention families, healthcare staff and senior study staff are aware of randomisation status.

Assessments

All assessments are conducted via participant–researcher interviews. At baseline and 1 and 2 years, interviews are conducted face-to-face in the participant's home. At 6 weeks, 6 and 18 months, interviews are conducted via telephone. All questionnaires except the initial screening survey are developed to be collected electronically on tablets. Women are able to voluntarily skip questions. Paper versions of assessments are provided in the case of electronic/technical malfunction, or if the woman cannot complete or declines a home visit but is happy to complete a hardcopy version. Described in detail in tables 1 and 2, the assessment at 2 years takes place in women's homes and includes measures of the primary outcomes and secondary outcomes. The procedure comprises: (1) standardised interview and observational assessment of the majority of outcome measures, (2) videoing of maternal–child interactions for later analysis, and (3) sampling of hair for cortisol testing.

Methods for retention

Researchers make every reasonable effort to follow each participant for the entire study period, recognising the importance of retention in maintaining the sample size, generalisability and comparability between the groups randomised to the intervention programme or usual care. The right@home families are considerably mobile, thus our sample size has been calculated for a retention rate of 60% of mothers until the assessment of the primary outcomes at age 2 years. Retention is promoted in the following ways:

- Maintaining regular contact with brief phone interviews at 6 weeks, 6 and 18 months in between the face-to-face assessments;
- Distribution of reminder postcards before each assessment;
- Reminder phone calls and text messages before face-to-face assessments;
- Distribution of end-of-year newsletters and seasons' greeting cards;
- Giving a $30 gift card for a national supermarket chain (excluding alcohol and tobacco purchases) as a token of appreciation for each of the three face-to-face assessments completed;
- Recording up to two alternate contacts for each participant, who the research team can contact in the case that they lose contact with the participant; and
- Consent from women to contact the Australian Department of Human Services for their updated contact details recorded by the Centrelink programme (an agency that provides a rebate for childcare costs, as well as means-tested social support and unemployment benefits).

Data management

All participants and nurses are given unique numerical identifiers (an ID code) for use throughout the study. A single, secure, purpose-built online electronic database (using Umbraco software) is used to record and store all participant and nurse details. Video data (collected by intervention nurses to conduct video feedback with families and by researchers at the face-to-face follow-up assessments) are uploaded as electronic files to external hard drives that are securely stored with written materials and hair samples in locked filing cabinets. Following Human Research Ethics Committee (HREC) storage requirements, all project materials are stored for the required period of time, that is, indefinitely if the participant consents to providing their data for data pooling or, otherwise, until the youngest participant is 25 years old. After that time, hardcopy materials will be destroyed by shredding, and any password-protected

electronic archives are permanently deleted. After hair samples are tested at an external laboratory, they are destroyed according to the laboratory's protocol.

Sample size calculation

Existing SNHV trials show relatively modest effects (effect sizes of 0.2–0.4 SDs) for outcomes such as child mental health and behaviour, and cognitive and language development, from infancy to mid-childhood.[19] While effect sizes of 0.25–0.3 SDs can be meaningful and impactful at the whole of population level,[59] targeted public health interventions such as SNHV include a cost and intensity such that larger effects in the short-to-medium term might be necessary to justify implementation at a population level. We do note the longer term cost-benefits that have been achieved despite the more limited short-term benefits. Interestingly, previous home visiting RCTs have rarely published sample size calculations. Given the primary objectives of the trial and measures collected in existing RCTs,[18 49] we chose to anchor our sample size calculation around detection of a minimum effect size of 0.3 for the responsivity subscale of the Home Observation Measurement of the Environment (HOME) Inventory (see table 2), to allow comparisons with the original MECSH trial and other international SNHV programmes.[60] The sample size applies across all of the subscales of the HOME Inventory and other continuous outcomes as based on number of SDs rather than the actual outcome distributions.

This is the first SNHV RCT to account for the potential effect of clustering in relation to the impact of each nurse on a group of women. The sample size was calculated twice: originally based on the expected nurse staffing for the intervention arm (n=14) and then based on the finalised staffing (n=18). The revised calculation in June 2014 considered the final staffing load of 18 nurses in the intervention arm and 18 pseudo-clusters in the usual care arm. To detect a minimum effect size of 0.3 with 80% power at the 0.05 significance level and assuming a modest average intraclass correlation of 0.02 within the clusters, the total sample size, allowing for attrition of 40% by 2 years, was N=714 (ie, n=357 in each arm). The anticipated attrition rate is based on results from other SNHV studies.[49]

Statistical analyses

The baseline characteristics of the mothers will be presented for each treatment arm using descriptors such as the mean, SDs, median and IQR for continuous data and proportions for categorical data. So that the effects attrition may have on the study findings may be considered, comparability between mothers participating at baseline and those who completed follow-up to 2 years will be examined for each of the treatment groups. These analyses will be used to determine the selectivity and loss of representativeness resulting from sample attrition.

Maternal and child outcome measures will be described by treatment arm. Comparisons will be made using regression models respecting the nature of the distribution of the outcomes, that is, linear regression for continuous or semicontinuous data, with presentation of mean differences and 95% CIs; and logistic regression for binary data with presentation of ORs and 95% CIs. Tobit regression will be used to confirm the sensitivity of linear regression to a non-normal distribution for outcomes with a censored normal distribution, and ordinal logistic regression for outcomes with up to five ordered categories. All regression analyses will be adjusted for study site and maternal parity in line with the stratification of the study randomisation. All regression analyses will also take account of any effects of the nurse (clustering), so that accurate effects of the intervention, regardless of child and family nurse delivering it, are estimated.

Subsequent analyses will adjust for factors that may not be balanced by randomisation and that are associated with family and child outcomes. These analyses will take into account maternal baseline and child characteristics identified a priori, for example, child's gender and age (at assessment), and maternal age, parity, antenatal risk, self-efficacy, mental health, education and socioeconomic status.

As noted in the UK Medical Research Council guidance described by Craig *et al*,[61] it is recommended that multiple outcomes are considered in evaluating the effectiveness of interventions which are complex in nature and are likely to result in responses across a diversity of family and child domains. As such, each of the multiple outcomes will be analysed individually with interpretations made across the consensus of evidence provided. This will involve careful examination and consideration of the magnitude, direction and statistical significance of the responsiveness estimated for each outcome. In recognition of the increased potential for false-positive findings arising through analysis of multiple outcomes, findings will be interpreted cautiously and in context with one another rather than in isolation. Patterns and consistency in the responsiveness of outcomes, and the overall balance of the evidence, will be examined rather than isolated findings which may have arisen by chance. It is particularly important that sufficient data are presented to enable comparability across SHNV programmes because of the complexity of this type of intervention and likely influence across multiple domains, and the extent to which SNHV programmes vary in their content, setting and target population.

Subgroup analyses: We will examine whether there is evidence that the intervention effect is modified for subgroups within the trial participants using tests of interaction between intervention and child and family factors as follows: parity (first-born vs other), antenatal risks (2 vs 3 or more risk factors at screening), maternal mental health at baseline (high vs low score)[18 62 63] and self-efficacy at baseline (poor vs normal mastery)[35]

using the regression models described above with additional terms for interaction between subgroup and trial arm. Should any of these interaction terms reveal evidence that the intervention effect varies between these groups, specific subgroup estimates and CIs will be presented. As we have not powered the trial to consider subgroups, these analyses are considered exploratory.

Per protocol analysis: In addition to the intention-to-treat analyses, we will conduct a per protocol analysis to examine how fidelity is related to effectiveness. In the intervention arm, fidelity is defined as having at least one antenatal visit and at least 19 visits in total with a right@home nurse during the course of the programme, that is, received 75% of the dose. In the usual care arm of the trial, fidelity is defined as having at least one visit with a CFH nurse and having fewer than 11 CFH nurse visits in total. This is to compare right@home full dose to usual care expected dose.

Women will be excluded from the per protocol analysis if they either do not fulfil the definition of fidelity, or do not complete the 2-year follow-up researcher assessment, or the child is removed from the primary carer, or the family experiences a critical event (such as miscarriage, late termination of pregnancy, stillbirth or neonatal death, or own critical health event). Child removal will be defined as children who have spent <4 nights per week with a primary carer as reported at the 2-year survey. If parents have shared custody then they will be excluded if the child spends <4 nights per week in the participants' care.

Missing data: The frequency and patterns of missing data will be examined and sensitivity analyses will be performed to compare the results of analyses restricted to families with complete data and analyses where those with missing data are considered using multiple imputation.[64 65]

Data monitoring: No data monitoring committee is needed for this study due to the known minimal risks. No interim analyses or stopping rules will be applied.

Cost evaluation

The economic analysis will use a cost consequences analysis from a government-as-payer perspective.[66] It will compare any additional costs experienced over the first 2 years of children's lives in the intervention group compared with the usual care group, to the changes in the multiple outcome measures at 2 years described in table 2. Costs are based on the health resources used by women from recruitment to child age 2 years. Data on health resource use are available by provider (nurse and maternity hospital) administrative records and by women's recalled service use in 6-monthly interviews. Provider data include the number and type (home or clinic based) of visits attended in intervention and usual care, and referrals made. Women report their use of health and other services (referred or other) over the previous 6 months. Measured health resource use will be valued with standard unit costs (eg, award rates for nurse salaries, Medicare fee schedule for referred services) and presented in 2016 Australian dollars, with second-year costs discounted at 5%. The trial-based economic evaluation results will be expressed as the change in costs of the intervention compared with usual care, relative to the change in effects of the intervention over and above the usual care arm at 2 years.

Study governance

The study is governed by a tri-partite partnership between the Australian Research Alliance for Children and Youth, a national not-for-profit organisation (responsible for overall project management including nurse contracts), the Centre for Community Child Health at the Murdoch Childrens Research Institute, Royal Children's Hospital, Melbourne (responsible for research evaluation) and the Translational Research and Social Innovation team, Western Sydney University (responsible for implementation of intervention). Study partners meet face-to-face quarterly, have regular meetings with state government partners and provide regular reports to funders.

Ethics, consent and permissions

A condition of approval is that any proposed amendments to the project, including changes to the protocol, participant information and consent form/s and participant materials are submitted to the reviewing HRECs for approval before use. The managerial research staff make safety and progress reports to the HRECs at least annually and within 3 months of study termination or completion at each site.

Consent: At the baseline home visit with the researcher, a signed consent form is obtained for each participant before any further survey administration. The consent form describes the purpose of the study, the procedures to be followed, and the risks and benefits of participation. The trained researcher conducts the informed consent discussion and checks that the participants comprehend the information provided and answer any questions about the study. Additional consents are collected throughout the study for aspects such as hair sampling and data linkage. To accommodate low literacy, women are offered the option of reading all consent invitations alone or reading it through with the researcher.

Consent is voluntary and free from coercion. At all times it is made clear that non-participation in the study does not affect the usual routine clinical management offered by any health providers, for example, the care they receive from the hospital or as part of the standard CFH service. The researcher who conducts the consent discussion also co-signs the informed consent forms. A copy of the consent form is given to the participant. Participant consent to the study is documented in their record on the study's electronic database. Each participant can choose to stop participating in the nurse service (intervention or control depending on randomisation status) at any point. Participants who choose to

stop participating in the nurse service will continue to be followed with the research assessments, unless they request to withdraw from the trial, in which case all research assessments will cease.

Confidentiality: Participant confidentiality is strictly held in trust by the investigators, research staff, and the sponsoring institutions and their agents, and is extended to cover clinical information relating to participants. The study protocol, documentation, data and all other information generated are held in strict confidence and in 'locked' electronic files. No information concerning the study or the data is released to any unauthorised third party, without prior written approval of the sponsoring institution. Investigators and students have access to the final data set via permissions maintained by the data managers.

Dissemination: The investigators and sponsor will communicate trial results to stakeholders, participants, healthcare professionals, the public and other relevant groups via presentations and publications.

DISCUSSION

This is the first multisite, multijurisdictional, Australian RCT to examine the effectiveness of SNHV in improving parenting and the home learning environment, when delivered via the existing universal child and family healthcare platform. The trial has been established as a partnership between academia, government, non-government and philanthropic organisations. The intent is to achieve the best 'real-life' study, focusing on generalisability, and within the confines of practicalities and budget. Should the intervention prove effective and cost-effective, this approach provides the greatest opportunity for research translation and full-scale implementation.

The trial has been designed with a number of methodological strengths. Recruitment is conducted via public hospitals, providing a study cohort that is representative of these target populations and thus generalisability of the findings to Australian families experiencing adversity. The intervention is built on those components for effective home visiting that were identified by a series of literature reviews (including the Australian MECSH study)[18 47–49] and is being conducted based on programme logic linking the intervention to impact and outcomes.[20] In 2014, we secured competitive funding from Australia's National Health and Medical Research Council, which will provide for follow-up to child age 5 years, allowing assessment of the effects and cost-effectiveness of the SNHV programme to school entry. At these older ages, assessments will incorporate more objective, face-to-face assessments of children's outcomes. Finally, the study governance arrangements allow for 'arm's length' evaluation of the intervention through a separate research organisation.

There are some limitations. As the trial does not blind participants, outcome reporting may be influenced by maternal perception and feelings about being in the trial, health knowledge, and well-being. However, as the parent is most often the closest observer of the child, they are best placed to report on the child's immediate environment and behaviour[67] and, at 2 years, parent report is the most feasible and powerful way to pick up any early signals that families and children are responding to the intervention. Direct observation measures like the HOME Inventory also help mitigate this limitation.

The exclusion criteria mean the findings may not generalise to non-English-speaking women or women with severe intellectual disability. The former is a limitation of home visiting trials generally, as using interpreters and translators may alter the type of family–nurse partnership necessary for effective behavioural change. While we use a population-based sampling strategy for recruitment, women stop receiving the intervention if they move out of a study region. This could be avoided if the service is delivered across the participating states (ie, following the intention of the real-life design).

This study is crucial for generating Australian evidence of an effective intervention to reduce the impact of social and environmental factors predisposing children to inequitable outcomes. The rigour and scope of this trial will make it possible to determine the effect of this comprehensive Australian SNHV programme. Despite the rhetoric regarding the benefit of SNHV, this is the first trial in Australia to test, at scale, the benefit and cost-benefit of an intervention programme that is delivered within the context of an existing (and therefore sustainable) universal health service system. In addition, the research and the intervention programme are being undertaken by two distinct organisations, with a third providing project management of the collaboration. This provides a more independent assessment of effectiveness than in many other SNHV trials where the research and implementation teams are the same. As such, this trial is a best practice implementation and evaluation model for professional home visiting in Australia.

Addressing inequity in outcomes for children across health and education is an issue of timely and significant policy interest at a state and federal level.[68 69] If right@home is effective and demonstrates benefit, the study design enables replicability at scale, with significant implications for the development of early childhood policy and strategy throughout Australia and internationally.

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