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Economic Evaluation of an Australian nurse home visiting program: a randomized trial at 3-years

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Economic Evaluation of an Australian nurse home visiting program: a randomized trial at 3-years

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ABSTRACT

Objectives

To report the cost-effectiveness of "right@home" Nurse Home Visiting (NHV) program in relation to improving maternal and child outcomes at child age 3 years.

Design

A cost-utility analysis from a government-as-payer perspective alongside a randomized trial of NHV over 3 year period. Costs and Quality-Adjusted Life Years (QALYs) were discounted at 5%. Analysis used an intention-to-treat approach with multiple imputation.

Setting

The right@home was implemented from 2013 in Victoria and Tasmania states of Australia, as a primary care service for pregnant women, delivered until child age 2 years.

Participants

722 pregnant Australian women experiencing adversity received NHV (n=363) or usual care (clinic visits) (n=359).

Primary and Secondary outcome measures

First, a cost-consequences analysis to compare the additional costs of NHV over usual care, accounting for any reduced costs of service use, and impacts on all maternal and child outcomes assessed at 3 years. Secondly, cost-utility analysis from a government-as-payer perspective compared additional costs to maternal QALYs to express cost-effectiveness in terms of additional cost per additional QALY gained.

Results

When compared to usual care at child age 3 years, the right@home intervention cost A$7685 extra per woman (95% CI: A$7006; A$8364) and generated 0.01 more QALYs (95% CI: -0.01; 0.02). The probability of right@home being cost-effective by child age 3 years is less than 20%, at a willingness to pay threshold of A$50,000 per QALY.

Conclusions

Benefits of NHV to parenting at 2 years and maternal health and wellbeing at 3 years translate into marginal maternal QALY gains. Like previous cost-effectiveness results for NHV programs, right@home is not cost-effective at 3 years. Given the relatively high up-front costs of NHV, long-term follow-up is needed to assess the accrual of health and economic benefits over time.

Trial registration number: ISRCTN89962120

Article Summary

Strengths and limitations of the study

- This article reports the costs and cost-effectiveness of the Australian "right@home" nurse home visiting program, when added to an existing universal child and family health service

- The addition of nurse home visiting results in improved parenting and maternal mental health outcomes, but also substantial upfront costs and marginal QALY gains at child age 3 years compared to usual care

- Strengths include the randomized controlled trial setting, with regular follow-up and good retention over time for this disadvantaged population

- Integration of a multi-attribute utility instrument and detailed resource use items into trial data collection enables comprehensive assessment of costs and QALY impact

- Longer-term follow-up will be required to assess whether emerging benefits over time, as seen in similar programs in the United States, recoup the large upfront cost

INTRODUCTION

Nurse Home Visiting (NHV) programs have been implemented in many high-income countries to improve the health and quality of life of mothers and their children.[1] As one of the few early interventions that have been shown to effectively reduce inequitable outcomes for families experiencing socioeconomic and psychosocial adversity, they have substantial policy appeal.[2] [3] Previous NHV programs have varied in their theory, content and targeted population.[4-8] Most experimental evidence comes from the United States (US).[9] In particular, the Nurse Family Partnership (NFP) has shown improvement in the parental care and material life course of high risk women in the US,[10] although similar benefits have been variable when translating this program to other countries.[4-8]

NHV programs are expensive, mostly due to providing additional professional services in-home at the family/individual level.[10] In this context opportunities to implement these programs are challenging with policy makers requiring rigorous evidence of effectiveness and cost-effectiveness.[11] Economic evaluations of NHV programs are important to highlight how initial program implementation costs weigh up against benefits and potential reduced service costs over time. Economic evaluations of NFP have found high upfront program costs ($12,265 per family in 2018 US$)[12] with benefits that accrue to participants and taxpayers over the child's lifetime, to produce positive returns on investment by child age 30 years.[12] [13] However, the evidence for cost-effectiveness of NHV programs in countries with universal healthcare remains unclear or limited.

From 2013, we trialed a NHV program (right@home) for pregnant women experiencing psychosocial and socioeconomic adversity in Australia.[14] The program was embedded into the universal child and family health (CFH) service, which also provided the comparator. The Australian universal CFH service provides nurse visits at key stages of child's health, learning and development. For example, in Victoria families receive CFH nurse visits following the

hospital discharge (home visit) and, at 2 weeks, 4 weeks, 8 weeks, 4 months, 8 months, 1 year, 18 months 2 years, and 3 and a half years at a local CFH clinic.[15] By the time the right@home NHV program was completed at child age 2 years, it had led to improved parenting and home environment outcomes over and above the usual service.[14] Consistent with the NHV literature, it is anticipated that these short-term benefits will generate longer-term benefits to maternal and child health and development, potentially with associated reductions in government services.[12 13] The aim of this economic evaluation is to analyze the cost-effectiveness of the right@home program to improve maternal and child outcomes one year after program delivery ended. Given the short (12-month) follow-up in the context of the NHV evidence base,[10 12 13] we did not expect the right@home program to be cost-effective by child age 3 years. Rather, we aimed to assess whether upfront program costs were offset by any early maternal and child outcomes, as an indication that the NHV program could achieve longer-term positive returns like those seen in the US.

METHODS

Design and analytic overview

The study design is an economic evaluation alongside a randomized controlled trial (RCT) of NHV compared to the usual CFH service. The evaluation considered pregnancy to child age 3 years and comprised two steps.

First, a cost-consequences analysis from a government-as-payer perspective compared the additional costs of NHV over usual care, accounting for any reduced costs of service use, and impacts on the maternal and child outcomes assessed at 3 years. This multi-criteria economic evaluation format incorporates all outcomes judged important in the trial, but results cannot be clearly interpreted as cost-effective or not.[16]

Second, cost-utility analysis from a government-as-payer perspective compared additional costs to maternal Quality-Adjusted Life Years (QALYs). This expresses cost-effectiveness in terms of additional cost per additional QALY gained, which can be interpreted against common Australian benchmarks, whereby programs with a cost-per-QALY of under A$50,000 are judged to be cost-effective.[17]

Participants and Procedures

The right@home RCT was implemented from 2013 in two states of Australia, Victoria and Tasmania, in accordance with CONSORT requirements.[14 18] Detailed methods are published elsewhere.[14] Briefly, researchers recruited 722 pregnant, English-speaking women, prioritized for their experience of adversity, who attended antenatal clinics at 10 public maternity hospitals from April 30 2013 to August 29 2014.[14 18] Participants enrolled by providing informed consent and completing a baseline interview. Participants randomized to the intervention (the right@home NHV program, n=363) were offered a schedule of 25 home visits (60-90 minutes each) from pregnancy to child age 2 years. The NHV program was delivered by a right@home-trained nurse recruited from the usual CFH service, and one or more visits from right@home-trained social care practitioners.[3] Participants allocated to usual care (n=359) received the universal CFH service, which included 6 (Tasmania) or 9 (Victoria) mainly office-based consultations to child age 2 years. When the NHV intervention finished at 2 years, N=558 families enrolled in extended follow-up to 6 years.

Ethics approval:

The ethics committees of the Royal Children's Hospital (HREC 32296); Deakin University (HREC 2013/147); Peninsula Health (HREC/13/PH/14); Ballarat Health Services (HREC/13/BHSSJOG/9); Southern Health (HREC 13084X); Northern Health (HREC P03/13) (all Victoria), and the University of Tasmania (HREC H0013113) approved this study.

Outcome measures

At the original endpoint of 2 years, the primary outcomes were multiple measures of parenting and the home environment; half showed small-to-moderate effect sizes in favor of the intervention and none favored usual care.[18] At 3 years, outcomes included multiple maternal health and wellbeing and child health and learning outcomes (see Supplementary Table 1). For this paper, the Assessment of Quality of Life (AQoL-8D)[19] was used to capture mothers' health-related quality of life at four time-points (baseline and child ages 1, 2, 3 years); we used the health-related utility score to calculate QALYs.[19] We did not estimate QALYs for children.

Economic evaluation

Costs are based on the health resources used by the woman and her child from recruitment to child age 3 years. Data on birth hospital admission and NHV/CFH service use (including the number and type, e.g. home/clinic/phone) were extracted from service records. Other health resources including hospital admissions and community-based services were self-reported by women in interviews conducted by phone (at child ages 6-weeks, and 6, 18 and 30 months) and face-to-face (at baseline and child ages 1, 2 and 3 years). Participants were asked to recall service use since the last questionnaire for hospital admissions (inpatient, outpatient and emergency visits) and community-based services (for example, general practice and specialist physician visits, breastfeeding/lactation consultations, use of helplines, pharmacy, physiotherapy, etc.). Unit costs for each item of service use were sourced from national-level estimates where possible (Table 1). All costs are presented in 2016/17 Australian dollars.

Implementation costs of NHV/CFH included nurse/practitioner visits, training, supervision and overheads. Nurses in both trial arms had similar qualifications (registered midwife/nurse with additional qualifications in maternal and child health).[14] Unit costs of CFH nurse visits were confirmed with providers and included travel time and costs, standard materials and overheads ($330 per home visit, $110 per clinic visit). Costs for the additional online and face-to-face training received by right@home (intervention) nurses included trainer and nurse time, venue hire, catering, materials and travel. These training costs were distributed over an assumed 5 year caseload of 60 women to avoid artificially overloading training costs onto the restricted number of RCT participants. The right@home program was associated with slightly higher supervision load than usual CFH service care, additional social worker time and parent materials costs (Table 3).[20] These "additional intervention costs" are accrued per-nurse and allocated top-down to each participant.

Patient and public involvement

There was no patient and public involvement in the development or analysis of the study.

Table 1: Unit cost of health resources

Service	Unit cost 2016/17 AUD	Unit	Resource
Hospital emergency department	$377.00	Per admission	Independent Hospital Pricing Authority [20]
Hospital outpatient clinic	$ 287.17	Per event	Independent Hospital Pricing Authority [32]
Hospital postnatal clinic	$ 226.39	Per event	Independent Hospital Pricing Authority [32]
Hospital breast feeding clinic	$ 226.39	Per event	Independent Hospital Pricing Authority [32]
Other hospital clinics	$ 287.17	Per event	Independent Hospital Pricing Authority [32]
Hospital someday admission	$1,249.00	Per admission	Independent Hospital Pricing Authority[32]
Hospital overnight admission	$2,065.00	Per day	Independent Hospital Pricing Authority [32]
Lactation consultations	$45.40	Per visit	Medicare Benefits Schedule Item 82140[33]
Parenting Centre day stays	$373.04	Per admission	Expert's opinion : Victorian parenting centers: private patients
Parenting Centre night stays	$734.35	Per night	Expert's opinion : Victorian parenting centers : private patients
Hospital midwife visit	$ 226.39	Per visit	Independent Hospital Pricing Authority [32]
CFHS clinic consultation	$110.00	Per visit	Expert's opinion : From intervention team

CFHS home consultation	$330.00	Per visit	Expert's opinion : From intervention team
CFHS phone consultation	$66.00	Per visit	Australian Psychology Association[34]
Social worker/care practitioner	$75.95	Per visit	Medicare Benefits Schedule Item 80160[35]
Helpline consultation	$20.72	per call	Fair work ombudsmen –Nurses Awards [36]
General Practice	$37.05	Per visit	Medicare Benefits Schedule Item 023[37]
Psychologist	$52.25	Per visit	Medicare Benefits Schedule Item 10968 [38]
Psychiatrist	$221.30	Per visit	Medicare Benefits Schedule Item 296[39]
Pediatrician	$224.35	Per visit	Medicare Benefits Schedule Item 135[40]
Obstetrician/Gynecologist	$224.35	Per visit	Medicare Benefits Schedule Item 132 [41]
Physiotherapy	$52.25	Per visit	Medicare Benefits Schedule Item 81335 [42]
Osteo/chiro practitioner	$52.25	Per visit	Medicare Benefits Schedule Item 10966 [42]
Dentist	$66.36	Per visit	Australian fee schedule of dental services [43]
Drug and Alcohol services	$176.08	Per visit	Independent Hospital Pricing Authority [32]

*CFHS: Child and Family Health Services

Analyses

Methods to address missing data: Characteristics of women who participated versus those lost to follow-up at 3 years were compared using t-tests for continuous and chi-square tests for categorical data. For the total health service cost and its sub-categories (hospital clinics, hospital admissions and primary health services), maternal and child outcomes, and QALY analyses, multiple imputation was used to account for loss to follow-up and missing data. Multiple imputation was conducted using multivariate normal regression within each of the two treatment groups to allow for differing mechanisms by which missing data may have arisen across the groups. Imputation models included all outcomes collected at 3 years, stratification factors and baseline covariates; 30 data sets were imputed. The health service use and intervention cost variables were not imputed because the high levels of missing data and collinearity prevented robust imputation; complete case data are presented for analyses involving these variables.

All comparisons are reported as mean differences and odds ratios, with 95% confidence intervals (CIs). Between-group analyses of health service use were grouped into hospital outpatient clinics, hospital (inpatient) admissions and primary health services, presented as the cost of service use per year. As cost data relate to the use of resources over three years, costs after the first year are discounted at 5% to present costs in net present value terms.[21] In economic evaluation, QALYs over three years are similarly discounted. Robust regression methods were used to account for the effects of nurse clustering.[14 18]

The Incremental Cost Effectiveness Ratio (ICER) was calculated as the mean difference in costs between intervention and usual care groups at 3 years divided by the mean difference in QALYs between groups at 3 years.[22] This presents the extra cost for each additional QALY gained. Uncertainty was illustrated using a cost effectiveness plane showing 95% CIs around the ICER generated using the bootstrap method (1000 simulations) and a cost effectiveness

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acceptability curve, which visually represents the probability that the intervention (compared to usual care) is cost-effective at varying threshold values of one QALY ($0 to $1.5m).[17]

Analyses were conducted in Microsoft Excel and Stata version 16.[23]

RESULTS

Participant characteristics (Figure 1, Table 2)

At 3 years, 495 women (89% of N=558 re-enrolled, 69% of original N=722) (Table 2) women provided data. More women were lost to follow up who during pregnancy were single, unemployed, reported high antenatal risk or poor mental health, or lived in more disadvantaged areas (lower Socio-Economic Indexes for Areas (SEIFA)), or had a female study child.

Table 2: Baseline characteristics according to follow-up status (i.e. retained or lost) at child age 3 years

Baseline characteristics (pregnancy)	Total (N = 722)		Intervention (N = 363)		Control (N = 359)		
	Retained (N=495)	Lost (N=227)	Retained (N=255)	Lost (N=108)	Retained (N=240)	Lost (N=119)	p-value[a]
Mother							
Age (years), mean (SD)	28.0 (6.2)	27.0 (6.3)	27.6 (5.9)	27.1 (6.4)	28.3 (6.4)	26.9 (6.2)	0.22
DASS Depression, mean (SD)	2.9 (3.3)	3.2 (3.8)	3.0 (3.5)	3.3 (4.0)	2.8 (3.1)	3.1 (3.6)	0.42
DASS Anxiety, mean (SD)	3.4 (3.3)	3.9 (3.6)	3.5 (3.4)	3.9 (3.5)	3.3 (3.1)	3.8 (3.7)	0.49
DASS Stress, mean (SD)	5.4 (4.0)	5.6 (4.5)	5.3 (4.0)	6.0 (4.8)	5.4 (3.9)	5.3 (4.3)	0.77
DASS Depression, >85th percentile score	15.4	19.8	17.3	18.5	13.3	21.0	0.23
DASS Anxiety, >85th percentile score	39.8	48.0	40.8	49.1	38.8	47.1	0.64
DASS Stress, >85th percentile score	19.6	19.4	19.2	22.2	20.0	16.8	0.83
Education status							0.43
Did not complete high school	23.8	27.7	21.3	33.7	26.5	22.3	-
Completed high school / vocational training	65.1	62.6	67.0	58.7	63.2	66.0	-
Completed a university degree	11.0	9.7	11.7	7.6	10.3	11.7	-
Marital status							0.54

Baseline characteristics (pregnancy)	Total (N = 722)		Intervention (N = 363)		Control (N = 359)		
	Retained (N=495)	Lost (N=227)	Retained (N=255)	Lost (N=108)	Retained (N=240)	Lost (N=119)	p-value[a]
Single / not living with partner	26.1	29.1	29.0	26.9	22.9	31.1	-
Married / living with partner	72.3	68.3	69.4	70.4	75.4	66.4	-
Separated / divorced	1.6	2.6	1.6	2.8	1.7	3.5	-
Currently unemployed	62.8	73.6	62.8	73.2	62.9	74.0	0.97
Family income from benefit or pension	41.8	44.9	42.4	47.2	41.3	42.9	0.26
Ever had a drug problem	12.6	21.7	12.2	18.5	13.0	24.6	0.78
Experienced domestic violence in past year	10.6	14.6	10.7	15.9	10.6	13.5	0.97
Child							
First born	36.8	37.4	38.8	34.3	34.6	40.3	0.33
Female	51.7	44.3	57.3	46.9	45.8	41.9	0.01
Family							
SEIFA Index of Social Disadvantage Quintile							0.55
1 (most disadvantaged)	42.1	42.9	44.2	45.2	39.8	40.9	
2	7.7	9.1	6.8	9.6	8.7	8.7	

Baseline characteristics (pregnancy)	Total (N = 722)		Intervention (N = 363)		Control (N = 359)		
	Retained (N=495)	Lost (N=227)	Retained (N=255)	Lost (N=108)	Retained (N=240)	Lost (N=119)	p-value[a]
3	39.2	34.7	39.4	32.7	39.0	36.5	
4	8.1	9.6	6.4	11.5	10.0	7.8	
5 (least disadvantaged)	2.9	3.7	3.2	1.0	2.6	6.1	
Language other than English	7.2	11.7	6.8	10.3	7.6	13.0	0.71

[a] p-value for chi-square tests (categorical measures) and t-tests (continuous measures) comparing those retained in the intervention and usual care groups.

All values are percentages, except where otherwise stated.

DASS= Depression, Anxiety, Stress Scale; SD=Standard Deviation; SEIFA=Socioeconomic Indexes for Areas Index of Relative Disadvantage

Range of Total N = 696-722, Intervention N =351-363, Control N= 345-359 due to missing data

Percentages may not add up to 100 due to rounding

Health service use and cost (Table 3)

Compared with usual care, the NHV program was associated with total increased costs over three years of A$7829 per family. This largely reflects the increased cost of nurse visits (primary health services category), due to increased number of visits received (see Supplementary Table 2) and increased proportion of home visits. The mean cost of nurse visits to child age 3 years summed to A$6772 in the intervention group and A$966 in the control group. Combined with social care practitioner visits and additional intervention costs, service costs were A$9415 in right@home compared to A$2162 in usual care, i.e. an additional cost of A$7254. As the intervention was delivered more intensively in the first year of child's life, the extra costs are largely accrued in the first year.

Other health service use varied, with no clear patterns across groups and no statistical evidence of differences at the aggregate level when combining all categories (except the above-mentioned primary health services) in any year or combining any category over three years. However, in the first year, the intervention group had higher use of hospital clinics and admissions than the usual care group. At the disaggregated level (Supplementary Table 2), we can see that this is driven by a higher number of visits by both mothers and babies to hospital outpatient clinics, and higher emergency department visits in the child's first year, which is reversed in the second year.

Table 3: Health service use and intervention costs (complete case analysis for discounted costs)

All costs in A\$ 2016/17	right@home n=363		usual care n=359		Mean difference	p value	95% CI
	N	Cost (mean (SD))	N	Cost (mean (SD))			
Hospital Clinics							
Year 1	317	2039.22 (2359.38)	304	1763.3 (1625.2)	275.93	0.046	-45;596
Year 2	251	1026.20 (1639.31)	226	1164.8 (2278.5)	-138.65	0.221	-493;216
Year 3	198	1022.64 (2054.50)	191	1046.3 (1842.1)	-23.64	0.453	-413;365
Hospital Admissions							
Year 1	336	6003.54 (29573.97)	330	3375.4 (11250.9)	2628.18	0.066	-788;6044
Year 2	309	2680.74 (8428.60)	290	2157.9 (5498.2)	522.87	0.186	-627;1673
Year 3	263	2294.75 (7173.01)	247	2658.4 (7729.9)	-363.60	0.291	-1660;933
Primary Health Services							
Year 1	303	6987.26 (2727.84)	317	2687.9 (1637.6)	4299.33	0.000	3946;4652
Year 2	292	3270.64 (1906.34)	306	1438.2 (1304.9)	1832.45	0.000	1571;2094
Year 3	247	1077.48 (1367.65)	230	936.3 (1014.9)	141.14	0.102	-77;359
Total Health Service cost							
Year 1	281	13144.14 (20147.19)	280	7861.1 (12864.8)	5283.05	0.000	2479;8088
Year 2	219	6564.58 (9339.43)	212	4922.1 (7592.5)	1642.43	0.023	28;3257

All costs in A$ 2016/17	right@home n=363		usual care n=359		Mean difference	p value	95% CI
	N	Cost (mean (SD))	N	Cost (mean (SD))			
Year 3	189	3967.05 (6981.44)	179	4275.2 (7935.3)	-308.15	0.346	-1838;1223
Additional intervention costs							
Year 1	363	826.29 (0.00)	359	347.5 (0.0)	478.77	-	-
Year 2	363	382.15 (0.00)	359	347.5 (0.0)	34.63	-	-
Total cost							
Year 1	281	13970.43 (20147.20)	280	8208.6 (12864.8)	5761.82	0.000	2957;8566
Year 2	219	6928.53 (9339.43)	212	5253.1 (7592.5)	1675.41	0.021	61;3290
Year 3	189	3967.05 (6981.44)	179	4275.2 (7935.3)	-308.15	0.346	-1838;1222
Over 3 years	121	22766.04 (15785.79)	119	14937.2 (12922.6)	7828.82	0.000	4157;11501

*Unadjusted mean costs

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Health outcomes and cost-consequences analysis

Table 4 shows that, compared with the usual care group, women in the intervention group reported improved mental health (Total DASS score ES=0.18, 95% CI: 0.00 to 0.36) at child age 3 years. There was little evidence for group differences in child outcomes. The difficulty in comparing a substantial cost difference to a combination of effect sizes across different outcome measures in cost-consequences analysis (Table 4) is a reason to progress to the pre-specified secondary cost-utility analysis. There was statistically significantly improved maternal QALYs in the third year (Figure 2, Table 5) but no overall significant difference over the whole 3 year period (Table 5).

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Table 4: Cost-consequences analysis of right@home at 3 years against all health-related outcomes (using multiple imputation).

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Outcome	Descriptive statistics		Comparative statistic: Intervention compared to Control				
	right@home (I)	usual care (C)	Adjusted			Effect Size	95% CI
	Mean	Mean	Mean Difference	95% CI	p		
Parent Care							
Warm parenting	4.63	4.64	-0.02	-0.13 ; 0.08	0.622	-0.05	-0.26 ; 0.17
Hostile parenting (reverse)	7.94	7.76	0.18	-0.16 ; 0.52	0.259	0.10	-0.09 ; 0.29
Parenting Efficacy	8.07	7.91	0.16	-0.15 ; 0.48	0.284	0.10	-0.09 ; 0.28
Child-parent conflict (reverse)	22.25	21.24	0.98	-0.34 ; 2.30	0.134	0.14	-0.05 ; 0.33
Child-parent closeness	32.28	32.33	-0.10	-0.73 ; 0.53)	0.739	-0.03	-0.21 ; 0.15
Maternal Health							
Mental health : DASS - Overall (Reverse scored)	53.79	51.74	1.85	0.05 ; 3.65	0.045	0.18	0.00 ; 0.36
Quality of life : AQoL	0.72	0.68	0.04	-0.01 ; 0.08	0.095	0.18	-0.04 ; 0.39
Stress **:** Maternal hair cortisol (pg/mg, reverse log transformed*)	1.49	1.58	0.10	-0.12 ; 0.32	0.359	0.10	-0.12 ; 0.31
Life satisfaction**:**Personal Wellbeing Index	58.95	56.23	2.37	-0.59 ; 5.34	0.103	0.17	-0.04 ; 0.37
Child Language							

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	Descriptive statistics		Comparative statistic: Intervention compared to Control				
Outcome	right@home (I)	usual care (C)	Adjusted			Effect Size	95% CI
	Mean	Mean	Mean Difference	95% CI	p		
Receptive and expressive language : CELF Sentence Structure	9.04	8.74	0.12	-0.55 ; 0.80	0.699	0.04	-0.17 ; 0.25
Receptive and expressive language : CELF Word Structure	7.94	7.63	0.15	-0.60 ; 0.89	0.682	0.04	-0.18 ; 0.26
Receptive and expressive language : CELF Expressive Vocabulary	8.31	8.00	0.19	-0.46 ; 0.84	0.532	0.06	-0.14 ; 0.26
Receptive and expressive language : CELF Core Language	90.75	89.01	0.83	-2.60 ; 4.27	0.609	0.05	-0.16 ; 0.26
Child Health							
Mental health and behaviour : SDQ Externalizing problems (reverse)	11.62	11.35	0.11	-0.78 ; 1.00	0.792	0.02	-0.17 ; 0.22
Mental health and behaviour : SDQ Internalizing problems (reverse)	16.03	15.85	0.14	-0.38 ; 0.66	0.580	0.04	-0.13 ; 0.22
Mental health and behaviour : SDQ Total behavior problems (reverse)	27.66	27.19	0.25	-0.87 ; 1.36	0.639	0.04	-0.14 ; 0.22
Quality of life : PedsQL Physical wellbeing	90.99	89.42	1.51	-1.17 ; 4.18	0.244	0.12	-0.09 ; 0.32

Outcome	Descriptive statistics		Comparative statistic: Intervention compared to Control				
	right@home (I)	usual care (C)	Adjusted			Effect Size	95% CI
	Mean	Mean	Mean Difference	95% CI	p		
Quality of life **:** PedsQL Socioemotional wellbeing	85.33	83.53	1.67	-1.20 ; 4.54	0.235	0.12	-0.08 ; 0.31
Stress**:** Child hair cortisol (pg/mg, reverse log transformed*)	1.93	1.69	-0.24	-0.54 ; 0.06	0.106	-0.21	-0.47 ; 0.06
Economic							
Total costs A$	26,192	18,507	7685	7006; 8364	0.000	0.28	0.26; 0.31

Adjusted for baseline characteristics of: child sex, family's Socio-Economic Index for Areas (SEIFA) score, maternal education, maternal age at child's birth, parity, antenatal risk, maternal self-efficacy and maternal mental health; plus child age at the 3-year assessment.

CI= Confidence Interval; CPRS = Child Parent Relationship Scale; DASS= Depression, Anxiety, Stress Scale; AQoL=Assessment of Quality of Life; PedsQL= Pediatric Quality of Life Inventory; SDQ = Strengths and Difficulties Questionnaire

* Natural log

Table 5: Quality Adjusted Life Years (using multiple imputation)

Outcome	Descriptive statistics QALYs		Comparative statistic: Intervention compared to Control				
	right@home (I)	usual care (C)	Adjusted			Effect Size	95% CI
	Mean	Mean	Mean Difference	95% CI	p		
Year 1	0.68 (0.16)	0.68 (0.16)	0.00	-0.00; 0.00	0.88	0.00	-0.02; 0.03
Year 2	0.69 (0.17)	0.69 (0.15)	0.00	-0.01; 0.01	0.12	-0.02	-0.04; 0.01
Year 3	0.65 (0.16)	0.64 (0.16)	0.01	-0.00; 0.01	0.00	0.05	0.03; 0.08
Over 3 years	2.02 (0.46)	2.01 (0.43)	0.01	-0.01; 0.02	0.36	0.01	-0.01; 0.04

*Adjusted for baseline characteristics of: child sex, family's Socio-Economic Index for Areas (SEIFA) score, maternal education, maternal age at child's birth, parity, antenatal risk, maternal self-efficacy and maternal mental health; plus child age at the 3-year assessmen

Incremental Cost Effectiveness Ratio (ICER)

The ICER of the NHV intervention compared to usual care was estimated to be $195,675 per QALY gained using complete case analysis and $258,476 per QALY using multiply imputed data taking account of missing data and loss to follow up. While all simulated cases demonstrated increased costs associated with the intervention, effects were far less certain (Figure 3). The cost effectiveness acceptability curve supports this, showing less than 20% probability of cost effectiveness at a willingness-to-pay of $50,000 per QALY at 3 years.

DISCUSSION

The economic evaluation confirms that the provision of a higher intensity and home-based nursing service in the right@home NHV program resulted in substantially increased healthcare costs. We found limited group differences in all other health resource use and associated costs up to child age 3 years. There was evidence of benefits to maternal mental health at child age 3 years, which combined with benefits to parenting at 2 years, translate into marginal maternal

QALY gains. At 12 months post-intervention, the intervention is not cost-effective; however, cost-effectiveness will improve over time if benefits continue to accrue to mothers and/or children.

The implementation costs of the right@home NHV program (A$7254) are similar to the range of costs reported for NHV programs in other high-income countries. The Nurse Family Partnership (NFP) estimated program costs of US$12,265[12] (A$17,503 in 2016/17 prices),[24 25] the Building Blocks program (based on NFP) in England estimated additional costs of GBP1,812 (A$4166)[4] and an earlier NHV program in England estimated additional costs of GBP3,246 (A$9523)[26]. Two previous studies have assessed the impact of NHV programs on QALYs. A 2011 economic evaluation of the Denver NFP to child age 9 years estimated 0.15 additional QALYs accrued to mother/child dyad over the 9-year period, largely from reduced maternal depression.[9 27] An economic evaluation of the UK's family nurse partnership program (Building Blocks) to child age 2 found 0.0036 additional QALYs per mother (95% CI: −0.017; 0.025).[4] In comparison, we find 0.01 additional QALYs per mother (95% CI: -0.01; 0.02) to child age 3.

Economic evaluations of NHV programs assess whether the benefits generated by the program represent value for money in comparison to the program costs. In the US healthcare system, the NFP program has generated increasing health and economic benefits over time. Cost-savings to government are estimated to outweigh upfront program costs between child age 9 and 30, depending on the effectiveness estimates used in analysis.[9 12 27] This means that decision-making on NHV programs should consider costs and outcomes over a sufficiently long time period, despite the inherent conflict between policy/decision timing and availability of follow-up data.

Applications of NHV programs in high-income countries have sought to address whether the positive results in the US context can be replicated when NHV is added to an existing universal

healthcare system. In Australia, for example, 'usual care' represents a higher level of CFH service delivery compared to the US context. The concept that NHV offers a small change from existing service delivery is posited as an explanation for lack of positive outcomes for trials of NHV in England.[4] For the right@home NHV program at child age 3 years, the economic evaluation demonstrates increased costs and only limited benefits; however, these findings may change at older ages in line with previous studies and the general early intervention literature where benefits emerge as children age and enter adulthood with benefit lags up to 30 years post intervention.[12]

Broader health service use costs were slightly higher for right@home compared to usual care in the first year, with some reversal in later years. The increased professional contact of the NHV program may directly identify health concerns, or improve predisposing individual factors like knowledge and awareness to prompt women to use healthcare services more often.[28] This should be interpreted as a positive outcome, as increasing women's connection to and use of appropriate services is an objective of this and other NHV programs. Although any increased use of services will have additional costs to government providers, if this is filling or narrowing a gap in appropriate care, it may well lead to concomitant or future improvements in health outcomes.

Strengths of the trial include the rigorous design and outcome assessments completed by researchers who were blinded to intervention status. The research retained a high proportion of study participants in both groups (69% over a 4-year study duration), despite the substantial adversity experienced by participants. For context, by the 2-year follow-up, the Building Blocks study retained 71% of their cohort for self-reported outcomes[29] and other European studies retained less than 50%.[6 30] Given the large, multi-site design of the trial, high participant retention and use of multiple imputation to address missing data arising from participant

attrition, we believe our findings should generalize to pregnant women experiencing adversity, in similar healthcare systems.

There are several limitations. Maternal report was used to measure broader health service use and quality of life outcomes and responses may be subject to perception influenced by participation in the intervention. There is a possibility of recall bias when answering service use questions over a 6 month recall period, although any bias should be distributed equally across trial arms.[31] Service use data excludes the use and costs of other government services such as child protection and associated legal services, as these data were not collected in this period of the trial. In addition, trial exclusion criteria meant that findings may not generalize to non-English speaking women or women with severe intellectual disability.

CONCLUSION

The embedding of a NHV program into the Australian universal health system demonstrates benefits to parenting and the home environment when the intervention ends at child age 2 years, and improves maternal mental health 12 months later. As expected, implementing a NHV program requires substantial up-front investment. Economic evaluation based on the outcomes evident by child age 3 years shows a lack of cost-effectiveness, due to a lack of short term cost-savings and only marginal maternal QALY gain. However, initial outcome differences suggest that NHV can help shift the impact of relative adversity. While encouraging, ongoing follow-up will assess whether continued accrual of benefits to mothers and children outweigh the increased up-front costs as shown in other NHV programs over a longer period of time.

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Contributors

SBM and LG conceptualized and conducted the economic evaluation. SG, LK, AP, FM, HB, SP, FO, PD, TB, DH, KN and HH conceptualized the study design, provided statistical expertise, contributed to the first draft and subsequent revisions of the manuscript. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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Conflict of Interest Disclosures

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Data Sharing Statement

Upon request to susan.perlen@mcri.edu.au, deidentified participant data, study protocols and statistical analysis plans can be made available after publication to researchers who provide a methodologically sound proposal for use of the data.

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Figures

Figure 1: Participant Flow Chart
Figure 2: QALYs over 3 years, using imputed data
Figure 3: Cost-effectiveness plane and Cost-effectiveness acceptability curve

Figures

Figure 1: Participant Flow Chart

Figure 2: QALYs over 3 years, using imputed data

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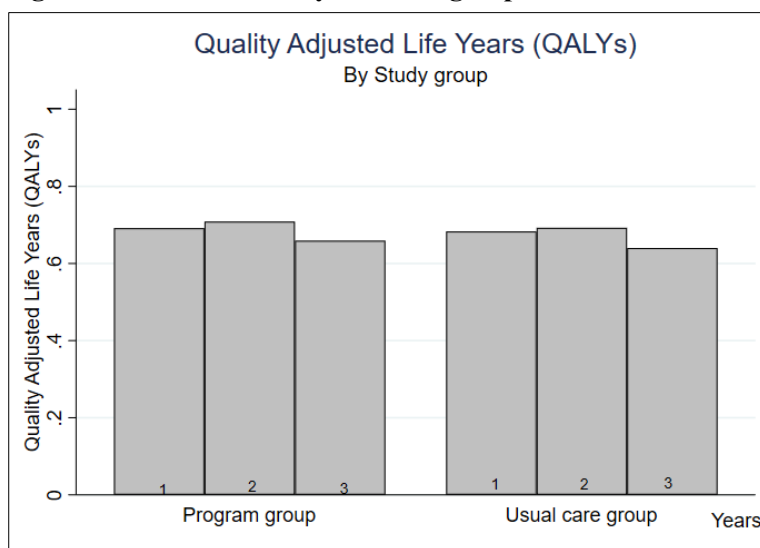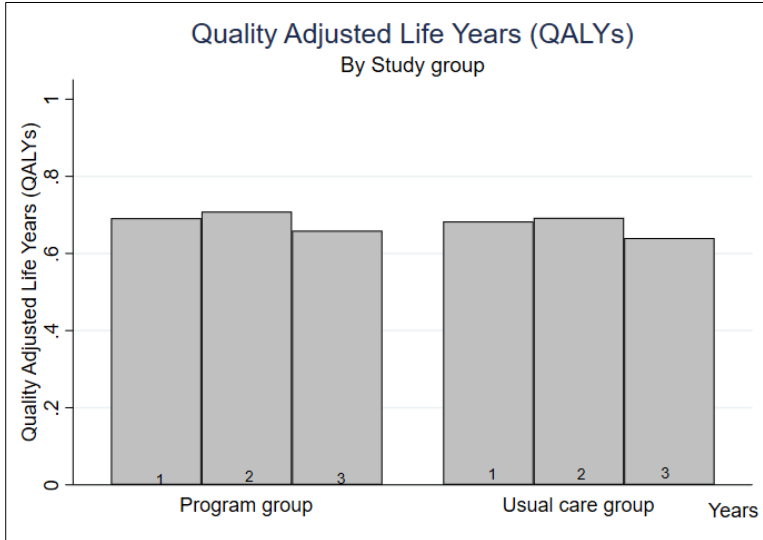
Figure 3: Cost-effectiveness plane and Cost-effectiveness acceptability curve

Supplementary Tables

Supplementary Table 1: Description of maternal and child outcome measures collected at 3 years

Item	Description
Parent care	
Warm parenting	6-item measure assessing parental warmth. Items rated on a 5-point scale ("never/almost never" to "always/almost always"), drawn from LSAC.[41]
Hostile parenting	5-item measure assessing parental hostility. Items rated on a 10-point scale ("not at all" to "all of the time"), drawn from LSAC.[41]
Parenting efficacy	4-item Parenting Efficacy scale. Items rated on a 10-point scale ("Not at all how I feel" to "Exactly how I feel") drawn from LSAC, and a single 5-point Parenting Efficacy item assessing mother's feelings about herself as a parent ("Not very good" to "Very good") drawn from LSAC.[41]
Child-parent closeness and conflict	15-item short-form of the Child-Parent Relationship Scale (CPRS)[42,43]. Self-report measure assessing parents' views of their relationship with their child, rated on a 5-point scale ("definitely does not apply" to "definitely applies"). Two subscale: Conflict (higher scores indicate greater conflict) and Closeness (higher scores indicate greater closeness).
Maternal health	
Maternal mental health	Depression, Anxiety and Stress Scales.[44] 21-item measure, rated on a 4-point scale ("not at all" to "most of the time") assessing the negative emotional states of depression, anxiety and tension/stress. Three subscales (7 items each): Depression, Anxiety and Stress used to derive a single Total DASS score.
Quality of life	Assessment of Quality of Life – 8D (AQoL-8D).[45,46] 35-item measure assessing health related quality of life. Provides a single overall utility-based quality of life measure.
Stress	Hair cortisol as a measure of maternal stress response over the past 3 months. The hair sample is a minimum length of 3cm, with the total density of the sample equating to approximately half a pencil's width (30-50mg). Cortisol concentrations are log transformed and reported as a continuous measure, reversed so that higher scores indicate lower long-term stress.[47]
Life satisfaction	Personal Wellbeing Index (International Wellbeing Group, 2013).[48] Single item assessing general life satisfaction, and 8 items assessing satisfaction with specific life domains, rated using a 10-point scale ("no satisfaction at all" to "completely satisfied").
Child language	
Receptive and expressive language	Clinical Evaluation of Language Fundamentals Preschool Second Edition (CELF-P2) Australian Standardised Edition.[49] Direct assessment of child expressive and receptive language skills across three subscales: Sentence Structure, Word Structure and

Item	Description
	Expressive Vocabulary, and a combined Core Language score. Subtest scores reported as age-specific normative scaled scores (m=10, SD=3) and Core Language score reported as standard score (m=100, SD=15).
Child health	
Mental health and behaviour	25-item Strengths and Difficulties Questionnaire (4–10-year-old version),[50,51] assessing Total difficulties and two domain scores of Internalizing difficulties (combined score of emotional and peer problems) and Externalizing difficulties (combined score of behaviour and attention/hyperactivity). Items rated on a 3-point scale ("not true"/"somewhat true"/"certainly true"). Reversed so that higher mean scores indicate fewer problems.
Quality of life	21-item Pediatric Quality of Life Inventory (PedsQl) [52] assessing child's general wellbeing. Two subscales used (Physical functioning and Socioemotional Functioning). Items rated on a 5-point scale ("never"/"almost never"/"sometimes"/"often"/"always") Higher scores indicate better wellbeing.
Child stress	Hair cortisol, see description for maternal stress above.

Supplementary Table 2: Health service use and cost per participant over three years (complete case analysis)

	right@home (I)					usual care(c)					MD and p value		
Health Service	**n**	**MV**	**SD**	**MC A$**	**SD**	**n**	**MV**	**SD**	**MC A$**	**SD**	**MV**	**MC A$**	**p value**
Emergency Department: Baby													
Year 1	345	1.1	1.8	411.4	693.8	339	0.9	1.3	332.2	509.2	0.2	79.2	0.05
Year 2	324	0.8	1.4	282.7	514.8	310	0.7	1.4	272.7	520.1	0.0	10.1	0.40
Year 3	266	0.7	1.6	260.0	558.0	252	0.6	1.4	202.7	499.4	0.2	57.3	0.11
Emergency Department: Mother													
Year 1	343	0.6	1.6	246.2	609.1	338	0.4	1.0	167.7	383.9	0.2	78.5	0.02
Year 2	324	0.4	0.9	160.9	320.7	314	0.6	1.7	226.5	639.4	-0.2	-65.6	0.05
Year 3	266	0.5	1.9	158.7	670.0	254	0.6	1.7	206.6	589.0	-0.1	-48.0	0.19
Hospital outpatient clinics: Baby													
Year 1	341	0.8	2.3	236.6	654.0	332	0.9	3.0	256.9	869.9	-0.1	-20.3	0.37
Year 2	322	0.7	2.6	186.9	707.4	309	0.6	2.4	162.9	641.5	0.1	24.0	0.33
Year 3	267	0.3	1.1	88.8	281.2	251	0.3	0.9	78.9	241.5	0.0	9.9	0.33
Hospital outpatient clinics: Mother													
Year 1	344	1.3	5.6	370.7	1599.3	338	0.8	2.7	222.6	769.0	0.5	148.1	0.06
Year 2	323	1.7	4.4	471.6	1200.0	310	2.1	5.9	564.6	1611.3	-0.3	-93.0	0.21
Year 3	259	2.2	6.1	571.2	1596.7	240	2.6	6.9	671.8	1804.5	-0.4	-100.6	0.26
Hospital Postnatal clinic													

Health Service	right@home (I)					usual care(c)					MD and p value		
	n	MV	SD	MC A$	SD	n	MV	SD	MC A$	SD	MV	MC A$	p value
Year 1	340	0.0	0.2	3.4	19.8	336	0.1	0.3	5.6	32.1	0.0	-2.1	0.15
Hospital Breastfeeding clinic													
Year 1	339	0.1	0.4	16.7	96.3	337	0.0	0.3	9.4	75.5	0.0	7.3	0.14
Hospital other outpatient clinics: Baby													
Year 1	342	0.3	1.5	71.4	441.5	333	0.1	0.4	32.8	119.7	0.1	38.6	0.06
Year 2	275	0.0	0.1	3.0	36.8	250	0.0	0.4	9.8	96.0	0.0	-6.9	0.14
Year 3	222	0.0	0.3	12.7	87.5	218	0.0	0.1	3.2	33.6	0.0	9.4	0.07
Hospital other outpatient clinics: Mother													
Year 1	339	0.2	2.3	59.3	663.4	337	0.1	0.4	20.5	99.4	0.1	38.9	0.14
Year 2	276	0.1	0.9	25.8	233.0	258	0.3	2.6	68.9	697.3	-0.2	-43.1	0.17
Year 3	231	0.0	0.2	12.2	79.3	222	0.2	1.6	53.8	574.2	-0.1	-41.6	0.14
Hospital admissions: Baby													
Year 1	338	2.1	13.4	4282.3	27582.0	332	0.9	3.9	1796.0	7987.4	1.2	2486.4	0.06
Year 2	316	0.4	1.9	813.4	3789.6	305	0.3	1.5	595.0	2915.9	0.1	218.4	0.20
Year 3	265	0.4	2.6	758.4	4787.2	249	0.2	0.9	317.9	1578.9	0.3	440.6	0.07
Hospital admissions: Mother													
Year 1	343	0.8	4.5	1668.4	9180.3	339	0.8	3.9	1551.2	7960.3	0.1	117.2	0.43
Year 2	316	1.0	4.0	1992.2	7906.4	297	0.8	2.3	1499.9	4563.9	0.2	492.2	0.18

Health Service	right@home (I)					usual care(c)					MD and p value		
	n	MV	SD	MC A$	SD	n	MV	SD	MC A$	SD	MV	MC A$	p value
Year 3	267	0.9	2.9	1525.9	5387.3	253	1.7	7.4	3037.6	13855.3	-0.8	-1511.7	0.05
Breastfeeding consultant													
Year 1	336	0.1	0.3	12.1	64.3	337	0.1	0.4	18.1	91.5	0.0	-6.0	0.16
Lactation consultant													
Year 1	336	0.4	1.3	84.9	302.2	329	0.3	1.1	66.1	251.9	0.1	18.8	0.19
Parent center day													
Year 1	344	0.2	0.9	65.1	350.9	339	0.2	0.9	67.9	342.4	0.0	0.1	0.50
Year 2	325	0.2	3.0	0.0	0.2	312	0.1	0.7	0.0	0.2	0.1	0.0	0.20
Year 3	260	0.1	1.6	0.0	0.1	242	0.0	0.1	0.0	0.1	0.1	0.0	0.18
Parent center night													
Year 1	341	0.1	1.6	94.8	1192.3	339	0.1	0.7	56.3	514.6	0.1	38.4	0.29
Year 2	325	0.0	0.8	0.0	0.1	311	0.0	0.0	0.0	0.1	0.0	0.0	0.16
Year 3	260	0.0	0.0	0.0	0.0	242	0.0	0.1	0.0	0.1	0.0	0.0	0.85
Hospital Midwife													
Year 1	340	1.8	2.5	668.2	937.7	334	2.0	1.5	750.5	555.3	-0.2	-82.4	0.08
Child & family health nurse													
Year 1	343	15.6	6.5	5154.0	2137.8	340	7.0	4.0	774.9	437.2	8.6	4379.1	0.00
Year 2	320	4.8	2.9	1496.8	911.3	308	1.4	1.6	148.6	170.5	3.3	1348.2	0.00
Year 3	261	0.4	0.8	121.6	231.1	247	0.4	0.7	42.4	68.6	0.0	79.2	0.00

Health Service	right@home (I)					usual care(c)					MD and p value		
	n	MV	SD	MC A$	SD	n	MV	SD	MC A$	SD	MV	MC A$	p value
Social worker/care practitioner											0.0	0.0	0.00
Year 1	343	2.4	6.4	179.6	484.9	336	1.0	4.0	78.7	300.6	1.3	100.9	0.00
Year 2	325	1.5	6.4	108.4	459.3	314	0.8	3.8	59.4	271.0	0.7	49.0	0.05
Year 3	269	1.2	4.8	83.7	328.2	253	0.4	2.3	29.1	157.9	0.8	54.6	0.01
Helpline													
Year 1	343	0.8	1.4	47.8	86.2	341	1.1	2.0	64.6	121.8	-0.3	-16.8	0.02
Year 2	325	0.7	3.2	40.1	183.3	313	0.5	1.2	30.5	67.7	0.2	9.6	0.19
Year 3	269	0.6	1.5	30.8	81.8	255	0.4	0.9	21.3	50.3	0.2	9.4	0.06
General practice													
Year 1	345	10.3	10.3	380.0	381.4	341	10.1	8.8	372.3	325.2	0.2	7.6	0.39
Year 2	325	9.0	8.6	316.9	303.3	314	10.0	9.3	352.8	327.7	-1.0	-35.9	0.08
Year 3	269	9.5	9.8	318.9	329.2	255	9.8	10.2	327.6	341.0	-0.3	-8.7	0.38
Psychologist													
Year 1	341	1.2	3.6	61.4	187.1	338	1.1	4.5	57.4	232.3	0.1	4.1	0.40
Year 2	324	0.8	2.8	40.1	140.0	313	1.0	3.3	50.4	165.2	-0.2	-10.3	0.20
Year 3	268	1.3	3.6	59.2	170.4	255	1.5	4.3	70.1	202.5	-0.2	-10.8	0.25
Psychiatrist													
Year 1	343	0.5	2.2	102.6	496.5	336	0.2	1.8	47.4	386.3	0.3	55.2	0.05
Year 2	325	0.2	1.5	50.6	319.7	314	0.2	1.4	39.6	287.4	0.1	11.0	0.32

Health Service	right@home (I)					usual care(c)					MD and p value		
	n	MV	SD	MC A$	SD	n	MV	SD	MC A$	SD	MV	MC A$	p value
Year 3	269	0.2	1.7	32.1	335.4	254	0.2	1.5	41.9	304.4	-0.1	-9.8	0.36
Pediatrician													
Year 1	340	0.6	1.5	140.6	335.4	332	0.7	1.6	156.8	364.1	-0.1	-16.2	0.27
Year 2	322	0.3	0.8	58.4	168.6	313	0.4	1.7	75.1	353.8	-0.1	-16.7	0.22
Year 3	269	0.2	0.7	47.7	151.4	253	0.4	1.3	74.8	272.8	-0.1	-27.1	0.08
Obstetrician/Gynecologist													
Year 1	339	0.4	1.0	96.6	230.6	335	0.5	1.6	104.5	352.7	0.0	-7.9	0.37
Year 2	325	0.4	1.1	79.6	235.0	312	0.6	2.1	124.6	448.4	-0.2	-45.1	0.06
Year 3	265	0.6	1.9	117.5	395.4	252	0.6	2.0	114.7	402.5	0.0	2.8	0.47
Physiotherapy													
Year 1	343	0.9	3.1	48.3	160.8	337	1.0	3.2	54.0	164.5	-0.1	-5.7	0.33
Year 2	325	1.1	4.4	53.1	216.4	313	0.9	3.9	46.4	194.8	0.1	6.7	0.34
Year 3	268	1.3	5.8	60.1	275.6	255	0.7	4.3	33.1	203.0	0.6	27.0	0.10
Osteo/chiro practitioner													
Year 1	342	1.9	7.1	99.0	373.1	337	1.4	5.6	73.6	290.9	0.5	25.4	0.16
Year 2	325	1.3	4.5	65.1	224.0	314	1.4	6.3	67.0	313.8	0.0	-2.0	0.46
Year 3	269	1.6	5.2	76.6	245.5	255	1.5	5.6	70.3	264.0	0.1	6.4	0.39
Dentist													
Year 1	344	0.7	1.6	49.2	105.4	337	0.7	1.7	46.1	114.6	0.1	3.1	0.36

Health Service	right@home (I)					usual care(c)					MD and p value		
	n	MV	SD	MC A$	SD	n	MV	SD	MC A$	SD	MV	MC A$	p value
Year 2	325	1.1	2.0	70.2	128.6	314	1.0	1.8	62.0	112.4	0.1	8.2	0.20
Year 3	269	1.4	2.4	85.9	145.7	254	1.4	2.4	82.9	141.7	0.1	3.0	0.41
Drug and Alcohol clinic													
Year 2	325	0.0	0.4	6.2	73.1	314	0.1	1.4	24.0	225.6	-0.1	-17.8	0.09
Year 3	269	0.0	0.3	7.1	49.2	254	0.3	2.6	42.1	420.0	-0.2	-35.0	0.09

*MV: Mean Visits, MC: Mean Costs, MD: Mean Difference

CHEERS Checklist
Items to include when reporting economic evaluations of health interventions

The **ISPOR CHEERS Task Force Report**, *Consolidated Health Economic Evaluation Reporting Standards (CHEERS)—Explanation and Elaboration: A Report of the ISPOR Health Economic Evaluations Publication Guidelines Good Reporting Practices Task Force,* provides examples and further discussion of the 24-item CHEERS Checklist and the CHEERS Statement.   It may be accessed via the *Value in Health* or via the ISPOR Health Economic Evaluation Publication Guidelines – CHEERS: Good Reporting Practices webpage: http://www.ispor.org/TaskForces/EconomicPubGuidelines.asp

Section/item	Item No	Recommendation	Reported on page No/ line No
Title and abstract			
Title	1	Identify the study as an economic evaluation or use more specific terms such as "cost-effectiveness analysis", and describe the interventions compared.	page 1
Abstract	2	Provide a structured summary of objectives, perspective, setting, methods (including study design and inputs), results (including base case and uncertainty analyses), and conclusions.	page 2
Introduction			
Background and objectives	3	Provide an explicit statement of the broader context for the study. Present the study question and its relevance for health policy or practice decisions.	page 4 & 5
Methods			
Target population and subgroups	4	Describe characteristics of the base case population and subgroups analysed, including why they were chosen.	page 6 para 2
Setting and location	5	State relevant aspects of the system(s) in which the decision(s) need(s) to be made.	page 7
Study perspective	6	Describe the perspective of the study and relate this to the costs being evaluated.	page 5 para 3
Comparators	7	Describe the interventions or strategies being compared and state why they were chosen.	page 4 para 3 & page 5 para1
Time horizon	8	State the time horizon(s) over which costs and consequences are being evaluated and say why appropriate.	page 7 para 2
Discount rate	9	Report the choice of discount rate(s) used for costs and outcomes and say why appropriate.	page 9 para 1
Choice of health outcomes	10	Describe what outcomes were used as the measure(s) of benefit in the evaluation and their relevance for the type of analysis performed.	page 7 para 1
Measurement of effectiveness	11a	*Single study-based estimates:* Describe fully the design features of the single effectiveness study and why the single study was a sufficient source of clinical effectiveness data.	page 6 & 10

	11b	*Synthesis-based estimates:* Describe fully the methods used for identification of included studies and synthesis of clinical effectiveness data.	not applicable	
Measurement and valuation of preference based outcomes	12	If applicable, describe the population and methods used to elicit preferences for outcomes.	page 6	
Estimating resources and costs	13a	*Single study-based economic evaluation:* Describe approaches used to estimate resource use associated with the alternative interventions. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs.	page 5 & 7	
	13b	*Model-based economic evaluation:* Describe approaches and data sources used to estimate resource use associated with model health states. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs.	not applicable	
Currency, price date, and conversion	14	Report the dates of the estimated resource quantities and unit costs. Describe methods for adjusting estimated unit costs to the year of reported costs if necessary. Describe methods for converting costs into a common currency base and the exchange rate.	page 7 para 2 & table 1	
Choice of model	15	Describe and give reasons for the specific type of decision-analytical model used. Providing a figure to show model structure is strongly recommended.	page 5 & 6	
Assumptions	16	Describe all structural or other assumptions underpinning the decision-analytical model.	page 8	
Analytical methods	17	Describe all analytical methods supporting the evaluation. This could include methods for dealing with skewed, missing, or censored data; extrapolation methods; methods for pooling data; approaches to validate or make adjustments (such as half cycle corrections) to a model; and methods for handling population heterogeneity and uncertainty.	page 11	
Results				
Study parameters	18	Report the values, ranges, references, and, if used, probability distributions for all parameters. Report reasons or sources for distributions used to represent uncertainty where appropriate. Providing a table to show the input values is strongly recommended.	table 3, 4 & 5	
Incremental costs and outcomes	19	For each intervention, report mean values for the main categories of estimated costs and outcomes of interest, as well as mean differences between the comparator groups. If applicable, report incremental cost-effectiveness ratios.	table 4, table 5 & page 23, para 1	
Characterising uncertainty	20a	*Single study-based economic evaluation:* Describe the effects of sampling uncertainty for the estimated incremental cost and incremental effectiveness parameters, together with the impact	page 23, para 1	

		of methodological assumptions (such as discount rate, study perspective).	
	20b	*Model-based economic evaluation:* Describe the effects on the results of uncertainty for all input parameters, and uncertainty related to the structure of the model and assumptions.	not applicable
Characterising heterogeneity	21	If applicable, report differences in costs, outcomes, or cost-effectiveness that can be explained by variations between subgroups of patients with different baseline characteristics or other observed variability in effects that are not reducible by more information.	table 4 & table 5

Discussion

Study findings, limitations, generalisability, and current knowledge	22	Summarise key study findings and describe how they support the conclusions reached. Discuss limitations and the generalisability of the findings and how the findings fit with current knowledge.	page 23 - 26

Other

Source of funding	23	Describe how the study was funded and the role of the funder in the identification, design, conduct, and reporting of the analysis. Describe other non-monetary sources of support.	page 31, para 2
Conflicts of interest	24	Describe any potential for conflict of interest of study contributors in accordance with journal policy. In the absence of a journal policy, we recommend authors comply with International Committee of Medical Journal Editors recommendations.	page 31, para 3

For consistency, the CHEERS Statement checklist format is based on the format of the CONSORT statement checklist

The **ISPOR CHEERS Task Force Report** provides examples and further discussion of the 24-item CHEERS Checklist and the CHEERS Statement.   It may be accessed via the *Value in Health* link or via the ISPOR Health Economic Evaluation Publication Guidelines – CHEERS: Good Reporting Practices webpage: http://www.ispor.org/TaskForces/EconomicPubGuidelines.asp

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Husereau D, Drummond M, Petrou S, et al. Consolidated health economic evaluation reporting standards (CHEERS)—Explanation and elaboration: A report of the ISPOR health economic evaluations publication guidelines good reporting practices task force. Value Health 2013;16:231-50.

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Economic Evaluation of an Australian nurse home visiting program: a randomized trial at 3-years

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Economic Evaluation of an Australian nurse home visiting program: a randomized trial at 3-years

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2   **ABSTRACT**

3   **Objectives**
4   To investigate the additional program cost and cost-effectiveness of "right@home" Nurse
5   Home Visiting (NHV) program in relation to improving maternal and child outcomes at child
6   age 3 years compared to usual care.

7   **Design**
8   A cost-utility analysis from a government-as-payer perspective alongside a randomized trial of
9   NHV over 3 year period. Costs and Quality-Adjusted Life Years (QALYs) were discounted at
10   5%. Analysis used an intention-to-treat approach with multiple imputation.

11   **Setting**
12   The right@home was implemented from 2013 in Victoria and Tasmania states of Australia, as
13   a primary care service for pregnant women, delivered until child age 2 years.

14   **Participants**
15   722 pregnant Australian women experiencing adversity received NHV (n=363) or usual care
16   (clinic visits) (n=359).

17   **Primary and Secondary outcome measures**
18   Firstly, a cost-consequences analysis to compare the additional costs of NHV over usual care,
19   accounting for any reduced costs of service use, and impacts on all maternal and child outcomes
20   assessed at 3 years. Secondly, cost-utility analysis from a government-as-payer perspective
21   compared additional costs to maternal QALYs to express cost-effectiveness in terms of
22   additional cost per additional QALY gained.

23   **Results**
24   When compared to usual care at child age 3 years, the right@home intervention cost A$7685
25   extra per woman (95% CI: A$7006; A$8364) and generated 0.01 more QALYs (95% CI: -
26   0.01; 0.02). The probability of right@home being cost-effective by child age 3 years is less
27   than 20%, at a willingness to pay threshold of A$50,000 per QALY.

28   **Conclusions**
29   Benefits of NHV to parenting at 2 years and maternal health and wellbeing at 3 years translate
30   into marginal maternal QALY gains. Like previous cost-effectiveness results for NHV
31   programs, right@home is not cost-effective at 3 years. Given the relatively high up-front costs
32   of NHV, long-term follow-up is needed to assess the accrual of health and economic benefits
33   over time.

34   **Trial registration number:** ISRCTN89962120

35   **Article Summary**

36   **Strengths and limitations of the study**
37   • A randomized controlled trial setting, with regular follow-up and good retention over
38   time for this disadvantaged population

39   • Integration of a multi-attribute utility instrument and detailed resource use items into
40   trial data collection enables comprehensive assessment of costs and QALY impact

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- Longer-term follow-up will be required to assess whether emerging benefits over time, as seen in similar programs in the United States, recoup the large upfront cost

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44   **INTRODUCTION**

45   Nurse Home Visiting (NHV) programs have been implemented in many high-income countries

46   to improve the health and quality of life of mothers and their children.[1] As one of the few early

47   interventions that have been shown to effectively reduce inequitable outcomes for families

48   experiencing socioeconomic and psychosocial adversity, they have substantial policy appeal.[2]

49   [3] Previous NHV programs have varied in their theory, content and targeted population.[4-8] Most

50   experimental evidence comes from the United States (US).[9] In particular, the Nurse Family

51   Partnership (NFP) has shown improvement in the parental care and material life course of high

52   risk women in the US,[10] although similar benefits have been variable when translating this

53   program to other countries.[4-8]

54   NHV programs are expensive, mostly due to providing additional professional services in-

55   home at the family/individual level.[10] In this context opportunities to implement these

56   programs are challenging with policy makers requiring rigorous evidence of effectiveness and

57   cost-effectiveness.[11] Economic evaluations of NHV programs are important to highlight how

58   initial program implementation costs weigh up against benefits and potential reduced service

59   costs over time. Economic evaluations of NFP have found high upfront program costs ($12,265

60   per family in 2018 US$)[12] with benefits that accrue to participants and taxpayers over the

61   child's lifetime, to produce positive returns on investment by child age 30 years.[12 13] However,

62   the evidence for cost-effectiveness of NHV programs in countries with universal healthcare

63   remains unclear or limited.

64   From 2013, we trialed a NHV program (right@home) for pregnant women experiencing

65   psychosocial and socioeconomic adversity in Australia.[14] The program was embedded into the

66   universal child and family health (CFH) service, which also provided the comparator. The

67   Australian universal CFH service provides nurse visits at key stages of child's health, learning

68   and development. For example, in Victoria families receive CFH nurse visits following the

69   hospital discharge (home visit) and, at 2 weeks, 4 weeks, 8 weeks, 4 months, 8 months, 1 year,

70   18 months 2 years, and 3 and a half years at a local CFH clinic.[15] By the time the right@home

71   NHV program was completed at child age 2 years, it had led to improved parenting and home

72   environment outcomes over and above the usual service.[14] Consistent with the NHV literature,

73   it is anticipated that these short-term benefits will generate longer-term benefits to maternal

74   and child health and development, potentially with associated reductions in government

75   services.[12 13] The aim of this economic evaluation is to analyze the cost-effectiveness of the

76   right@home program to improve maternal and child outcomes one year after program delivery

77   ended. Given the short (12-month) follow-up in the context of the NHV evidence base,[10 12 13]

78   we did not expect the right@home program to be cost-effective by child age 3 years. Rather,

79   we aimed to assess whether upfront program costs were offset by any early maternal and child

80   outcomes, as an indication that the NHV program could achieve longer-term positive returns

81   like those seen in the US.

82   **METHODS**

83   **Design and analytic overview**

84   The study design is an economic evaluation alongside a randomized controlled trial (RCT) of

85   NHV compared to the usual CFH service. The evaluation considered pregnancy to child age 3

86   years and comprised two steps.

87   First, a cost-consequences analysis from a government-as-payer perspective compared the

88   additional costs of NHV over usual care, accounting for any reduced costs of service use, and

89   impacts on the maternal and child outcomes assessed at 3 years. This multi-criteria economic

90   evaluation format incorporates all outcomes judged important in the trial, but results cannot be

91   clearly interpreted as cost-effective or not.[16]

92   Second, cost-utility analysis from a government-as-payer perspective compared additional

93   costs to maternal Quality-Adjusted Life Years (QALYs). This expresses cost-effectiveness in

94   terms of additional cost per additional QALY gained, which can be interpreted against common

95   Australian benchmarks, whereby programs with a cost-per-QALY of under A$50,000 are

96   judged to be cost-effective.[17]

Participants and Procedures

98   The right@home RCT was implemented from 2013 in two states of Australia, Victoria and

99   Tasmania, in accordance with CONSORT requirements.[14 18] Detailed methods are published

100   elsewhere.[14] Briefly, researchers recruited 722 pregnant, English-speaking women, prioritized

101   for their experience of adversity (at least two of: young pregnancy; not living with another

102   adult; no support in pregnancy; poor health; a long-term illness, health problem, or disability

103   that limits daily activities; currently smokes; stress, anxiety, or difficulty coping; low

104   education; no person in the household currently earning an income; and never having had a job

105   before) who attended antenatal clinics at 10 public maternity hospitals from April 30 2013 to

106   August 29 2014.[14 18] Participants enrolled by providing informed consent and completing a

107   baseline interview. Participants randomized to the intervention (the right@home NHV

108   program, n=363) were offered a schedule of 25 home visits (60-90 minutes each) from

109   pregnancy to child age 2 years instead of the usual 8 CFH visits. The NHV program was

110   delivered by a right@home-trained nurse recruited from the usual CFH service, and one or

111   more visits from right@home-trained social care practitioners who provided psychosocial

112   support for the families: brief counseling, assisting families with housing, service access, and

113   financial issues (one dedicated social care practitioner per site, per 100 families)[3] Participants

114   allocated to usual care (n=359) received the universal CFH service, which included 6

115   (Tasmania) or 9 (Victoria) mainly office-based consultations to child age 2 years. When the

116   NHV intervention finished at 2 years, N=558 families enrolled in extended follow-up to 6

117   years.

Ethics approval:

119   The ethics committees of the Royal Children's Hospital (HREC 32296); Deakin University

120   (HREC 2013/147); Peninsula Health (HREC/13/PH/14); Ballarat Health Services

121   (HREC/13/BHSSJOG/9); Southern Health (HREC 13084X); Northern Health (HREC

122   P03/13) (all Victoria), and the University of Tasmania (HREC H0013113) approved this

123   study.

Outcome measures

125   At the original endpoint of 2 years, the primary outcomes were multiple measures of parenting

126   and the home environment; half showed small-to-moderate effect sizes in favour of the

127   intervention and none favoured usual care.[18] At 3 years, outcomes included multiple maternal

128   health and wellbeing and child health and learning outcomes (see Supplementary Table 1). For

129   this paper, the Assessment of Quality of Life (AQoL-8D)[19] was used to capture mothers'

130   health-related quality of life at four time-points (baseline and child ages 1, 2, 3 years); we used

131   the health-related utility score to calculate QALYs.[19] QALYs were calculated as linear

132   interpolation using AQoL data at time points x and (x+1). Data were complete at baseline;

133   where data were missing at later time points, QALYs were interpolated over a maximum of 2

134   years (from x to (x+2)). We did not estimate QALYs for children.

Economic evaluation

136   Costs are based on the health resources used by the woman and her child from recruitment to

137   child age 3 years. Data on birth hospital admission and NHV/CFH service use (including the

138   number and type, e.g. home/clinic/phone) were extracted from service records. Other health

139   resources including hospital admissions and community-based services were self-reported by

140   women in interviews conducted by phone (at child ages 6-weeks, and 6, 18 and 30 months)

141   and face-to-face (at baseline and child ages 1, 2 and 3 years). Participants were asked to recall

142   service use since the last questionnaire for hospital admissions (inpatient, outpatient and

143   emergency visits) and community-based services (for example, general practice and specialist

144   physician visits, breastfeeding/lactation consultations, use of helplines, pharmacy,

145   physiotherapy, etc.). Unit costs for each item of service use were sourced from national-level

146   estimates where possible (Table 1). All costs are presented in 2016/17 Australian dollars.

147   Implementation costs of NHV/CFH included nurse/practitioner visits, training, supervision and

148   overheads. Nurses in both trial arms had similar qualifications (registered midwife/nurse with

149   additional qualifications in maternal and child health).[14] Unit costs of CFH nurse visits were

150   confirmed with providers and included travel time and costs, standard materials and overheads

151   ($330 per home visit, $110 per clinic visit). Costs for the additional online and face-to-face

152   training received by right@home (intervention) nurses included trainer and nurse time, venue

153   hire, catering, materials and travel. These training costs were distributed over an assumed 5

154   year caseload of 60 women to avoid artificially overloading training costs onto the restricted

155   number of RCT participants. The right@home program was associated with slightly higher

156   supervision load than usual CFH service care, additional social worker time and parent

157   materials costs.[20] These "additional intervention costs" are accrued per-nurse and allocated top-

158   down to each participant.

159   **Patient and public involvement**

160   There was no patient and public involvement in the development or analysis of the study

161   **Table 1: Unit cost of health resources**

Service	Unit cost 2016/17 AUD	Unit	Resource
Hospital emergency department	$377.00	Per admission	Independent Hospital Pricing Authority [20]
Hospital outpatient clinic	$ 287.17	Per event	Independent Hospital Pricing Authority [21]
Hospital postnatal clinic	$ 226.39	Per event	Independent Hospital Pricing Authority [21]
Hospital breast feeding clinic	$ 226.39	Per event	Independent Hospital Pricing Authority [21]
Other hospital clinics	$ 287.17	Per event	Independent Hospital Pricing Authority [21]
Hospital someday admission	$1,249.00	Per admission	Independent Hospital Pricing Authority[21]
Hospital overnight admission	$2,065.00	Per day	Independent Hospital Pricing Authority [21]
Lactation consultations	$45.40	Per visit	Medicare Benefits Schedule Item 82140[22]
Parenting Centre day stays	$373.04	Per admission	Expert's opinion : Victorian parenting centers: private patients
Parenting Centre night stays	$734.35	Per night	Expert's opinion : Victorian parenting centers : private patients
Hospital midwife visit	$ 226.39	Per visit	Independent Hospital Pricing Authority [21]
CFHS clinic consultation	$110.00	Per visit	Expert's opinion : From intervention team

CFHS home consultation	$330.00	Per visit	Expert's opinion : From intervention team
CFHS phone consultation	$66.00	Per visit	Australian Psychology Association[23]
Social care practitioner	$75.95	Per visit	Medicare Benefits Schedule Item 80160[24]
Helpline consultation	$20.72	per call	Fair work ombudsmen –Nurses Awards [25]
General Practice	$37.05	Per visit	Medicare Benefits Schedule Item 023[26]
Psychologist	$52.25	Per visit	Medicare Benefits Schedule Item 10968 [27]
Psychiatrist	$221.30	Per visit	Medicare Benefits Schedule Item 296[28]
Pediatrician	$224.35	Per visit	Medicare Benefits Schedule Item 135[29]
Obstetrician/Gynecologist	$224.35	Per visit	Medicare Benefits Schedule Item 132 [30]
Physiotherapy	$52.25	Per visit	Medicare Benefits Schedule Item 81335 [31]
Osteo/chiro practitioner	$52.25	Per visit	Medicare Benefits Schedule Item 10966 [31]
Dentist	$66.36	Per visit	Australian fee schedule of dental services [32]
Drug and Alcohol services	$176.08	Per visit	Independent Hospital Pricing Authority [21]

162   *CFHS: Child and Family Health Services

Analyses

164 Methods to address missing data: Characteristics of women who participated versus those lost

165 to follow-up at 3 years were compared using t tests for continuous and Chi square tests for

166 categorical data. For the total health service cost and its sub-categories (hospital clinics,

167 hospital admissions and primary health services), maternal and child outcomes, and QALY

168 analyses, multiple imputation was used to account for loss to follow-up and missing data.

169 Multiple imputation was conducted using multivariate normal regression within each of the

170 two treatment groups to allow for differing mechanisms by which missing data may have arisen

171 across the groups. Imputation models included all outcomes collected at 3 years, stratification

172 factors and baseline covariates; 30 data sets were imputed. The health service use and

173 intervention cost variables were not imputed because the high levels of missing data and

174 collinearity prevented robust imputation; complete case data are presented for analyses

175 involving these variables.

176 All comparisons are reported as mean differences (MD) and odds ratios (OR), with 95%

177 confidence intervals (CIs) obtained using linear regression and logistic regression models,

178 respectively, adjusted for baseline characteristics of, child sex, family's Socio-Economic Index

179 for Areas (SEIFA) score, maternal education, maternal age at child's birth, parity, antenatal

180 risk, maternal self-efficacy and maternal mental health; plus child age at the 3-year assessment.

181 Results in the tables are reported MDs, standardized effect sizes (ES) or ORs with 95% CI. To

182 make comparisons of intervention effect comparable between outcomes, standardized effect

183 sizes (ES) were obtained by running the linear regression described above on Z-scores

184 calculated on each of the continuous outcomes.

185 Between-group analyses of health service use were grouped into hospital outpatient clinics,

186 hospital (inpatient) admissions and primary health services, presented as the cost of service use

187 per year. As cost data relate to the use of resources over three years, costs after the first year

188   are discounted at 5% (the rate required by Australian guidelines)[33] to present costs in net

189   present value terms.[34] In economic evaluation, QALYs over three years are similarly

190   discounted. All regression analyses accounted for effects of nurse clustering.[14 18]

191   The Incremental Cost Effectiveness Ratio (ICER) was calculated as the mean difference in

192   costs between intervention and usual care groups at 3 years divided by the mean difference in

193   QALYs between groups at 3 years.[35] This presents the extra cost for each additional QALY

194   gained. Uncertainty was illustrated using a cost effectiveness plane showing 95% CIs around

195   the ICER generated using the bootstrap method (1000 simulations) and a cost effectiveness

196   acceptability curve, which visually represents the probability that the intervention (compared

197   to usual care) is cost-effective at varying threshold values of one QALY ($0 to $1.5m).[17]

198   Analyses were conducted in Microsoft Excel and Stata version 16.[36]

199   **RESULTS**

200   **Participant characteristics**

201   At 3 years, 495 women (89% of N=558 re-enrolled, 69% of original N=722) (Table 2, Figure

202   1) women provided data. More women were lost to follow up who during pregnancy were

203   younger, unemployed, reported high antenatal risk or poor mental health, or spoke a language

204   other than English (Table 2).

205 **Table 2: Baseline characteristics according to follow-up status (i.e. retained or lost) at child age 3 years**

Baseline characteristics (pregnancy)	Total (N = 722)			Intervention (N = 363)		Control (N = 359)		
	Retained (N=495)	Lost (N=227)	p-value[a]	Retained (N=255)	Lost (N=108)	Retained (N=240)	Lost (N=119)	p-value[b]
Mother								
Age (years), mean (SD)	28.0 (6.2)	27.0 (6.3)	0.05	27.6 (5.9)	27.1 (6.4)	28.3 (6.4)	26.9 (6.2)	0.22
DASS Depression, mean (SD)	2.9 (3.3)	3.2 (3.8)	0.41	3.0 (3.5)	3.3 (4.5)	2.8 (3.1)	3.1 (3.6)	0.42
DASS Anxiety, mean (SD)	3.4 (3.3)	3.9 (3.6)	0.06	3.5 (3.4)	3.9 (3.5)	3.3 (3.1)	3.8 (3.7)	0.49
DASS Stress, mean (SD)	5.4 (4.0)	5.6 (4.5)	0.43	5.3 (4.0)	6.0 (4.8)	5.4 (3.9)	5.3 (4.3)	0.77
DASS Depression, >85th percentile score	15.4	19.8	0.14	17.3	18.5	13.3	21.0	0.23
DASS Anxiety, >85th percentile score	39.8	48.0	0.04	40.8	49.1	38.8	47.1	0.64
DASS Stress, >85th percentile score	19.6	19.4	0.95	19.2	22.2	20.0	16.8	0.83
Education status			0.56					0.43
Did not complete high school	23.8	27.7		21.3	33.7	26.5	22.3	-
Completed high school / vocational training	65.1	62.6		67.0	58.7	63.2	66.0	-
Completed a university degree	11.0	9.7		11.7	7.6	10.3	11.7	-
Marital status			0.42					0.54
Single / not living with partner	26.1	29.1		29.0	26.9	22.9	31.1	-
Married / living with partner	72.3	68.3		69.4	70.4	75.4	66.4	-
Separated / divorced	1.6	2.6		1.6	2.8	1.7	3.5	-
Currently unemployed	62.8	73.6	0.005	62.8	73.2	62.9	74.0	0.97

Family income from benefit or pension	41.8	44.9	0.44	42.4	47.2	41.3	42.9	0.26
Ever had a drug problem	12.6	21.7	0.002	12.2	18.5	13.0	24.6	0.78
Experienced domestic violence in past year	10.6	14.6	0.13	10.7	15.9	10.6	13.5	0.97
Quality of life: AQoL	0.6 (0.2)	0.6 (0.2)	0.53	0.6 (0.2)	0.6 (0.2)	0.6 (0.2)	0.6 (0.2)	0.85
Life satisfaction: Personal Wellbeing Index	58.6 (10.6)	58.7 (11.7)	0.87	59.2 (10.6)	59.1 (11.0)	58.4 (12.4)	57.9 (10.5)	0.17
Child								
First born	36.8	37.4	0.86	38.8	34.3	34.6	40.3	0.33
Female	51.7	44.3	0.075	57.3	46.9	45.8	41.9	0.01
Family								
SEIFA Index of Social Disadvantage Quintile			0.77					0.55
1 (most disadvantaged)	42.1	42.9		44.2	45.2	39.8	40.9	
2	7.7	9.1		6.8	9.6	8.7	8.7	
3	39.2	34.7		39.4	32.7	39.0	36.5	
4	8.1	9.6		6.4	11.5	10.0	7.8	
5 (least disadvantaged)	2.9	3.7		3.2	1.0	2.6	6.1	
Language other than English	7.2	11.7	0.045	6.8	10.3	7.6	13.0	0.71

206   [a] p-value for Chi square tests (categorical measures) and t tests (continuous measures) comparing those lost to those retained for the combined cohort.

207   [b] p-value for Chi square tests (categorical measures) and t tests (continuous measures) comparing those retained in the intervention and usual care groups.

208   All values are percentages, except where otherwise stated.

209   DASS= Depression, Anxiety, Stress Scale (Higher scores indicate worse health); SD=Standard Deviation; SEIFA=Socioeconomic Indexes for Areas Index of
210   Relative Disadvantage.

211   Range of Total N = 696-722, Intervention N =351-363, Control N= 345-359 due to missing data

212   Percentages may not add up to 100 due to rounding

213   **Health service use and cost**

214   Compared with usual care, the NHV program was associated with total increased costs over

215   three years of A$7829 (95% CI 4157; 11501) per family (Table 3). This largely reflects the

216   increased cost of nurse visits (primary health services category), due to increased number of

217   visits received (see Supplementary Table 2) and increased proportion of home visits. The mean

218   cost of nurse visits to child age 3 years summed to A$6772 in the intervention group and A$966

219   in the control group. Combined with social care practitioner visits and additional intervention

220   costs, service costs were A$9415 in right@home compared to A$2162 in usual care, i.e. an

221   additional cost of A$7254. As the intervention was delivered more intensively in the first year

222   of child's life, the extra costs are largely accrued in the first year.

223   Other health service use varied, with no clear patterns across groups and no statistical evidence

224   of differences at the aggregate level when combining all categories (except the above-

225   mentioned primary health services) in any year or combining any category over three years.

226   However, in the first year, the intervention group had higher use of hospital clinics and

227   admissions than the usual care group. At the disaggregated level (Supplementary Table 2), we

228   can see that this is driven by a higher number of visits by both mothers and babies to hospital

229   outpatient clinics, and higher emergency department visits in the child's first year, which is

230   reversed in the second year.

231 **Table 3: Health service use and intervention costs (complete case analysis for discounted costs)**

All costs in A$ 2016/17	right@home n=363		usual care n=359		Mean difference	p value	95% CI
	N	Cost (mean (SD))	N	Cost (mean (SD))			
Hospital Clinics							
Year 1	317	2039.22 (2359.38)	304	1763.3 (1625.2)	275.93	0.046	-45; 596
Year 2	251	1026.20 (1639.31)	226	1164.8 (2278.5)	-138.65	0.221	-493; 216
Year 3	198	1022.64 (2054.50)	191	1046.3 (1842.1)	-23.64	0.453	-413; 365
Hospital Admissions							
Year 1	336	6003.54 (29573.97)	330	3375.4 (11250.9)	2628.18	0.066	-788; 6044
Year 2	309	2680.74 (8428.60)	290	2157.9 (5498.2)	522.87	0.186	-627; 1673
Year 3	263	2294.75 (7173.01)	247	2658.4 (7729.9)	-363.60	0.291	-1660; 933
Primary Health Services (includes NHV of the intervention)							
Year 1	303	6987.26 (2727.84)	317	2687.9 (1637.6)	4299.33	0.000	3946; 4652
Year 2	292	3270.64 (1906.34)	306	1438.2 (1304.9)	1832.45	0.000	1571; 2094
Year 3	247	1077.48 (1367.65)	230	936.3 (1014.9)	141.14	0.102	-77; 359
Total Health Service cost							
Year 1	281	13144.14 (20147.19)	280	7861.1 (12864.8)	5283.05	0.000	2479; 8088
Year 2	219	6564.58 (9339.43)	212	4922.1 (7592.5)	1642.43	0.023	28; 3257

All costs in A$ 2016/17	right@home n=363		usual care n=359		Mean difference	p value	95% CI
	N	Cost (mean (SD))	N	Cost (mean (SD))			
Year 3	189	3967.05 (6981.44)	179	4275.2 (7935.3)	-308.15	0.346	-1838; 1223
Additional intervention costs [a]							
Year 1	363	826.29 (0.00)	359	347.5 (0.0)	478.77	-	-
Year 2	363	382.15 (0.00)	359	347.5 (0.0)	34.63	-	-
Total cost							
Year 1	281	13970.43 (20147.0)	280	8208.6 (12864.8)	5761.82	0.000	2957; 8566
Year 2	219	6928.53 (9339.43)	212	5253.1 (7592.5)	1675.41	0.021	61; 3290
Year 3	189	3967.05 (6981.44)	179	4275.2 (7935.3)	-308.15	0.346	-1838;1222
Over 3 years	121	22766.04 (15785.79)	119	14937.2 (12922.6)	7828.82	0.000	4157;11501

232 *Unadjusted mean costs, [a] Training/material/supervision costs at the nurse level, in addition to the intervention costs included in primary health
233 services.

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234 **Health outcomes and cost-consequences analysis**

235 Table 4 shows that, compared with the usual care group, women in the intervention group

236 reported improved mental health (Total DASS score ES=0.18, 95% CI: 0.00 to 0.36) at child

237 age 3 years. There was little evidence for group differences in child outcomes. The difficulty

238 in comparing a substantial cost difference to a combination of effect sizes across different

239 outcome measures in cost-consequences analysis (Table 4) is a reason to progress to the pre-

240 specified secondary cost-utility analysis.

241   **Table 4: Cost-consequences analysis of right@home at 3 years against all health-related outcomes (using multiple imputation).**

Outcome	Descriptive statistics		Comparative statistic: Intervention compared to Control				
	right@home (I)	usual care (C)	Adjusted			Effect Size	95% CI
	Mean	Mean	Mean Difference	95% CI	p		
Parent Care							
Warm parenting	4.63	4.64	-0.02	-0.13 ; 0.08	0.622	-0.05	-0.26 ; 0.17
Hostile parenting (reverse)	7.94	7.76	0.18	-0.16 ; 0.52	0.259	0.10	-0.09 ; 0.29
Parenting Efficacy	8.07	7.91	0.16	-0.15 ; 0.48	0.284	0.10	-0.09 ; 0.28
Child-parent conflict (reverse)	22.25	21.24	0.98	-0.34 ; 2.30	0.134	0.14	-0.05 ; 0.33
Child-parent closeness	32.28	32.33	-0.10	-0.73 ; 0.53	0.739	-0.03	-0.21 ; 0.15
Maternal Health							
Mental health : DASS - Overall (Reverse scored)	53.79	51.74	1.85	0.05 ; 3.65	0.045	0.18	0.00 ; 0.36
Quality of life : AQoL	0.72	0.68	0.04	-0.01 ; 0.08	0.095	0.18	-0.04 ; 0.39
Stress **:** Maternal hair cortisol (pg/mg, reverse log transformed*)	1.49	1.58	0.10	-0.12 ; 0.32	0.359	0.10	-0.12 ; 0.31
Life satisfaction**:**Personal Wellbeing Index	58.95	56.23	2.37	-0.59 ; 5.34	0.103	0.17	-0.04 ; 0.37
Child Language							
Receptive and expressive language : CELF Sentence Structure	9.04	8.74	0.12	-0.55 ; 0.80	0.699	0.04	-0.17 ; 0.25

Receptive and expressive language **:** CELF Word Structure	7.94	7.63	0.15	-0.60 ; 0.89	0.682	0.04	-0.18 ; 0.26
Receptive and expressive language **:** CELF Expressive Vocabulary	8.31	8.00	0.19	-0.46 ; 0.84	0.532	0.06	-0.14 ; 0.26
Receptive and expressive language **:** CELF Core Language	90.75	89.01	0.83	-2.60 ; 4.27	0.609	0.05	-0.16 ; 0.26
Child Health							
Mental health and behaviour **:** SDQ Externalizing problems (reverse)	11.62	11.35	0.11	-0.78 ; 1.00	0.792	0.02	-0.17 ; 0.22
Mental health and behaviour **:** SDQ Internalizing problems (reverse)	16.03	15.85	0.14	-0.38 ; 0.66	0.580	0.04	-0.13 ; 0.22
Mental health and behaviour **:** SDQ Total behavior problems (reverse)	27.66	27.19	0.25	-0.87 ; 1.36	0.639	0.04	-0.14 ; 0.22
Quality of life **:** PedsQL Physical wellbeing	90.99	89.42	1.51	-1.17 ; 4.18	0.244	0.12	-0.09 ; 0.32
Quality of life **:** PedsQL Socioemotional wellbeing	85.33	83.53	1.67	-1.20 ; 4.54	0.235	0.12	-0.08 ; 0.31
Stress**:** Child hair cortisol (pg/mg, reverse log transformed*)	1.93	1.69	-0.24	-0.54 ; 0.06	0.106	-0.21	-0.47 ; 0.06
Economic							
Total costs A$	26,192	18,507	7685	7006; 8364	0.000	0.28	0.26; 0.31

242   Adjusted for baseline characteristics of: child sex, family's Socio-Economic Index for Areas (SEIFA) score, maternal education, maternal age at child's birth,

243   parity, antenatal risk, maternal self-efficacy and maternal mental health; plus child age at the 3-year assessment.

244   CI= Confidence Interval; CPRS = Child Parent Relationship Scale; DASS= Depression, Anxiety, Stress Scale; AQoL=Assessment of Quality of Life;

245   PedsQL= Pediatric Quality of Life Inventory; SDQ = Strengths and Difficulties Questionnaire

246   * Natural lo

247   There was statistically significantly improved maternal QALYs in the third year (Figure 2,

248   Table 5) but no overall significant difference over the whole 3 year period (Table 5).

249   **Table 5: Quality Adjusted Life Years (using multiple imputation)**

Outcome	Descriptive statistics QALYs		Comparative statistic: Intervention compared to Control				
	right@home (I)	usual care (C)	Adjusted			Effect Size	95% CI
	Mean	Mean	Mean Difference	95% CI	p		
Year 1	0.68 (0.16)	0.68 (0.16)	0.00	-0.00; 0.00	0.88	0.00	-0.02; 0.03
Year 2	0.69 (0.17)	0.69 (0.15)	0.00	-0.01; 0.01	0.12	-0.02	-0.04; 0.01
Year 3	0.65 (0.16)	0.64 (0.16)	0.01	-0.00; 0.01	0.00	0.05	0.03; 0.08
Over 3 years	2.02 (0.46)	2.01 (0.43)	0.01	-0.01; 0.02	0.36	0.01	-0.01; 0.04

250   *Adjusted for baseline characteristics of: quality of life, child sex, family's Socio-Economic Index for
251   Areas (SEIFA) score, maternal education, maternal age at child's birth, parity, antenatal risk, maternal
252   self-efficacy and maternal mental health; plus child age at the 3-year assessment

253   **Incremental Cost Effectiveness Ratio (ICER)**

254   The ICER of the NHV intervention compared to usual care was estimated to be $195,675 per

255   QALY gained using complete case analysis and $258,476 per QALY using multiply imputed

256   data taking account of missing data and loss to follow up. While all simulated cases

257   demonstrated increased costs associated with the intervention, effects were far less certain

258   (Figure 3). The cost effectiveness acceptability curve supports this, showing less than 20%

259   probability of cost effectiveness at a willingness-to-pay of $50,000 per QALY at 3 years.

260   **DISCUSSION**

261   The economic evaluation confirms that the provision of a higher intensity and home-based

262   nursing service in the right@home NHV program resulted in substantially increased healthcare

263   costs. We found limited group differences in all other health resource use and associated costs

264   up to child age 3 years. There was evidence of benefits to maternal mental health at child age

265   3 years, which combined with benefits to parenting at 2 years, translate into marginal maternal

266   QALY gains. At 12 months post-intervention, the intervention is not cost-effective.

267   The implementation costs of the right@home NHV program (A$7254) are similar to the range

268   of costs reported for NHV programs in other high-income countries. The Nurse Family

269   Partnership (NFP) estimated program costs of US$12,265[12] (A$17,503 in 2016/17 prices),[37 38]

270   the Building Blocks program (based on NFP) in England estimated additional costs of

271   GBP1,812 (A$4166)[4] and an earlier NHV program in England estimated additional costs of

272   GBP3,246 (A$9523)[39]. Two previous studies have assessed the impact of NHV programs on

273   QALYs. A 2011 economic evaluation of the Denver NFP to child age 9 years estimated 0.15

274   additional QALYs accrued to mother/child dyad over the 9-year period, largely from reduced

275   maternal depression.[9 40] An economic evaluation of the UK's family nurse partnership program

276   (Building Blocks) to child age 2 found 0.0036 additional QALYs per mother (95% CI: −0.017;

277   0.025).[4] In comparison, we find 0.01 additional QALYs per mother (95% CI: -0.01; 0.02) to

278   child age 3.

279   Economic evaluations of NHV programs assess whether the benefits generated by the program

280   represent value for money in comparison to the program costs. In the US healthcare system,

281   the NFP program has generated increasing health and economic benefits over time. Cost-

282   savings to government are estimated to outweigh upfront program costs between child age 9

283   and 30, depending on the effectiveness estimates used in analysis.[9 12 40] This means that

284   decision-making on NHV programs should consider costs and outcomes over a sufficiently

285   long time period, despite the inherent conflict between policy/decision timing and availability

286   of follow-up data. While the right@home NHV program is not cost-effective at 12 months

287   post-intervention, cost-effectiveness may improve over time if benefits continue to accrue to

288   mothers and/or children; ongoing follow-up of right@home will collect cost and outcome data

289   up to school age.

290 Applications of NHV programs in high-income countries have sought to address whether the

291 positive results in the US context can be replicated when NHV is added to an existing universal

292 healthcare system. In Australia, for example, 'usual care' represents a higher level of CFH

293 service delivery compared to the US context. The concept that NHV offers a small change from

294 existing service delivery is posited as an explanation for lack of positive outcomes for trials of

295 NHV in England.[4] For the right@home NHV program at child age 3 years, the economic

296 evaluation demonstrates increased costs and only limited benefits; however, these findings may

297 change at older ages in line with previous studies and the general early intervention literature

298 where benefits emerge as children age and enter adulthood with benefit lags up to 30 years post

299 intervention.[12]

300 Broader health service use costs were slightly higher for right@home compared to usual care

301 in the first year, with some reversal in later years. The increased professional contact of the

302 NHV program may directly identify health concerns, or improve predisposing individual

303 factors like knowledge and awareness to prompt women to use healthcare services more

304 often.[41] This should be interpreted as a positive outcome, as increasing women's connection to

305 and use of appropriate services is an objective of this and other NHV programs. Although any

306 increased use of services will have additional costs to government providers, if this is filling or

307 narrowing a gap in appropriate care, it may well lead to concomitant or future improvements

308 in health outcomes.

309 Strengths of the trial include the rigorous design and outcome assessments completed by

310 researchers who were blinded to intervention status. The research retained a high proportion of

311 study participants in both groups (69% over a 4-year study duration), despite the substantial

312 adversity experienced by participants. For context, by the 2-year follow-up, the Building

313 Blocks study retained 71% of their cohort for self-reported outcomes[42] and other European

314 studies retained less than 50%.[6 43] Given the large, multi-site design of the trial, high participant

315   retention and use of multiple imputation to address missing data arising from participant

316   attrition, we believe our findings should generalize to pregnant women experiencing adversity,

317   in similar healthcare systems.

318   There are several limitations. Maternal report was used to measure broader health service use

319   and quality of life outcomes and responses may be subject to perception influenced by

320   participation in the intervention. There is a possibility of recall bias when answering service

321   use questions over a 6 month recall period, although any bias should be distributed equally

322   across trial arms.[44] Quality of life data for children were not included in QALY measures.

323   Service use data excludes the use and costs of other government services such as child

324   protection and associated legal services, as these data were not collected in this period of the

325   trial. Women were more likely to be lost to follow up if they were younger, unemployed or

326   reported higher antenatal risk; despite multiple imputation of outcome data, the cost and cost-

327   effectiveness results may not fully represent these women. In addition, trial exclusion criteria

328   meant that findings may not generalize to non-English speaking women or women with severe

329   intellectual disability.

CONCLUSION

The embedding of a NHV program into the Australian universal health system demonstrates benefits to parenting and the home environment when the intervention ends at child age 2 years,[18] and improves maternal mental health 12 months later. As expected, implementing a NHV program requires substantial up-front investment. Economic evaluation based on the outcomes evident by child age 3 years shows a lack of cost-effectiveness, due to a lack of short term cost-savings and only marginal maternal QALY gain. Ongoing follow-up will assess whether continued accrual of benefits to mothers and children outweigh the increased up-front costs as shown in other NHV programs over a longer period of time.

ACKNOWLEDGEMENTS

Conflict of Interest Disclosures

The "right@home" sustained nurse home visiting trial is a research collaboration between the Australian Research Alliance for Children and Youth (ARACY); the Translational Research and Social Innovation (TReSI) Group at Western Sydney University; and the Centre for Community Child Health (CCCH), which is a department of The Royal Children's Hospital and a research group of Murdoch Children's Research Institute. Ownership of the right@home implementation and support licence, which is purchased by Australian state governments for roll out, is shared between institutes.

Data Sharing Statement

We invite researchers to request access to the data from the Melbourne Children's Campus LifeCourse institutional data access platform (https://lifecourse.melbournechildrens.com/data-access/) or the governing Royal Children's Hospital HREC (https://www.rch.org.au/ethics/).

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521   **Figures**

522   Figure 1: Participant Flow Chart
523   Figure 2: QALYs over 3 years, using imputed data
524   Figure 3: Cost-effectiveness plane and Cost-effectiveness acceptability curve

Figures

Figure 1: Participant Flow Chart


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Screened pregnant women          Excluded
N = 5586                         - Fewer than 2 risk factors (n=3411)
                                 - Outside area (n=397)
                                 - More than 36 weeks gestation (n=163)
                                 - Due date after study end (n=136)
                                 - Did not comprehend recruitment (n=13)
                                 - Part of CU@Home (n=13)
                                 - No mode of contact (n=8)
                                 - No reason recorded (n=18)

Eligible                         Declined (n=346)
n = 1427, 25.5%                  Excluded
                                 - Unable to contact (n=343)
                                 - Critical event (n=2)

Enrolled                         Declined (n=2)
n = 736, 51.6%                   Excluded
                                 - Unable to contact (n=5)
                                 - Part of CU@Home (n=4)
                                 - Did not comprehend recruitment (n=1)

Randomized                       Excluded
n = 724, 98.4%                   - Randomized in error (outside area) (n=2)

Allocated
n = 722
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Usual Care Group
n = 359

Program Group
n = 363

1 year follow-up completed, n = 311 (87%)
2 year follow-up completed, n = 290 (81%)

1 year follow-up completed, n = 326 (90%)
2 year follow-up completed, n = 306 (84%)

Consented to extended follow-up
n = 270 (75%)

Consented to extended follow-up
n = 288 (79%)

3 year follow-up completed, n = 240 (89%)

3 year follow-up completed, n = 255 (89%)

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Figure 2: QALYs over 3 years, using imputed data

Quality Adjusted Life Years (QALYs)
By Study group

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3 **Figure 3: Cost-effectiveness plane and Cost-effectiveness acceptability curve**
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Supplementary Tables

Supplementary Table 1: Description of maternal and child outcome measures collected at 3 years

Item	Description
Parent care	
Warm parenting	6-item measure assessing parental warmth. Items rated on a 5-point scale ("never/almost never" to "always/almost always"), drawn from LSAC.[1]
Hostile parenting	5-item measure assessing parental hostility. Items rated on a 10-point scale ("not at all" to "all of the time"), drawn from LSAC.[1]
Parenting efficacy	4-item Parenting Efficacy scale. Items rated on a 10-point scale ("Not at all how I feel" to "Exactly how I feel") drawn from LSAC, and a single 5-point Parenting Efficacy item assessing mother's feelings about herself as a parent ("Not very good" to "Very good") drawn from LSAC.[1]
Child-parent closeness and conflict	15-item short-form of the Child-Parent Relationship Scale (CPRS)[2, 3]. Self-report measure assessing parents' views of their relationship with their child, rated on a 5-point scale ("definitely does not apply" to "definitely applies"). Two subscale: Conflict (higher scores indicate greater conflict) and Closeness (higher scores indicate greater closeness).
Maternal health	
Maternal mental health	Depression, Anxiety and Stress Scales.[4] 21-item measure, rated on a 4-point scale ("not at all" to "most of the time") assessing the negative emotional states of depression, anxiety and tension/stress. Three subscales (7 items each): Depression, Anxiety and Stress used to derive a single Total DASS score.
Quality of life	Assessment of Quality of Life – 8D (AQoL-8D).[5, 6] 35-item measure assessing health related quality of life. Provides a single overall utility-based quality of life measure.
Stress	Hair cortisol as a measure of maternal stress response over the past 3 months. The hair sample is a minimum length of 3cm, with the total density of the sample equating to approximately half a pencil's width (30-50mg). Cortisol concentrations are log transformed and reported as a continuous measure, reversed so that higher scores indicate lower long-term stress.[7]
Life satisfaction	Personal Wellbeing Index (International Wellbeing Group, 2013).[8] Single item assessing general life satisfaction, and 8 items assessing satisfaction with specific life domains, rated using a 10-point scale ("no satisfaction at all" to "completely satisfied").
Child language	
Receptive and expressive language	Clinical Evaluation of Language Fundamentals Preschool Second Edition (CELF-P2) Australian Standardised Edition.[9] Direct assessment of child expressive and receptive language skills across three subscales: Sentence Structure, Word Structure and

Item	Description
	Expressive Vocabulary, and a combined Core Language score. Subtest scores reported as age-specific normative scaled scores (m=10, SD=3) and Core Language score reported as standard score (m=100, SD=15).
Child health	
Mental health and behaviour	25-item Strengths and Difficulties Questionnaire (4–10-year-old version),[10, 11] assessing Total difficulties and two domain scores of Internalizing difficulties (combined score of emotional and peer problems) and Externalizing difficulties (combined score of behaviour and attention/hyperactivity). Items rated on a 3-point scale ("not true"/"somewhat true"/"certainly true"). Reversed so that higher mean scores indicate fewer problems.
Quality of life	21-item Pediatric Quality of Life Inventory (PedsQl) [12] assessing child's general wellbeing. Two subscales used (Physical functioning and Socioemotional Functioning). Items rated on a 5-point scale ("never"/"almost never"/"sometimes"/"often"/"always") Higher scores indicate better wellbeing.
Child stress	Hair cortisol, see description for maternal stress above.

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Supplementary Table 2: Health service use and cost per participant over three years (complete case analysis)

Health Service	right@home (I)					usual care(c)					MD and p value		
	n	MV	SD	MC A$	SD	n	MV	SD	MC A$	SD	MV	MC A$	p value
Emergency Department: Baby													
Year 1	345	1.1	1.8	411.4	693.8	339	0.9	1.3	332.2	509.2	0.2	79.2	0.05
Year 2	324	0.8	1.4	282.7	514.8	310	0.7	1.4	272.7	520.1	0.0	10.1	0.40
Year 3	266	0.7	1.6	260.0	558.0	252	0.6	1.4	202.7	499.4	0.2	57.3	0.11
Emergency Department: Mother													
Year 1	343	0.6	1.6	246.2	609.1	338	0.4	1.0	167.7	383.9	0.2	78.5	0.02
Year 2	324	0.4	0.9	160.9	320.7	314	0.6	1.7	226.5	639.4	-0.2	-65.6	0.05
Year 3	266	0.5	1.9	158.7	670.0	254	0.6	1.7	206.6	589.0	-0.1	-48.0	0.19
Hospital outpatient clinics: Baby													
Year 1	341	0.8	2.3	236.6	654.0	332	0.9	3.0	256.9	869.9	-0.1	-20.3	0.37
Year 2	322	0.7	2.6	186.9	707.4	309	0.6	2.4	162.9	641.5	0.1	24.0	0.33
Year 3	267	0.3	1.1	88.8	281.2	251	0.3	0.9	78.9	241.5	0.0	9.9	0.33
Hospital outpatient clinics: Mother													
Year 1	344	1.3	5.6	370.7	1599.3	338	0.8	2.7	222.6	769.0	0.5	148.1	0.06
Year 2	323	1.7	4.4	471.6	1200.0	310	2.1	5.9	564.6	1611.3	-0.3	-93.0	0.21
Year 3	259	2.2	6.1	571.2	1596.7	240	2.6	6.9	671.8	1804.5	-0.4	-100.6	0.26
Hospital Postnatal clinic													
Year 1	340	0.0	0.2	3.4	19.8	336	0.1	0.3	5.6	32.1	0.0	-2.1	0.15

Health Service	right@home (I)					usual care(c)					MD and p value		
	n	MV	SD	MC A$	SD	n	MV	SD	MC A$	SD	MV	MC A$	p value
Hospital Breastfeeding clinic													
Year 1	339	0.1	0.4	16.7	96.3	337	0.0	0.3	9.4	75.5	0.0	7.3	0.14
Hospital other outpatient clinics: Baby													
Year 1	342	0.3	1.5	71.4	441.5	333	0.1	0.4	32.8	119.7	0.1	38.6	0.06
Year 2	275	0.0	0.1	3.0	36.8	250	0.0	0.4	9.8	96.0	0.0	-6.9	0.14
Year 3	222	0.0	0.3	12.7	87.5	218	0.0	0.1	3.2	33.6	0.0	9.4	0.07
Hospital other outpatient clinics: Mother													
Year 1	339	0.2	2.3	59.3	663.4	337	0.1	0.4	20.5	99.4	0.1	38.9	0.14
Year 2	276	0.1	0.9	25.8	233.0	258	0.3	2.6	68.9	697.3	-0.2	-43.1	0.17
Year 3	231	0.0	0.2	12.2	79.3	222	0.2	1.6	53.8	574.2	-0.1	-41.6	0.14
Hospital admissions: Baby													
Year 1	338	2.1	13.4	4282.3	27582.0	332	0.9	3.9	1796.0	7987.4	1.2	2486.4	0.06
Year 2	316	0.4	1.9	813.4	3789.6	305	0.3	1.5	595.0	2915.9	0.1	218.4	0.20
Year 3	265	0.4	2.6	758.4	4787.2	249	0.2	0.9	317.9	1578.9	0.3	440.6	0.07
Hospital admissions: Mother													
Year 1	343	0.8	4.5	1668.4	9180.3	339	0.8	3.9	1551.2	7960.3	0.1	117.2	0.43
Year 2	316	1.0	4.0	1992.2	7906.4	297	0.8	2.3	1499.9	4563.9	0.2	492.2	0.18
Year 3	267	0.9	2.9	1525.9	5387.3	253	1.7	7.4	3037.6	13855.3	-0.8	-1511.7	0.05

Health Service	right@home (I)					usual care(c)					MD and p value		
	n	MV	SD	MC A$	SD	n	MV	SD	MC A$	SD	MV	MC A$	p value
Breastfeeding consultant													
Year 1	336	0.1	0.3	12.1	64.3	337	0.1	0.4	18.1	91.5	0.0	-6.0	0.16
Lactation consultant													
Year 1	336	0.4	1.3	84.9	302.2	329	0.3	1.1	66.1	251.9	0.1	18.8	0.19
Parent center day													
Year 1	344	0.2	0.9	65.1	350.9	339	0.2	0.9	64.9	342.4	0.0	0.1	0.50
Year 2	325	0.2	3.0	0.0	0.2	312	0.1	0.7	0.0	0.2	0.1	0.0	0.20
Year 3	260	0.1	1.6	0.0	0.1	242	0.0	0.1	0.0	0.1	0.1	0.0	0.18
Parent center night													
Year 1	341	0.1	1.6	94.8	1192.3	339	0.1	0.7	56.3	514.6	0.1	38.4	0.29
Year 2	325	0.0	0.8	0.0	0.1	311	0.0	0.0	0.0	0.1	0.0	0.0	0.16
Year 3	260	0.0	0.0	0.0	0.0	242	0.0	0.1	0.0	0.1	0.0	0.0	0.85
Hospital Midwife													
Year 1	340	1.8	2.5	668.2	937.7	334	2.0	1.5	750.5	555.3	-0.2	-82.4	0.08
Child & family health nurse													
Year 1	343	15.6	6.5	5154.0	2137.8	340	7.0	4.0	774.9	437.2	8.6	4379.1	0.00
Year 2	320	4.8	2.9	1496.8	911.3	308	1.4	1.6	148.6	170.5	3.3	1348.2	0.00
Year 3	261	0.4	0.8	121.6	231.1	247	0.4	0.7	42.4	68.6	0.0	79.2	0.00
Social worker/care practitioner											0.0	0.0	0.00

Health Service	right@home (I)					usual care(c)					MD and p value		
	n	MV	SD	MC A$	SD	n	MV	SD	MC A$	SD	MV	MC A$	p value
Year 1	343	2.4	6.4	179.6	484.9	336	1.0	4.0	78.7	300.6	1.3	100.9	0.00
Year 2	325	1.5	6.4	108.4	459.3	314	0.8	3.8	59.4	271.0	0.7	49.0	0.05
Year 3	269	1.2	4.8	83.7	328.2	253	0.4	2.3	29.1	157.9	0.8	54.6	0.01
Helpline													
Year 1	343	0.8	1.4	47.8	86.2	341	1.1	2.0	64.6	121.8	-0.3	-16.8	0.02
Year 2	325	0.7	3.2	40.1	183.3	313	0.5	1.2	30.5	67.7	0.2	9.6	0.19
Year 3	269	0.6	1.5	30.8	81.8	255	0.4	0.9	21.3	50.3	0.2	9.4	0.06
General practice													
Year 1	345	10.3	10.3	380.0	381.4	341	10.1	8.8	372.3	325.2	0.2	7.6	0.39
Year 2	325	9.0	8.6	316.9	303.3	314	10.0	9.3	352.8	327.7	-1.0	-35.9	0.08
Year 3	269	9.5	9.8	318.9	329.2	255	9.8	10.2	327.6	341.0	-0.3	-8.7	0.38
Psychologist													
Year 1	341	1.2	3.6	61.4	187.1	338	1.1	4.5	57.4	232.3	0.1	4.1	0.40
Year 2	324	0.8	2.8	40.1	140.0	313	1.0	3.3	50.4	165.2	-0.2	-10.3	0.20
Year 3	268	1.3	3.6	59.2	170.4	255	1.5	4.3	70.1	202.5	-0.2	-10.8	0.25
Psychiatrist													
Year 1	343	0.5	2.2	102.6	496.5	336	0.2	1.8	47.4	386.3	0.3	55.2	0.05
Year 2	325	0.2	1.5	50.6	319.7	314	0.2	1.4	39.6	287.4	0.1	11.0	0.32
Year 3	269	0.2	1.7	32.1	335.4	254	0.2	1.5	41.9	304.4	-0.1	-9.8	0.36

Health Service	right@home (I)					usual care(c)					MD and p value		
	n	MV	SD	MC A$	SD	n	MV	SD	MC A$	SD	MV	MC A$	p value
Pediatrician													
Year 1	340	0.6	1.5	140.6	335.4	332	0.7	1.6	156.8	364.1	-0.1	-16.2	0.27
Year 2	322	0.3	0.8	58.4	168.6	313	0.4	1.7	75.1	353.8	-0.1	-16.7	0.22
Year 3	269	0.2	0.7	47.7	151.4	253	0.4	1.3	74.8	272.8	-0.1	-27.1	0.08
Obstetrician/Gynecologist													
Year 1	339	0.4	1.0	96.6	230.6	335	0.5	1.6	104.5	352.7	0.0	-7.9	0.37
Year 2	325	0.4	1.1	79.6	235.0	312	0.6	2.1	124.6	448.4	-0.2	-45.1	0.06
Year 3	265	0.6	1.9	117.5	395.4	252	0.6	2.0	114.7	402.5	0.0	2.8	0.47
Physiotherapy													
Year 1	343	0.9	3.1	48.3	160.8	337	1.0	3.2	54.0	164.5	-0.1	-5.7	0.33
Year 2	325	1.1	4.4	53.1	216.4	313	0.9	3.9	46.4	194.8	0.1	6.7	0.34
Year 3	268	1.3	5.8	60.1	275.6	255	0.7	4.3	33.1	203.0	0.6	27.0	0.10
Osteo/chiro practitioner													
Year 1	342	1.9	7.1	99.0	373.1	337	1.4	5.6	73.6	290.9	0.5	25.4	0.16
Year 2	325	1.3	4.5	65.1	224.0	314	1.4	6.3	67.0	313.8	0.0	-2.0	0.46
Year 3	269	1.6	5.2	76.6	245.5	255	1.5	5.6	70.3	264.0	0.1	6.4	0.39
Dentist													
Year 1	344	0.7	1.6	49.2	105.4	337	0.7	1.7	46.1	114.6	0.1	3.1	0.36
Year 2	325	1.1	2.0	70.2	128.6	314	1.0	1.8	62.0	112.4	0.1	8.2	0.20

Health Service	right@home (I)					usual care(c)					MD and p value		
	n	MV	SD	MC A$	SD	n	MV	SD	MC A$	SD	MV	MC A$	p value
Year 3	269	1.4	2.4	85.9	145.7	254	1.4	2.4	82.9	141.7	0.1	3.0	0.41
Drug and Alcohol clinic													
Year 2	325	0.0	0.4	6.2	73.1	314	0.1	1.4	24.0	225.6	-0.1	-17.8	0.09
Year 3	269	0.0	0.3	7.1	49.2	254	0.3	2.6	42.1	420.0	-0.2	-35.0	0.09

*MV: Mean Visits, MC: Mean Costs, MD: Mean Difference

CHEERS Checklist
Items to include when reporting economic evaluations of health interventions

The **ISPOR CHEERS Task Force Report**, *Consolidated Health Economic Evaluation Reporting Standards (CHEERS)—Explanation and Elaboration: A Report of the ISPOR Health Economic Evaluations Publication Guidelines Good Reporting Practices Task Force,* provides examples and further discussion of the 24-item CHEERS Checklist and the CHEERS Statement.   It may be accessed via the *Value in Health* or via the ISPOR Health Economic Evaluation Publication Guidelines – CHEERS: Good Reporting Practices webpage: http://www.ispor.org/TaskForces/EconomicPubGuidelines.asp

Section/item	Item No	Recommendation	Reported on page No/ line No
Title and abstract			
Title	1	Identify the study as an economic evaluation or use more specific terms such as "cost-effectiveness analysis", and describe the interventions compared.	page 1
Abstract	2	Provide a structured summary of objectives, perspective, setting, methods (including study design and inputs), results (including base case and uncertainty analyses), and conclusions.	page 2
Introduction			
Background and objectives	3	Provide an explicit statement of the broader context for the study. Present the study question and its relevance for health policy or practice decisions.	page 4 & 5
Methods			
Target population and subgroups	4	Describe characteristics of the base case population and subgroups analysed, including why they were chosen.	page 6 para 2
Setting and location	5	State relevant aspects of the system(s) in which the decision(s) need(s) to be made.	page 7
Study perspective	6	Describe the perspective of the study and relate this to the costs being evaluated.	page 5 para 3
Comparators	7	Describe the interventions or strategies being compared and state why they were chosen.	page 4 para 3 & page 5 para1
Time horizon	8	State the time horizon(s) over which costs and consequences are being evaluated and say why appropriate.	page 7 para 2
Discount rate	9	Report the choice of discount rate(s) used for costs and outcomes and say why appropriate.	page 9 para 1
Choice of health outcomes	10	Describe what outcomes were used as the measure(s) of benefit in the evaluation and their relevance for the type of analysis performed.	page 7 para 1
Measurement of effectiveness	11a	*Single study-based estimates:* Describe fully the design features of the single effectiveness study and why the single study was a sufficient source of clinical effectiveness data.	page 6 & 10

		11b	*Synthesis-based estimates:* Describe fully the methods used for identification of included studies and synthesis of clinical effectiveness data.	not applicable
Measurement and valuation of preference based outcomes		12	If applicable, describe the population and methods used to elicit preferences for outcomes.	page 6
Estimating resources and costs		13a	*Single study-based economic evaluation:* Describe approaches used to estimate resource use associated with the alternative interventions. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs.	page 5 & 7
		13b	*Model-based economic evaluation:* Describe approaches and data sources used to estimate resource use associated with model health states. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs.	not applicable
Currency, price date, and conversion		14	Report the dates of the estimated resource quantities and unit costs. Describe methods for adjusting estimated unit costs to the year of reported costs if necessary. Describe methods for converting costs into a common currency base and the exchange rate.	page 7 para 2 & table 1
Choice of model		15	Describe and give reasons for the specific type of decision-analytical model used. Providing a figure to show model structure is strongly recommended.	page 5 & 6
Assumptions		16	Describe all structural or other assumptions underpinning the decision-analytical model.	page 8
Analytical methods		17	Describe all analytical methods supporting the evaluation. This could include methods for dealing with skewed, missing, or censored data; extrapolation methods; methods for pooling data; approaches to validate or make adjustments (such as half cycle corrections) to a model; and methods for handling population heterogeneity and uncertainty.	page 11
Results				
Study parameters		18	Report the values, ranges, references, and, if used, probability distributions for all parameters. Report reasons or sources for distributions used to represent uncertainty where appropriate. Providing a table to show the input values is strongly recommended.	table 3, 4 & 5
Incremental costs and outcomes		19	For each intervention, report mean values for the main categories of estimated costs and outcomes of interest, as well as mean differences between the comparator groups. If applicable, report incremental cost-effectiveness ratios.	table 4, table 5 & page 23, para 1
Characterising uncertainty		20a	*Single study-based economic evaluation:* Describe the effects of sampling uncertainty for the estimated incremental cost and incremental effectiveness parameters, together with the impact	page 23, para 1

		of methodological assumptions (such as discount rate, study perspective).	
	20b	*Model-based economic evaluation:* Describe the effects on the results of uncertainty for all input parameters, and uncertainty related to the structure of the model and assumptions.	not applicable
Characterising heterogeneity	21	If applicable, report differences in costs, outcomes, or cost-effectiveness that can be explained by variations between subgroups of patients with different baseline characteristics or other observed variability in effects that are not reducible by more information.	table 4 & table 5

Discussion

Study findings, limitations, generalisability, and current knowledge	22	Summarise key study findings and describe how they support the conclusions reached. Discuss limitations and the generalisability of the findings and how the findings fit with current knowledge.	page 23 - 26

Other

Source of funding	23	Describe how the study was funded and the role of the funder in the identification, design, conduct, and reporting of the analysis. Describe other non-monetary sources of support.	page 31, para 2
Conflicts of interest	24	Describe any potential for conflict of interest of study contributors in accordance with journal policy. In the absence of a journal policy, we recommend authors comply with International Committee of Medical Journal Editors recommendations.	page 31, para 3

For consistency, the CHEERS Statement checklist format is based on the format of the CONSORT statement checklist

The **ISPOR CHEERS Task Force Report** provides examples and further discussion of the 24-item CHEERS Checklist and the CHEERS Statement. It may be accessed via the *Value in Health* link or via the ISPOR Health Economic Evaluation Publication Guidelines – CHEERS: Good Reporting Practices webpage: http://www.ispor.org/TaskForces/EconomicPubGuidelines.asp

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