

Nurse Home Visiting for Families Experiencing Adversity: A Randomized Trial

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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) responsiveness, 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.



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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.

To cite: Goldfeld S, Price A, Smith C, et al. Nurse Home Visiting for Families Experiencing Adversity: A Randomized Trial. *Pediatrics*. 2019;143(1):e20181206

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 law³) 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) program¹⁶ 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 development²⁹⁻³¹ (rather than families being selected only on the basis of risks such as young age, parity, or single parenthood¹³); 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 MECOSH 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 protocol¹⁸), 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 priori¹⁸ 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 analyses¹⁸ (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 13084x), 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

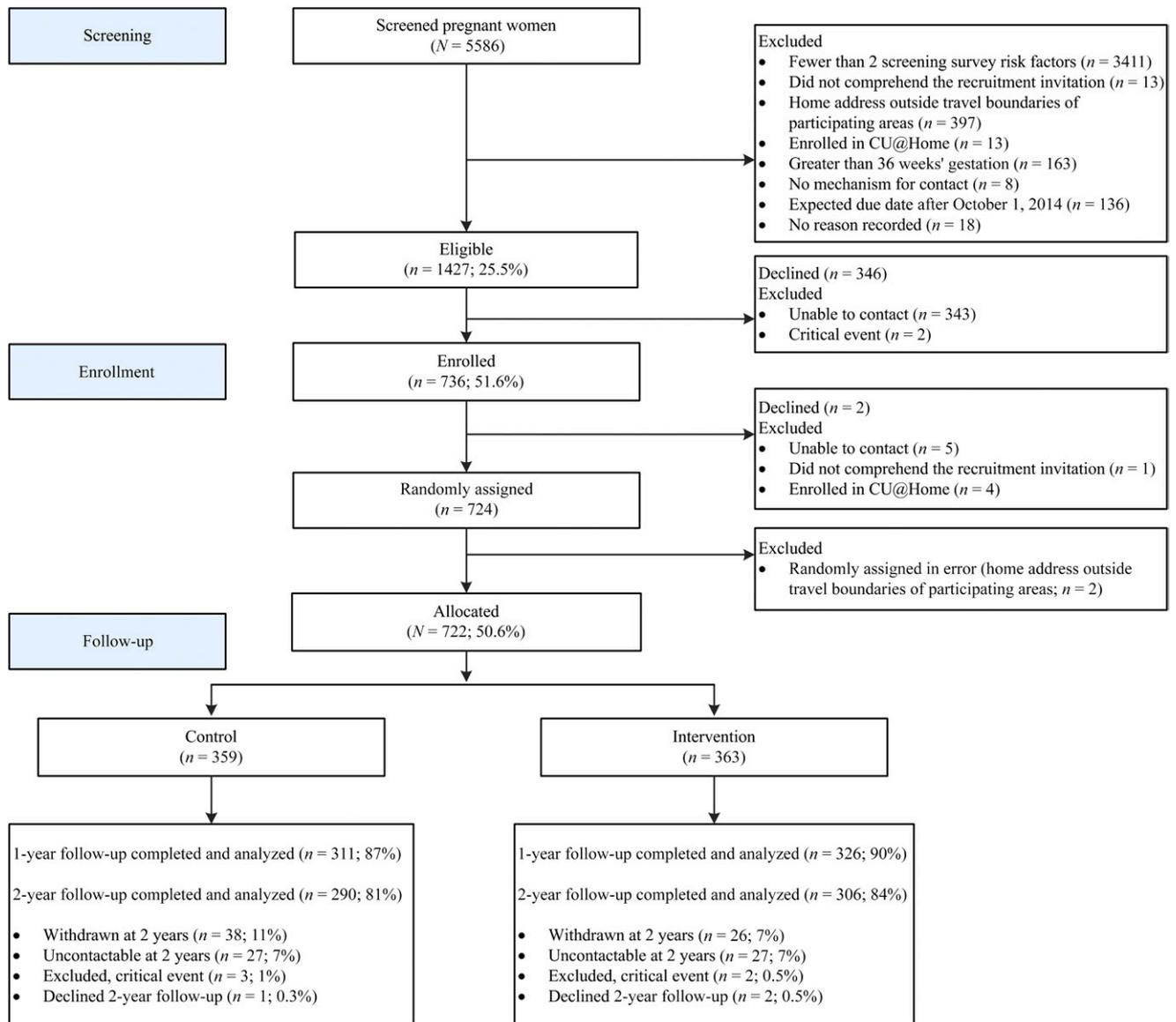


FIGURE 1
Consort diagram.

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

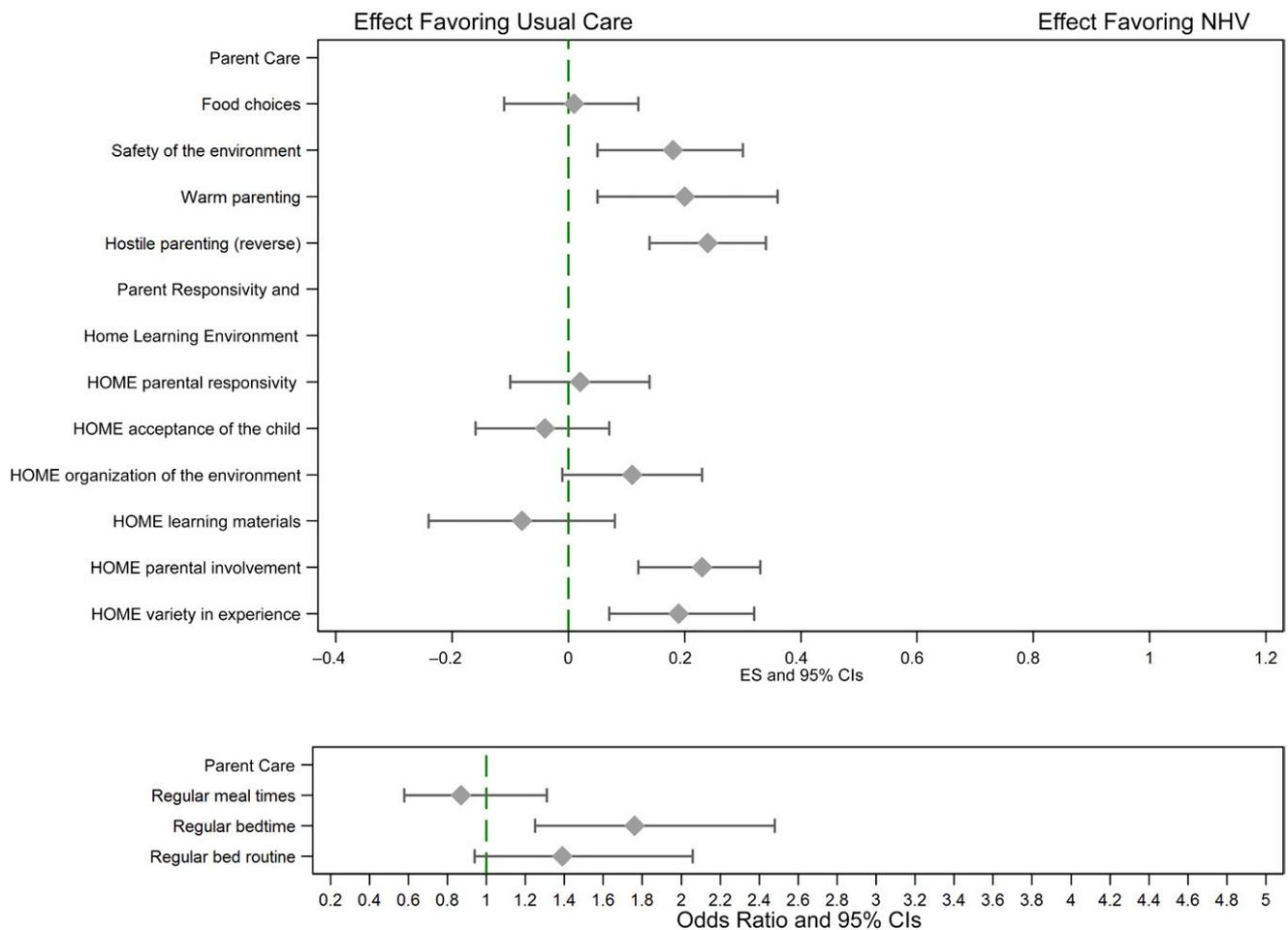


FIGURE 2 Continuous and categorical adjusted primary outcomes at child age 2 years.

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, 64¹⁴). 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 al⁴⁸) 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.

ACKNOWLEDGMENTS

The right@home NHV trial is a research collaboration between the Australian Research Alliance for Children and Youth, the Translational Research and Social Innovation group at Western Sydney University, and the Centre for Community Child Health, which is a department of The Royal Children's Hospital and a research group of Murdoch Children's Research Institute. We thank all the families, researchers, nurses,

and social care practitioners working on the right@home trial; the antenatal clinic staff at participating hospitals who helped facilitate the research; and the Expert Reference Group for its guidance in designing the trial. MECSH is a licensed program of the University of New South Wales.

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

sponsor; the Australian Research Alliance for Children and Youth), and contributed to the first and subsequent drafts of the report; Dr Mensah conceptualized and implemented the study design, provided statistical expertise in the trial design and conduct of the statistical analysis, and contributed to the first and subsequent drafts of the report; Ms Orsini provided statistical expertise in the trial design, conducted the data cleaning and statistical analysis, and contributed to the first and subsequent drafts of the report; Ms Bryson implemented the study design, conducted the data cleaning and statistical analysis, coordinated and supervised data collection, and contributed to the first and subsequent drafts of the report; Ms Smith and Dr Perlen implemented the study design, coordinated and supervised data collection, and contributed to the first and subsequent drafts of the report; and all authors approved the final version of the manuscript as submitted and agree to be accountable for all aspects of the work.

This trial has been registered with the ISRCTN Register (<http://isrctn.org>) (identifier ISRCTN89962120).

DOI: <https://doi.org/10.1542/peds.2018-1206>

Accepted for publication Oct 16, 2018

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PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

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FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

FUNDING: Supported by the state governments of Victoria and Tasmania, the Ian Potter Foundation, Sabemo Trust, the Sidney Myer Fund, the Vincent Fairfax Family Foundation, and the National Health and Medical Research Council (1079418). The Murdoch Children's Research Institute administered the research grant for the study and provided infrastructural support to its staff but played no role in the conduct or analysis of the trial. Research at the Murdoch Children's Research Institute is supported by the Victorian Government's Operational Infrastructure Support Program. Drs Goldfeld and Hiscock were supported by National Health and Medical Research Council Career Development Awards (1082922 and 607351, respectively). Dr Mensah was supported by National Health and Medical Research Council Early Career and Career Development fellowships (1037449 and 1111160, respectively). Dr Gold was supported by a National Health and Medical Research Council Early Career Fellowship (1035100). The funding bodies had no role in relation to the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the article; and decision to submit the article for publication.

POTENTIAL CONFLICT OF INTEREST: The authors have indicated they have no potential conflicts of interest to disclose.

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Nurse Home Visiting for Families Experiencing Adversity: A Randomized Trial

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Pediatrics 2019;143;

DOI: 10.1542/peds.2018-1206 originally published online December 27, 2018;

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Pediatrics 2019;143;

DOI: 10.1542/peds.2018-1206 originally published online December 27, 2018;

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