Nurse Home Visiting for Families Experiencing Adversity: A Randomized Trial

Sharon Goldfeld, PhD,[a,b,c] Anna Price, PhD,[a,b,c] Charlene Smith, PhD,[d] Tracey Bruce, MHSM,[e] Hannah Bryson, BA(Hons),[a,b] Fiona Mensah, PhD,[c,f] Francesca Orsini, MSc,[f,g] Lisa Gold, PhD,[h] Harriet Hiscock, PhD,[a,b,c] Lara Bishop, PhD,[a] Ashlee Smith, MPsych,[a,b] Susan Perlen, PhD,[a,b] Lynn Kemp, PhD[e]

abstract

OBJECTIVES: Nurse home visiting (NHV) may redress inequities in children's health and development evident by school entry. We tested the effectiveness of an Australian NHV program (right@home), offered to pregnant women experiencing adversity, hypothesizing improvements in (1) parent care, (2) responsivity, and (3) the home learning environment at child age 2 years.

METHODS: A randomized controlled trial of NHV delivered via universal child and family health services was conducted. Pregnant women experiencing adversity (≥2 of 10 risk factors) with sufficient English proficiency were recruited from antenatal clinics at 10 hospitals across 2 states. The intervention comprised 25 nurse visits to child age 2 years. Researchers blinded to randomization assessed 13 primary outcomes, including Home Observation of the Environment (HOME) Inventory (6 subscales) and 25 secondary outcomes.

RESULTS: Of 1427 eligible women, 722 (50.6%) were randomly assigned; 306 of 363 (84%) women in the intervention and 290 of 359 (81%) women in the control group provided 2-year data. Compared with women in the control group, those in the intervention reported more regular child bedtimes (adjusted odds ratio 1.76; 95% confidence interval [CI] 1.25 to 2.48), increased safety (adjusted mean difference [AMD] 0.22; 95% CI 0.07 to 0.37), increased warm parenting (AMD 0.09; 95% CI 0.02 to 0.16), less hostile parenting (reverse scored; AMD 0.29; 95% CI 0.16 to 0.41), increased HOME parental involvement (AMD 0.26; 95% CI 0.14 to 0.38), and increased HOME variety in experience (AMD 0.20; 95% CI 0.07 to 0.34).

CONCLUSIONS: The right@home program improved parenting and home environment determinants of children's health and development. With replicability possible at scale, it could be integrated into Australian child and family health services or trialed in countries with similar child health services.

[a]*Population Health,* [f]*Clinical Epidemiology and Biostatistics Unit, and* [g]*Melbourne Children's Trials Centre, Murdoch Children's Research Institute, and* [b]*Centre for Community Child Health, The Royal Children's Hospital, Parkville, Victoria, Australia;* [c]*Department of Paediatrics, University of Melbourne, Parkville, Victoria, Australia;* [d]*Australian Research Alliance for Children and Youth, Canberra City, Australia;* [e]*Ingham Institute for Applied Medical Research, Western Sydney University, Sydney, New South Wales,* Australia; *and* [h]*School of Health and Social Development, Deakin University, Burwood, Victoria, Australia*

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WHAT'S KNOWN ON THIS SUBJECT: Nurse home visiting programs may be used to redress inequities for children experiencing adversity. International trials demonstrate mixed results; some have led to improved outcomes for children and families in the short- and long-term but with small-to-moderate effect sizes.

WHAT THIS STUDY ADDS: The right@home nurse home visiting program improved parenting and the home learning environment for families experiencing adversity compared with existing services. It could be integrated into well-child health care in Australia or trialed in other countries with appropriate health care provision.

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Sustained socioeconomic and psychosocial adversity during the early years of life has wide-ranging and long-lasting consequences well into adulthood, including lower educational attainment, poorer health, and lower income.[1,2] Families experiencing this adversity often encounter barriers in accessing health and support services, which contribute to poorer outcomes for their children (described as the inverse care law[3]) contributing to the persistence of developmental inequities among children in high-income countries.[4–7]

More recent economic, health, and social research reveals that efforts to redress inequities have the greatest benefits if they are delivered during early childhood (pregnancy to 8 years of age).[8–10] Given the enduring effects of the home environment on children's development,[11,12] nurse home visiting (NHV) is an increasingly popular model of service delivery to improve service access and outcomes for families experiencing adversity. It is championed by international organizations such as the United Nations Children's Fund and was a commitment of US President Barack Obama's 2014 budget, with $1.5 billion in funding over 10 years (2015–2024) to maintain and expand evidence-based home visiting services. Despite the appeal of NHV, previous studies suggest that even the most successful programs have moderate effects in the short-term and mixed benefits in the longer-term,[13] with findings not consistently replicated across contexts. For example, researchers in a recent UK evaluation of Nurse-Family Partnership (NFP) program concluded no evidence for improved primary outcomes (smoking in pregnancy, birth weight, emergency hospital attendance and admission for the child, and subsequent pregnancy)[14]; however, researchers in a Dutch evaluation reported improved smoking, breastfeeding, and child-protection outcomes.[15]

In Australia, only the Maternal Early Childhood Sustained Home-Visiting (MECSH) program[16] has been rigorously evaluated when delivered via the existing universal, nurse-led child and family health (CFH) services.[17] Compared with those who receive usual care, mothers who were offered the intervention (25 visits from pregnancy to child age 2 years) showed results consistent with those in international NHV programs at child age 2 years; mothers were more responsive to children's needs and breastfed for longer, and those who reported psychosocial distress in pregnancy also reported benefits to their children's development and experience of motherhood.[17] This small study (N = 208) suggested that NHV has the potential for improving children's health and developmental outcomes.

To address the needs of families living in adversity in Australia, we collaborated with the Victorian and Tasmanian state governments and philanthropic organizations to develop and evaluate the largest multisite, multistate, randomized trial of NHV to be delivered through the existing Australian universal CFH services (right@home).[18] Given the limitations in previous research regarding impact across contexts,[19,20] we conducted a thorough development process[13,21,22] to ensure that our NHV program could be effective for an appropriately targeted population within an existing health care system.[23] We paid particular attention to program design, logic, and fidelity that are often missing from published NHV research.[24]

Like other NHV programs,[13,19] including the well-known NFP program, right@home identifies a target group of women who are at risk, aims to improve outcomes for these women and their children, uses a structured schedule of visiting, and has some commonalities in the underpinning theories and evidence base.[25–27]

However, right@home differs from these programs in the following ways:

- It was designed and tested for delivery within (and not separate from) an existing system of early childhood services.[28]
- Families were recruited who were
  - identified by using a broad range of psychosocial and socioeconomic risk factors known to negatively impact children's learning and development[29–31] (rather than families being selected only on the basis of risks such as young age, parity, or single parenthood[13]); and
  - most likely to benefit from an NHV service focused on prevention (rather than focused only on the families that were the most acutely disadvantaged [eg, those with alcohol and drug abuse]).[13]
- It was delivered by a multidisciplinary team (nurses and social care practitioners) with a strong program focus on service system engagement.[18]
- Visits (limited to ~25) with intentionally increasing space between were scheduled to build families' problem-solving, aspirational, and self-management capacity and service system engagement.

We aimed to test whether the right@home NHV program could be used to improve outcomes in domains related to parenting and the home environment that are known to predict beneficial child developmental trajectories.[13] We hypothesized that at child age 2 years and when compared with those who are offered usual care, mothers who are offered the intervention would demonstrate improved (1) care of

the child (sleeping, feeding, and safety), (2) responsivity (parenting and bonding), and (3) home learning environment (language and literacy activities).

METHODS

Design and Participants

We compared a randomized controlled trial (RCT) of NHV from pregnancy to child age 2 years with the existing CFH services (usual care). This was conducted as a superiority trial with 2 parallel groups and a primary end point at child age 2 years. Researchers recruited pregnant women attending antenatal clinics at 10 public maternity hospitals across Victoria and Tasmania from April 30, 2013, to August 29, 2014.[18] We used a brief risk factor survey of 10 broad-ranging psychosocial and socioeconomic risk factors for poorer child outcomes developed and piloted for the study, which showed that 2 (17%) or more adverse risk factors identified 61% of women who reported other more sensitive risk factors (eg, alcohol and drug use and domestic violence) in the standard clinical appointment.[32] Eligible women (1) had due dates before October 1, 2014; (2) were <37 weeks' gestation; (3) had sufficient English to complete interviews; (4) had ≥2 of 10 risk factors identified at screening (Supplemental Table 4)[29,32]; and (5) had home addresses within travel boundaries specified by participating areas. Women were excluded if they (1) were enrolled in an existing Tasmanian NHV program for 15- to 19-year-olds, (2) did not comprehend the recruitment invitation (eg, intellectual disability or insufficient English), (3) had no mechanism for contact (telephone number or e-mail address), or (4) experienced a critical event (eg, termination of pregnancy, stillbirth, or child death). Participants provided informed consent before completing the home-based baseline interview.

Randomization and Masking

After the baseline interview, participants were randomly assigned to the control or intervention arm with a 1:1 allocation following a computer-generated schedule stratified by site and parity (first-time parent versus parent with children) by using permuted blocks of sizes 2, 4, or 6. The research managerial staff, participants, and intervention teams were aware of allocation. Usual care nurses were not informed which clients were in the control group. Researchers who conducted assessments were blinded to randomization, with families being asked not to disclose their group status. Statisticians excluded randomization until all 2-year data were collected to maintain blinding.

Procedures

The right@home program was structured around the core MECSH framework and training[16,17] and bolstered by 5 evidence-based strategies for content (sleep, safety, nutrition, regulation, and bonding and/or relationship) and 2 for the delivery process (video feedback and motivational interviewing strategies), which were termed focus modules.[18] We developed a logic model that was focused on the alignment of right@home content and aimed at outcomes at child age 2 years, specifically changes in parental care and the home learning environment.

Women in the intervention were offered ∼25 nurse visits (60–90 minutes each; content is in the protocol[18]), which commenced antenatally and were delivered mostly by the same trained right@home nurse. The intervention also included ≥1 visit by the program social care practitioner, who supported the nurse to deliver the intervention and provided brief counseling interventions and case management for families as needed. In contrast, the usual CFH services include 6 (Tasmania) or 9 (Victoria) consultations up to child age 2 years; the first is offered in families' homes, and successive consultations occur at a local center, with some limited program flexibility depending on family need.[18]

Outcomes

Researchers conducted assessments in participants' homes at child age 2 years. Given the complex intervention,[33] we identified 13 outcomes across the 3 domains (Table 1), which were selected a priori according to program logic and content and chosen as key determinants of child outcomes (Supplemental Tables 5 and 6). Given the complex nature of the right@home intervention, a focus on a single measure of outcome was likely to understate the effect of the trial. We therefore used multiple outcomes that could be considered in the interpretation of the effectiveness of the trial.[33] We chose secondary outcomes to reflect additional potential benefits of the intervention and enable comparison with existing NHV trials.[18] This does rely on multiple outcomes, which by their nature are related, but each reflect a different aspect of the effectiveness of the intervention. Data reduction techniques, such as using factor analysis to derive a composite, although simplifying the analyses would result in a loss of interpretability around the particular aspects of the home environment that are responsive to the intervention and conversely those in which responsiveness has not been evident. Our approach also aligns with Prinsen et al,[34] who suggest using a core outcome set to assess and report in clinical trials and to choose only 1 outcome measurement instrument for each outcome (eg, construct or domain), which we have done because each of our outcomes reflect

TABLE 1 Description of Primary Outcome Measures

Item	Description
Regular meal times	Single 5-point item (“never” to “always”); study design based on the Sleep Well Be Well Regular Bedtime item[37]
Food choices	12-item measure of food choices over last 24 h rated on a 3-point scale (“not at all,” “once,” or “more than once”) and drawn from the LSAC[38]
Regular bedtime	Single 5-point item (“never” to “always”) adapted from the Sleep Well, Be Well study[37]
Regular bed routine	Single 5-point item (“never” to “always”) drawn from the Sleep Well Be Well study[37]
Safety of the environment	Items used to assess 11 aspects of home safety, which are dichotomized into “safe” versus “not safe”; study design based on The Royal Children’s Hospital Safety Centre and Kidsafe checklists[39,40]
Warm parenting	6-item measure used to assess parental warmth; items rated on a 5-point scale (“never and/or almost never” to “always and/or almost always”) and drawn from the LSAC[38]
Hostile parenting	5-item measure used to assess parental hostility; items rated on a 10-point scale (“not at all” to “all of the time”) and drawn from the LSAC[38]
Parent responsivity and the home learning environment (6 subscales)	HOME Inventory[41]; 45-item measure composed of observation only (18 items), parent report only (8 items), and observation or parent report (19 items) used to assess the quality and quantity of stimulation and support available to a child in the home environment. Items are dichotomized (“not observed or reported” versus “observed and/or reported”) and summed. Continuous total scores range from 0 to 45, with higher scores indicating a better home environment. The 6 subscales scored are parental responsivity (11 items), acceptance of the child (8 items), organization of the environment (6 items), learning materials (9 items), parental involvement (6 items), and variety in experience (5 items).

a different construct. However, we recognize the relatedness of outcomes and opportunity this affords for chance positive findings. Rather than correcting for multiple testing, we present estimated effects for each of the outcomes along with their respective confidence intervals (CIs). With this presentation of all of the outcomes, we avoid “sifting the evidence.”[35] By presenting the direction, magnitude, and confidence of each estimate, evidence toward a treatment benefit is more clearly evident than through the consideration of significant versus nonsignificant findings, which can be overly conservative, particularly when correction for multiple testing is undertaken.[36]

Together with participant rating and feedback measures (Supplemental Table 5), implementation and fidelity data were also extracted from the electronic records of each nurse and/or practitioner contact with families, including visit content. Costs were calculated from a government-as-payer perspective and presented in 2017 Australian dollars. Regarding intervention costs, we used nurse records of training and supervision and electronic records of practitioner contact; participants retrospectively reported other service use at 6-monthly data collection.

A cost-consequences analysis, in which the difference in costs between groups is presented alongside the set of differences across multiple outcomes, was not included. We present outcomes (Table 3, Supplemental Tables 12 and 13) and costs separately.

Statistical Analyses

The sample size was calculated to detect a minimum effect size (ES) of 0.3 SDs for the responsivity subscale of the Home Observation of the Environment (HOME) Inventory (Table 1). This represents a medium, standardized ES that allows for comparison with existing NHV literature, which typically ranges from 0.2 to 0.4 SDs.[19] To detect a minimum ES of 0.3 with 80% power at the 0.05 significance level, assuming an average intraclass correlation of 0.02 across the 18 nurse clusters (and 18 corresponding clusters reflecting varying nurse staffing in the usual care arm), the total sample size required was 714 participants (n = 357 per arm), allowing for attrition of 40% by child age 2 years.[18]

Baseline characteristics of trial arms were described by using means, SDs, medians, and interquartile ranges for continuous data and proportions for categorical data. Continuous outcomes were described by using means and SDs, and binary outcomes were described with proportions, both by treatment arm. Between-group outcome comparisons were made by following intention to treat. In unadjusted regression models (linear and/or logistic regression for continuous and/or binary outcomes), we only accounted for the stratification factors used during randomization: parity and study site. In adjusted models, we additionally accounted for baseline characteristics identified a priori: child sex, child age at the 2-year assessment, family’s Socio-Economic Indexes for Areas (SEIFA) score (Supplemental Table 4), maternal education, maternal age at child’s birth, parity, antenatal risk count, maternal self-efficacy, and maternal mental health. Results were reported as mean differences (plus standardized ESs to convey the size of the effect relative to the variability in the sample) and odds ratios with 95% CIs. In all regression analyses, we accounted for effects of nurse clustering.

For exploratory purposes, we conducted 4 subgroup analyses specified a priori[18] to investigate whether the intervention effect was modified according to parity (first child versus second or later child), antenatal risks (≥3 vs 2 antenatal

TABLE 2 Baseline Characteristics According to Follow-up Status (ie, Retained or Lost in right@home Study) at Child Age 2 Years

Baseline Characteristics (Pregnancy)	Total (N = 722)		Intervention (N = 363)		Control (N = 359)	
	Retained (n = 596)	Lost (n = 126)	Retained (n = 306)	Lost (n = 57)	Retained (n = 290)	Lost (n = 69)
Mother						
Age in y, mean (SD)	27.7 (6.2)	27.2 (6.2)	27.6 (6.1)	27.0 (6.2)	27.9 (6.4)	27.4 (6.2)
DASS						
Depression, mean (SD)	2.9 (3.4)	3.3 (3.7)	3.0 (3.6)	3.5 (4.0)	2.9 (3.2)	3.1 (3.5)
Anxiety, mean (SD)	3.4 (3.4)	4.1 (3.4)	3.4 (3.4)	4.5 (3.8)	3.4 (3.4)	3.8 (3.1)
Stress, mean (SD)	5.4 (4.1)	5.8 (4.2)	5.3 (4.2)	6.5 (4.7)	5.4 (4.1)	5.2 (3.6)
Depression >85th percentile score, %	15.6	22.2	16.3	24.6	14.8	20.3
Anxiety >85th percentile score, %	40.1	53.2	40.9	56.1	39.3	50.7
Stress >85th percentile score, %	19.3	20.6	18.6	28.1	20.0	14.5
Education status, %						
Did not complete high school	24.4	28.0	24.0	29.8	24.8	26.7
Completed high school, vocational training	64.5	63.6	65.1	61.7	63.9	65.0
Completed a university degree	11.1	8.4	10.9	8.5	11.3	8.3
Marital status, %						
Single, not living with partner	25.3	34.9	28.1	29.8	22.4	39.1
Married, living with partner	73.2	61.1	70.3	66.7	76.2	56.5
Separated, divorced	1.5	4.0	1.6	3.5	1.4	4.4
Currently unemployed, %	64.3	75.6	64.1	75.4	64.5	75.4
Family income from benefit or pension, %	41.3	50.0	42.5	50.9	40.0	49.3
Ever had a drug problem, %	13.5	24.8	13.1	19.3	13.9	29.4
Experienced domestic violence in past y, %	11.0	15.9	11.2	17.5	10.8	14.5
Child						
Firstborn, %	37.6	34.1	38.2	33.3	36.9	34.8
Female sex, %	50.8	42.0	55.2	48.9	46.2	36.4
Family						
SEIFA Index of Social Disadvantage quintile, %						
1 (most disadvantaged)	41.4	47.1	42.5	55.6	40.1	40.3
2	7.8	9.9	7.7	7.4	7.9	11.9
3	39.6	28.9	39.5	25.9	39.8	31.3
4	8.5	9.1	7.7	9.3	9.3	9.0
5 (least disadvantaged)	2.8	5.0	2.7	1.9	2.9	7.5
Language other than English, %	8.6	8.8	7.6	8.8	9.5	8.8

The total range is 696 to 722, the intervention range is 351 to 363, and the control range is 345 to 359 because of missing data. Percentages may not add to 100 because of rounding. DASS, Depression, Anxiety, and Stress Scale.

risk factors), maternal mental health at baseline (poor mental health [top 15% according to UK normative data] versus not [<85th percentile]),[18,42] and self-efficacy at baseline (any lack of self-efficacy versus no lack of self-efficacy) using the adjusted regression models described above with additional terms for interaction between subgroups and trial arms.

Sensitivity analyses were conducted by using Tobit regression and ordered logistic regression to confirm that estimates from linear regression were robust for measures that did not follow a normal distribution. In sensitivity analyses, we also compared analyses that were restricted to families with complete data with those including all mothers who were initially randomly assigned, using multiple imputation techniques to account for missing data. Multiple imputation models included all the primary outcomes and covariates, with most secondary outcomes also included to improve model specification as far as model capacity would allow; 70 data sets were imputed by using chained equations. Results were not substantially altered in the sensitivity or per protocol analyses[18] (Goldfeld et al; unpublished observations). Data were analyzed by using Intercooled Stata version 14.2 for Windows (Stata Corp, College Station, TX).

The right@home program was approved by these human research ethics committees: The Royal Children's Hospital (HREC 32296), Peninsula Health (HREC/13/PH/14), Ballarat Health Services (HREC/13/BHSSJOG/9), Southern Health (HREC 13084×), Northern Health in Victoria (HREC P03/13), and the University of Tasmania (HREC H0013113).

RESULTS

Of 5586 women screened between April 30, 2013, and August 29, 2014 (Fig 1), 1427 (25.5%) were eligible for right@home; most of those who were excluded had <2 risk factors. Of 1427 women, 736 completed the baseline interview and 722 (50.6%) were enrolled in the trial, reporting slightly more

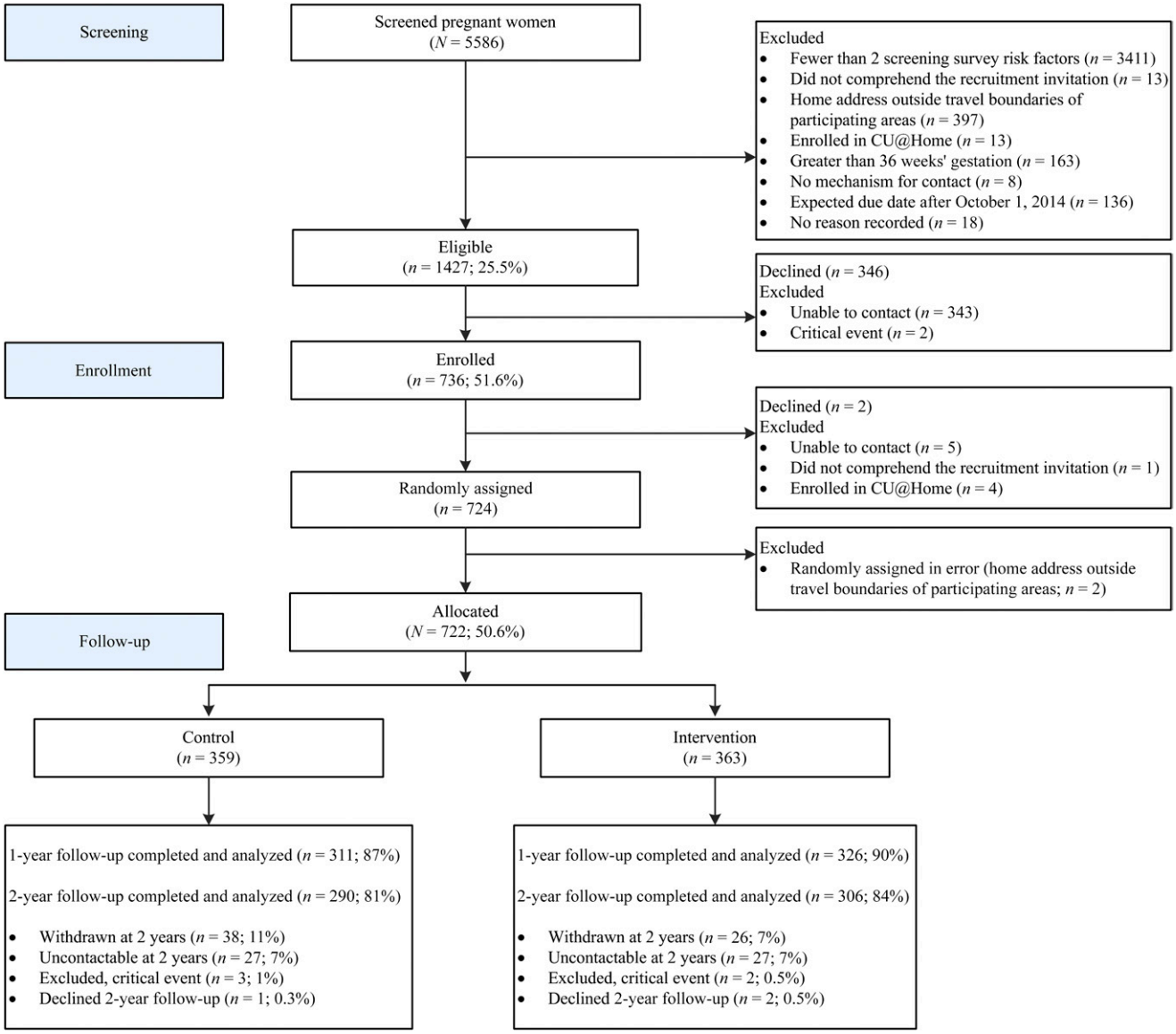

FIGURE 1
Consort diagram.

risk factors (mean = 3.2; SD = 1.3) than those who declined (mean = 3.0; SD = 1.2). Of the 722 women, 596 (82.5%) provided data at child age 2 years: 306 of 363 (84.3%) in the intervention arm and 290 of 359 (80.8%) in the control arm. Table 2 presents the selection of baseline characteristics used in the analyses; a visual inspection revealed that characteristics were similar between groups at follow-up.

The trial included women experiencing a range of adversities. Compared with mothers of infants in the nationally representative Longitudinal Study of Australian Children (LSAC),[43] women in the trial reported lower levels of tertiary qualifications (29% vs 11%), were less likely to be married or living with a partner (89% vs 73%), and more likely to live in the most socially disadvantaged areas (19% vs 41%). Women in the trial were more likely to have poor mental health compared with UK normative data,[42] and the screening risk factors presented in Supplemental Table 4 reveal high levels of antenatal risk factors of poorer global health (72%), no household income (33%), smoking (33%), and young pregnancy (27%).

Unadjusted (Supplemental Table 7) and adjusted analyses for the primary outcomes (Table 3) revealed a similar estimation of intervention effects. The intervention improved 6 of the 13 primary outcomes (small-to-moderate ESs); no effects favored the control group (Table 3, Fig 2). There was no evidence of differential effects according to whether women were at higher or lower risk for any of the 4 prespecified subgroup

TABLE 3 Results of Adjusted Regression Analyses in Which the 2 Trial Arms Are Compared on Parent Care, Responsivity, and Home Learning Primary Outcomes at Child Age 2 Years

Outcome	Descriptive Statistics				Comparative Statistic: Intervention Compared With Control				
	Intervention		Control		Adjusted				
	N	Summary[a]	*N*	Summary[a]	Statistic[b]	95% CI	*P*	ES	95% CI
Parent care									
Regular meal times[c]	298	261 (87.6)	286	255 (89.2)	0.87	0.58 to 1.31	.503	—	—
Food choices	292	10.53 (2.1)	281	10.47 (2.1)	0.01	−0.23 to 0.26	.906	0.01	−0.11 to 0.12
Regular bedtime[c]	301	261 (86.7)	286	233 (81.5)	1.76	1.25 to 2.48	.001	—	—
Regular bed routine[c]	301	251 (83.4)	286	227 (79.4)	1.39	0.94 to 2.06	.104	—	—
Safety of the environment	301	8.47 (1.17)	287	8.21 (1.32)	0.22	0.07 to 0.37	.007	0.18	0.05 to 0.30
Warm parenting	298	4.61 (0.42)	284	4.54 (0.45)	0.09	0.02 to 0.16	.012	0.20	0.05 to 0.36
Hostile parenting (reverse)	303	8.55 (1.12)	285	8.25 (1.27)	0.29	0.16 to 0.41	<.001	0.24	0.14 to 0.34
Parent responsivity and the home learning environment									
HOME parental responsivity	279	10.33 (1.18)	267	10.27 (1.13)	0.02	−0.12 to 0.17	.738	0.02	−0.10 to 0.14
HOME acceptance of the child	278	6.51 (1.26)	267	6.52 (1.27)	−0.06	−0.20 to 0.09	.446	−0.04	−0.16 to 0.07
HOME organization of the environment	294	5.44 (0.66)	283	5.33 (0.75)	0.08	−0.01 to 0.16	.079	0.11	−0.01 to 0.23
HOME learning materials	294	8.23 (1.00)	284	8.32 (1.00)	−0.08	−0.24 to 0.08	.310	−0.08	−0.24 to 0.08
HOME parental involvement	295	4.68 (1.09)	282	4.39 (1.21)	0.26	0.14 to 0.38	<.001	0.23	0.12 to 0.33
HOME variety in experience	294	3.82 (0.98)	284	3.61 (1.07)	0.20	0.07 to 0.34	.005	0.19	0.07 to 0.32

—, not applicable.

[a] Summary statistics are shown as mean (SD) except when specified as dichotomous.

[b] The comparative statistic is the mean difference for continuous outcomes (intervention minus control) and odds ratio for dichotomous outcomes (the risk of receiving the intervention compared with receiving usual care).

[c] Outcome is dichotomous (percentage).

analyses: parity, antenatal risks, maternal mental health, and self-efficacy (Supplemental Tables 8 through 11). There was evidence of positive impacts on secondary outcomes, including parenting efficacy, maternal health, and child language (Supplemental Tables 12 and 13, Supplemental Figs 3 and 4 [adjusted], Supplemental Tables 14 and 15 [unadjusted]). One secondary outcome favored the control group: child ate breakfast today (Supplemental Table 12, Supplemental Fig 3).

The 352 women in the intervention with visit data available received an average of 22.7 home visits (SD 7.4). The 301 women in the control group with CFH data available saw their CFH nurses an average of 7.6 times (SD 4.3), of which 1.4 were home visits. Per protocol guidelines,[18] 244 of 301 (81.1%) women in the control group attended at least 1 and <11 visits, and 251 of 352 (71.3%) women in the intervention received at least 75% of the 25 scheduled visits, including at least 1 antenatal visit. These proportions exclude the 11 women in the intervention and 58 women in the control group with no visit data available. The 71.3% program fidelity for the intervention arm did not meet the a priori per protocol rate of 75% of families receiving >75% of visits, including at least 1 antenatal visit, because of the high number of families (n = 56) that were recruited too late in pregnancy to receive an antenatal visit. Women in the intervention received an average of 1.5 more visits from social care practitioners than women in the control group (2.76 vs 1.26). Participants receiving the intervention reported more satisfaction with the intervention and more enablement to care for themselves and their children than participants receiving usual care (Supplemental Tables 12 and 13, Supplemental Figs 3 and 4 [adjusted], Supplemental Tables 14 and 15 [unadjusted]). These data were collected by blinded research assistants and compared with controls.

Combined intervention costs of CFH staff training, supervision, and visits delivered over the full program averaged $9385 per intervention participant and $1879 per control participant, an additional cost of ~$7500 that largely reflects the differential number of home visits received. There were no substantial differences in other health service use reported by participants, including allied health professionals and hospitalizations.

DISCUSSION

The right@home RCT revealed evidence of benefit across the 3 primary outcome domains of parental care, responsivity, and the home learning environment for families living in adversity. Specifically, the intervention led to more regular child bedtimes, safer home environments, warmer and less hostile parenting, improved parental involvement as a facilitator in children's learning, and more opportunities for variety in daily

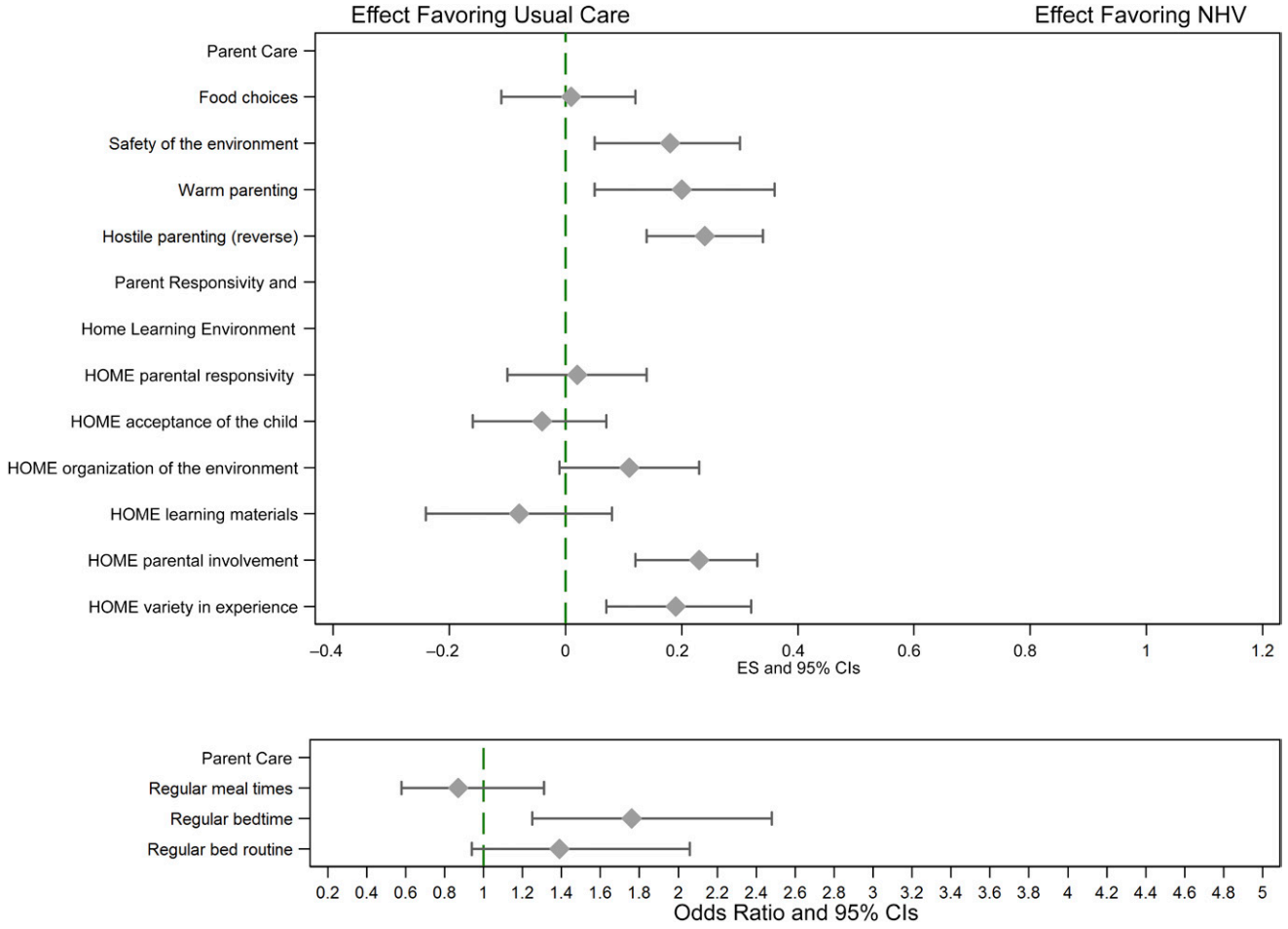

FIGURE 2
Continuous and categorical adjusted primary outcomes at child age 2 years.

stimulation and social interactions with adults other than the primary caregiver. Group differences were evident for a limited number of secondary outcomes; 6 favored the intervention group, reinforcing the primary outcomes and suggesting a broader impact of right@home (eg, parenting and maternal general health) and potential benefit for child development. The right@home program was delivered with high fidelity and retention, was well received, and significantly impacted participants' self-reported capacity to care for themselves and their children. Incremental costs were similar or less than in previous NHV interventions[14,44] but with higher retention, suggesting that the program may prove to be cost-effective in the longer-term.[44]

Within the context of NHV trials internationally, NFP (Family Nurse Partnership in the United Kingdom) has been the most frequently tested, with multiple US trials revealing improved birth, health, and child development outcomes and reductions in child maltreatment; however, findings are limited to young, first-time mothers and their children.[45] In right@home there were no differential benefits for any of these subgroups. On the US–based home visiting evidence of effectiveness Web site (https://homvee.acf.hhs.gov/), the effectiveness of NHV programs that have been tested via randomized trial according to basic criteria regarding number of impacts is reported more broadly. In comparing right@home, we found 18 other programs that managed children to 2 years of age with some similar outcome areas but variable results regarding impact. The right@home program had ESs similar to other effective NHV programs.[46] We add to the existing NHV evidence by demonstrating effectiveness when the program is (1) embedded in a population-wide system of care rather than a specialist service; (2) offered to women experiencing adversity regardless of parity, age, and antenatal risk profile; and (3) delivered with higher retention (71% receiving 75% of the program compared with, for example, 40%–52% receiving 80%[47]) and fewer visits (25 compared with,

for example, 64[14]). This evidence of effectiveness through existing care systems suggests that when scaled and even with modest ESs, the program should have a public health impact at the population level.

This study had several strengths. The high retention of participants in both groups strengthens the research findings and was achieved despite the substantial adversity experienced by participants. Our findings should be generalized to pregnant women presenting to public hospitals who are experiencing high levels of adversity, a population that is often hard to recruit and retain in health care. We believe that the intervention is generalizable to similar populations (women living in adversity) in similar health care systems. This is evident locally through take up in 2 Australian states in addition to the trial and internationally through the MECSH adaptation in the United Kingdom, Korea, and the United States. In addition, our mixed-methods process evaluation (detailed in Goldfeld et al[48]) included a theory of change analysis that revealed a high correlation between nurse delivery and family expectation. Generalizability is further strengthened by the study's multisite implementation. Given the program's effectiveness across Australian states and sites, administrators start to address issues of program implementation and population generalizability. The partnership with state governments enabled the trial to be implemented at a scale that was meaningful for Australian policy makers.

An additional strength of the study is the consideration of a wide range of primary outcomes that reflect the expected benefits for families according to our program logic.[48] When considered in the context of selecting multiple primary outcomes, the consistency of effectiveness across the 3 outcome domains suggests that the findings represent genuine effects rather than isolated effects observed by chance.[33] The extensive set of secondary outcomes enables an extended evaluation of the program and comparison with outcome areas of existing home-visiting trials. This also allows for sufficient evaluation of the effectiveness of our intervention over a number of domains.[33]

There are several limitations. Because of the exclusion criteria, the findings may not generalize to non–English-speaking women or women with severe intellectual disability. If taken to scale, it would be important to consider whether the intervention should be adapted (and elements further tested) and offered in other languages and whether it would be suitable for women with intellectual disabilities. Although sensitivity analyses for missing data did not reveal changes to the results, the cessation of program delivery has the potential to introduce unmeasured bias because the reasons for cessation are unknown (ie, they could be positive, such as the family doing well and no longer requiring support, or negative, such as families being dissatisfied and refusing the service). At child age 2 years, we focused on maternal report of parenting and home learning environment outcomes per our program logic, noting these as predictors for future child outcomes.[12] Therefore, we limited our direct child observations. Although intuitively measures such as serious injuries or failure to thrive are attractive and appear to be more objective, these can be subject to ascertainment bias, particularly in this context, in which the women in 1 group are in more frequent contact with a health professional through the provision of intervention. Similarly, there is a trade-off between waiting for the children to be old enough for reliable direct developmental assessment and publishing findings. This issue has clearly vexed the researchers in other home-visit trials. For example, when we examined 11 highly-rated studies in which researchers assessed 7 models of home visiting on home visiting evidence of effectiveness, only 4 of these models included studies which assessed child behavior, development, or language using direct child assessment. Among those in which researchers used direct child assessment, only 3[49–51] included statistically significant results when using 2 measures (Bayley Scales of Infant Development used in 2 studies, Infant-Toddler Developmental Assessment used in 1 study). Parent report was otherwise used as an assessment measure. Maternal report may be subject to perception influenced by participation in the intervention. However, primary outcomes at child age 2 years were necessarily by maternal report to reflect the typical routines and interactions undertaken in caring for the children and the quality and physical safety of the home environment. Direct observation measures, such as the use of the HOME Inventory,[52] were undertaken to help mitigate the potential for bias in maternal report measures according to participation in the intervention. Direct assessments of child development will be administered at child ages 3, 4, and 5 years when these measures become feasible and reliable.[18] These include measures of learning and literacy, language proficiency, executive function and attention, social and emotional well-being, height, weight, and dental checks. Finally, researchers in previous studies have noted the differential impact of NHV on specific subpopulations, such as those with more limited psychological resources,[18] which may be important for policy makers and practitioners in terms of rationalizing service implementation. However, we were not sufficiently powered to demonstrate these differences and

indeed saw no intervention effects based on our interaction analyses for the 4 subpopulations.

CONCLUSIONS

Our study findings reveal that right@home may have the potential to effect change when delivered in health care systems and targeting children and families.[53,54] The latent effects of previous NHV studies reveal that short-term outcomes can translate to substantial longer-term benefits, which in turn support the cost-effectiveness of the substantial upfront investment required for NHV.[44] Given the excellent rates of fidelity and retention, we suggest that replicability is possible at scale such that the right@home program could be integrated into well-child health care in Australia or trialed in other countries with suitable health care provision to improve outcomes for families experiencing adversity. Notwithstanding these results, to truly redress inequity for these families and their children, future researchers should investigate the potential mutual benefit of services that are both continuous and complementary over early childhood.[55] This study is a crucial contribution to the evidence that interventions can be effectively delivered within existing services to reduce the impact of social and environmental factors predisposing children to inequitable outcomes.

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ABBREVIATIONS

CFH: child and family health
ES: effect size
HOME: Home Observation of the Environment
LSAC: Longitudinal Study of Australian Children
MECSH: Maternal Early Childhood Sustained Home-Visiting
NFP: Nurse-Family Partnership
NHV: nurse home visiting
RCT: randomized controlled trial
SEIFA: Socio-Economic Indexes for Areas

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Address correspondence to Prof Sharon Goldfeld, The Royal Children's Hospital, 50 Flemington Rd, Parkville, VIC 3052, Australia. E-mail: sharon.goldfeld@rch.org.au

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REFERENCES

1. Duncan GJ, Magnuson K. The importance of poverty early in childhood. *Policy Q*. 2013;9(2):12–17
2. Pavalko EK, Caputo J. Social inequality and health across the life course. *Am Behav Sci*. 2013;57(8):1040–1056
3. Hart JT. The inverse care law. *Lancet*. 1971;1(7696):405–412
4. Fram MS. Managing to Parent: Social Support, Social Capital, and Parenting Practices among Welfare-Participating Mothers with Young Children. Discussion Paper 1263-03. Washington, DC: Institute for Research on Poverty. 2003
5. Ghate D, Hazel N. *Parenting in Poor Environments: Stress, Support and Coping*. London, United Kingdom: Jessica Kingsley Publishers; 2002
6. Offord DR. Prevention of behavioral and emotional disorders in children. *J Child Psychol Psychiatry*. 1987;28(1):9–19
7. Watson J, White A, Taplin S, et al. *Prevention and Early Intervention Literature Review*. Sydney, Australia: New South Wales Department of Community Services; 2005
8. Kelly Y, Sacker A, Del Bono E, Francesconi M, Marmot M. What role for the home learning environment and parenting in reducing the socioeconomic gradient in child development? Findings from the Millennium Cohort Study. *Arch Dis Child*. 2011;96(9):832–837
9. Schuster MA, Fuentes-Afflick E. Caring for children by supporting parents. *N Engl J Med*. 2017;376(5):410–413
10. Caspi A, Houts RM, Belsky DW, et al. Childhood forecasting of a small segment of the population with large economic burden. *Nat Hum Behav*. 2016;1:0005
11. Foster MA, Lambert R, Abbott-Shim M, McCarty F, Franze S. A model of home learning environment and social risk factors in relation to children's emergent literacy and social outcomes. *Early Child Res Q*. 2005;20(1):13–36
12. Melhuish EC, Phan MB, Sylva K, Sammons P, Siraj-Blatchford I, Taggart B. Effects of the home learning environment and preschool center experience upon literacy and numeracy development in early primary school. *J Soc Issues*. 2008;64(1):95–114
13. McDonald M, Moore T, Goldfeld S. *Sustained Nurse Home Visiting for Families and Children: A Review of Effective Programs. Prepared for Australian Research Alliance for Children and Youth*. Parkville, Australia: The Royal Children's Hospital Centre for Community Child Health, Murdoch Children's Research Institute; 2012
14. Robling M, Bekkers M-J, Bell K, et al. Effectiveness of a nurse-led intensive home-visitation programme for first-time teenage mothers (Building Blocks): a pragmatic randomised controlled trial. *Lancet*. 2016;387(10014):146–155
15. Mejdoubi J, van den Heijkant SC, van Leerdam FJ, Heymans MW, Hirasing RA, Crijnen AA. Effect of nurse home visits vs. usual care on reducing intimate partner violence in young high-risk pregnant women: a randomized controlled trial. *PLoS One*. 2013;8(10):e78185
16. Kemp L, Harris E, McMahon C, et al. Miller Early Childhood Sustained Home-visiting (MECSH) trial: design, method and sample description. *BMC Public Health*. 2008;8:424
17. Kemp L, Harris E, McMahon C, et al. Child and family outcomes of a long-term nurse home visitation programme: a randomised controlled trial. *Arch Dis Child*. 2011;96(6):533–540
18. Goldfeld S, Price A, Bryson H, et al. '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. *BMJ Open*. 2017;7(3):e013307
19. US Department of Health and Human Services. Home visiting evidence of effectiveness. Available at: http://homvee.acf.hhs.gov. Accessed November 4, 2015
20. Olds D. Building evidence to improve maternal and child health. *Lancet*. 2016;387(10014):105–107
21. McDonald M, Moore T, Goldfeld S. *Sustained Nurse Home Visiting for Families and Children: A Review of Effective Processes and Strategies. Prepared for Australian Research Alliance for Children and Youth*. Parkville, Australia: The Royal Children's Hospital Centre for Community Child Health, Murdoch Children's Research Institute; 2012
22. Moore T, McDonald M, Sanjeevan S. *Evidence-Based Service Modules for a Sustained Nurse Home Visiting Program: A Literature Review. Prepared for the Australian Research Alliance for Children and Youth*. Parkville, Australia: Centre for Community Child Health, Murdoch Children's Research institute; 2012
23. Marmot M, Allen J, Goldblatt P, et al. *The Marmot Review: Fair Society, Healthy Lives: Strategic review of health inequalities in England post-2010. Global Health Equity Group, Department of Epidemiology and Public Health*. London, UK: University College London; 2010
24. Filene JH, Kaminski JW, Valle LA, Cachat P. Components associated with home visiting program outcomes: a meta-analysis. *Pediatrics*. 2013;132(suppl 2):S100–S109
25. Olds DL, Eckenrode J, Henderson CRJ Jr, et al. Long-term effects of home visitation on maternal life course and child abuse and neglect. Fifteen-year follow-up of a randomized trial. *JAMA*. 1997;278(8):637–643
26. Olds DL, Henderson CRJ, Cole R, et al. Long-term effects of nurse home visitation on children's criminal and antisocial behaviour: 15-year follow-up of a randomized controlled trial. *JAMA*. 1998;280(14):1238–1244
27. Olds DL, Kitzman H, Cole R, et al. Effects of nurse home-visiting on maternal life course and child development: age 6 follow-up results of a randomized trial. *Pediatrics*. 2004;114(6):1550–1559
28. Daro D. *Embedding Home Visitation Programs Within a System of Early Childhood Services. Chapin Hall Issue*

Brief. Chicago, IL: The University of Chicago; 2009

29. Goldfeld S, D'Abaco E, Bryson H, Mensah F, Price AM. Surveying social adversity in pregnancy: the antenatal risk burden experienced by Australian women. *J Paediatr Child Health*. 2018;54(7):754–760
30. Goldfeld S, O'Connor M, Chong S, et al. The impact of multidimensional disadvantage over childhood on developmental outcomes in Australia [published online ahead of print May 29, 2018]. *Int J Epidemiol*. doi:10.1093/ije/dyy087
31. Goldfeld S, O'Connor M, Cloney D, et al. Understanding child disadvantage from a social determinants perspective. *J Epidemiol Community Health*. 2018;72(3):223–229
32. Price AM, Bryson HE, Mensah F, Kemp L, Bishop L, Goldfeld S. The feasibility and acceptability of a population-level antenatal risk factor survey: cross-sectional pilot study. *J Paediatr Child Health*. 2017;53(6):572–577
33. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M; Medical Research Council Guidance. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ*. 2008;337:a1655
34. Prinsen CAC, Vohra S Sr, Rose MR, et al. How to select outcome measurement instruments for outcomes included in a "Core Outcome Set" - a practical guideline. *Trials*. 2016;17(1):449
35. Sterne JAC, Smith GD. Sifting the evidence-what's wrong with significance tests? *Phys Ther*. 2001;81(8):1464–1469
36. Perneger TV. What's wrong with Bonferroni adjustments. *BMJ*. 1998;316(7139):1236–1238
37. Quach J, Gold L, Arnup S, Sia KL, Wake M, Hiscock H. Sleep well–be well study: improving school transition by improving child sleep: a translational randomised trial. *BMJ Open*. 2013;3(10):e004009
38. Zubrick SR, Lucas N, Westrupp EM, et al. *Parenting Measures in the Longitudinal Study of Australian Children: Construct Validity and Measurement Quality, Waves 1 to 4*. Canberra, Australia: Department of Social Services; 2014
39. Kidsafe Child Accident Prevention Foundation of Australia. Home safety checklist
40. The Royal Children's Hospital. Home safety checklist: Safety Centre. Available at: www.rch.org.au/uploadedFiles/Main/Content/safetycentre/120544%20Home%20Safety%20Checklist%20A4.pdf. Accessed May 11, 2016
41. Caldwell BM, Bradley RH. *Home Observation for Measurement of the Environment: Administration Manual*. Tempe, AZ: Family and Human Dynamics Research Institute, Arizona State University; 2003
42. Henry JD, Crawford JR. The short-form version of the Depression Anxiety Stress Scales (DASS-21): construct validity and normative data in a large non-clinical sample. *Br J Clin Psychol*. 2005;44(pt 2):227–239
43. Australian Institute of Family Studies. Annual statistical reports. 2011. Available at: https://data.growingupinaustralia.gov.au/pubs/asr/2010/asr2010.pdf. Accessed July 19, 2018
44. Stamuli E, Richardson G, Duffy S, Robling M, Hood K. Systematic review of the economic evidence on home visitation programmes for vulnerable pregnant women. *Br Med Bull*. 2015;115(1):19–44
45. Avellar SA, Supplee LH. Effectiveness of home visiting in improving child health and reducing child maltreatment. *Pediatrics*. 2013;132(suppl 2):S90–S99
46. Sama-Miller E, Akers L, Mraz-Esposito A, et al. *Home Visiting Evidence of Effectiveness Review (HomVEE): Executive Summary*. Washington, DC: US Administration for Children and Families, Office of Planning, Research, and Evaluation; 2016
47. Daro D, Boller K, Hart B. *Implementation Fidelity in Early Childhood Home Visiting: Successes Meeting Staffing Standards, Challenges Hitting Dosage and Duration Targets. Mathematica Policy Research*. Chicago, IL: The University of Chicago; 2014
48. Goldfeld S, Price A, Kemp L. Designing, testing, and implementing a sustainable nurse home visiting program: right@home. *Ann N Y Acad Sci*. 2018;1419(1):141–159
49. Lowell DI, Carter AS, Godoy L, Paulicin B, Briggs-Gowan MJ. A randomized controlled trial of Child FIRST: a comprehensive home-based intervention translating research into early childhood practice. *Child Dev*. 2011;82(1):193–208
50. Olds DL, Robinson J, O'Brien R, et al. Home visiting by paraprofessionals and by nurses: a randomized, controlled trial. *Pediatrics*. 2002;110(3):486–496
51. Caldera D, Burrell L, Rodriguez K, Crowne SS, Rohde C, Duggan A. Impact of a statewide home visiting program on parenting and on child health and development. *Child Abuse Negl*. 2007;31(8):829–852
52. Caldwell B, Bradley R. *Home Observation for Measurement of the Environment: Administration Manual*. Tempe, AZ: Family and Human Dynamics Research Institute, Arizona State University; 2003
53. McLean K, Goldfeld S, Molloy C, et al. *Screening and Surveillance in Early Childhood Health: Rapid Review of Evidence for Effectiveness and Efficiency of Models*. Ultimo, NSW, Australia: The Sax Institute; 2014
54. Kuo AA, Inkelas M, Lotstein DS, Samson KM, Schor EL, Halfon N. Rethinking well-child care in the United States: an international comparison. *Pediatrics*. 2006;118(4):1692–1702
55. Heckman JJ, Mosso S. The economics of human development and social mobility. *Annu Rev Econ*. 2014;6(1):689–733

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