Nurse Home Visiting and Maternal Mental Health: 3-Year Follow-Up of a Randomized Trial

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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.

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Data Sharing Statement: Upon request to the corresponding author (sharon.goldfeld@rch.org.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.

Abbreviations: CFH - child and family health; DASS – Depression Anxiety and Stress Scales; NHV - nurse home visiting, RCT - randomized controlled trial; SEIFA-Socioeconomic Index for Areas.

Article Summary:

The right@home nurse home visiting trial, implemented within existing child and family health services, demonstrated benefits for maternal mental health and wellbeing at one-year post-intervention.

What's Known on This Subject:

Maternal mental health is a crucial aspect of optimal health for mothers and their children. Nurse home visiting (NHV) is an established model of healthcare delivery available in multiple countries but with mixed results in relation to maternal mental health.

What This Study Adds:

Benefits of the right@home NHV program were evident for maternal mental health and wellbeing at one-year post-intervention completion (child age 3 years). A NHV program that is designed for women experiencing adversity can lead to latent mental health benefits.

Contributors' Statement Page

Prof. Sharon Goldfeld, Dr. Anna Price, Prof. Harriet Hiscock and Prof Lynn Kemp conceptualized and implemented the study design, and contributed to the first draft and subsequent revisions of the manuscript.

Dr. Hannah Bryson implemented the study design, coordinated and supervised data collection, conducted the data cleaning and statistical analysis, and contributed to the first draft and subsequent revisions of the manuscript.

Dr. Fiona Mensah conceptualized and implemented the study design, provided statistical expertise in the trial design and conduct of the statistical analysis, and contributed to the first draft and subsequent revisions of the manuscript.

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Ms. Penelope Dakin and Ms. Diana Harris implemented the study design and on behalf of the sponsor ARACY, as the funding holder, and contributed to the first draft and subsequent revisions of the manuscript.

Ms Diana Harris implemented the study design, and 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.

ABSTRACT

Background: Poor mental health is recognized as one of the greatest global burdens of disease. Maternal mental health is crucial for the optimal health of mothers and their children. We examined the effects of an Australian Nurse Home Visiting (NHV) program (right@home), offered to pregnant women experiencing adversity, on maternal mental health and wellbeing at child age 3 years.

Methods: A randomized controlled trial (RCT) of NHV delivered via universal child and family health services (2013 to 2016). Pregnant women experiencing adversity (≥2 of 10 risk factors) were recruited from 10 antenatal clinics across two states. Intervention comprised 25 home visits until child age 2 years. Outcomes assessed 1-year post intervention completion were maternal self-report of mental health symptoms (Depression, Anxiety and Stress Scales: DASS) and positive aspects of mental health (personal wellbeing and self-efficacy).

Results: Of the 722 women enrolled in the RCT, 255/363 (70%) intervention and 240/359 (67%) control group women provided data at 3 years. Compared with controls, the intervention group reported better mental health (reverse DASS scores): effect sizes of 0.25 (depression, 95% confidence interval [CI]: 0.08 to 0.32), 0.20 (anxiety, 95% CI: 0.05 to 0.30), 0.17 (stress, 95% CI: 0.09 to 0.37) and 0.23 (total score, 95% CI: 0.12 to 0.38); 0.16 (95% CI 0.04 to 0.29) for personal well-being and odds ratio 1.60 (95% CI 1.19 to 2.16) for self-efficacy.

Conclusions: A NHV designed to support mothers experiencing adversity can lead to later maternal mental health benefits even after the program ends.

Trial registration number: ISRCTN89962120

INTRODUCTION

Poor mental health is recognized as one of the greatest global burdens of disease.[1,2] In the United States (US) alone, annual spending on mental illness is estimated at US $89 billion, not including the economic cost of lost earnings and productivity.[3] In Australia an estimated 8 million working days are lost annually due to mental illness, and international estimates are similar.[4,5] For mothers and children, the estimated annual societal cost in the US of maternal mental illness from birth to 5 years is US $14.2 billion.[6] In high income countries like the US and Australia, poor mental health is two-to-three times higher for those in the lowest income quintile compared to the highest.[4,7] Similarly, mothers experiencing social adversities such as relationship difficulties, social isolation, unemployment and low educational attainment are at higher risk of poorer mental health.[3,4,7,8] The economic and psychosocial stressors of the COVID-19 pandemic (e.g. unemployment, income loss, isolation and strain on family relationships) are likely to put mothers at heightened risk of poor mental health, with greater impact for those experiencing adversity who are already disproportionately at risk.[9] A national survey of Australian households found almost half of parents (48%) reported that the pandemic had negatively impacted their mental health, and this was more likely amongst those who had experienced financial impacts.[10]

Maternal mental health and wellbeing are crucial aspects of the optimal health of mothers and for their children's health and wellbeing.[2,11-13] From conception to preschool age, poor maternal mental health and wellbeing can hinder the provision of optimal care at a time when children are most sensitive to their environments.[12] Global prevalence estimates suggest that 9-16% of women experience depression and 10-15% experience an anxiety disorder in the perinatal period (antenatal to 1-year postpartum)[14,15] with limited data on prevalence rates for women with older children.[8,16,17]

Nurse home visiting (NHV) is an established model of healthcare delivery with potential to address inequities in maternal mental health, and subsequently children's development. NHV prioritizes women experiencing social adversity and overcomes barriers to health service access through outreach to women's homes. It shows promise for improving early parent care and home learning environments, with some studies showing greater benefits of NHV for women with poorer mental health.[18,19] However, few NHV studies have reported on these benefits beyond the first year postpartum. For example, only 6 (all from the US) of the 21 high quality[20] (i.e. randomized trial level evidence) NHV models that followed cohorts between child ages 2 and 4 years examined the impact of NHV on maternal mental health and wellbeing. Of these, three reported small to modest benefits (effect size (ES) 0.10 to 0.56) for maternal depression symptoms and parenting stress,[21-23] and three reported no evidence of these benefits.[18,24,25]

Given the parallel international policy interest in NHV and preventing inequitable rates of poor mental health, and the mixed results to date, it is timely to examine the potential benefits of NHV for maternal mental health and wellbeing. The right@home randomized controlled trial (RCT) is the largest multi-site trial of NHV in Australia and has demonstrated benefits to the primary outcomes of parent care, parent responsivity and the home learning environment when children turned two.[26] The program was designed for women experiencing adversity who may benefit from additional support beginning in pregnancy, rather than as a specific mental health intervention. However, maternal mental health and wellbeing support (e.g. nurse-led discussion of maternal mood, coping and identification of additional support needs) were offered as components within the program. Fidelity monitoring showed these supports were the most frequently delivered program components, provided in over 88% of nurse visits.[27,28] As such, in designing the follow-up study we anticipated that the significant parenting-related benefits (more confident parenting e.g. increased parent warmth, parental

involvement and parenting efficacy) seen at two years may translate to later benefits in maternal mental health and wellbeing as an important potential latent effect. We hypothesized that, when compared with women who were offered the universal child and family health (CFH) service (usual care), mothers who received the NHV intervention would report better maternal mental health and wellbeing outcomes at child age 3 years.

METHODS

Design: A randomized controlled trial (RCT) of NHV from pregnancy to child age 2 years, compared with the existing universal CFH service (usual care). Conducted as a superiority trial with two parallel groups and a primary endpoint at child age 2 years.[26,29] The current paper reports on mental health and wellbeing from extended follow-up of trial outcomes at child age 3 years. The published protocol describes the RCT methods to child age 2 years.[29]

Participants: Researchers recruited pregnant women attending antenatal clinics of 10 public maternity hospitals across the Australian states of Victoria and Tasmania from 30 April 2013 to 29 August 2014. Eligible women: (i) had due dates before 1 October 2014, (ii) were less than 37 weeks gestation, (iii) had sufficient English to complete face-to-face interviews, (iv) lived within travel boundaries specified by participating areas; and (v) had ≥2 of 10 risk factors identified at screening (young pregnancy; not living with another adult; no support in pregnancy; poor health; a long-term illness, health problem, or disability that limits daily activities; currently smokes; stress, anxiety or difficulty coping; low education; no person in the household currently earning an income; and never having had a job before).[29,30] Women were excluded if they: (i) were enrolled in an existing Tasmanian NHV program for 15-19-year-olds, (ii) did not comprehend the recruitment invitation (e.g. intellectual disability, or insufficient English), (iii) had no mechanism for contact, or (iv) experienced a critical event (e.g. termination of pregnancy, stillbirth or child death).

Procedures: Eligible women were identified in antenatal clinics and invited into the RCT. Participants provided informed consent for the RCT (initially to 2 years) and completed a home-based baseline interview assessing maternal demographic, economic and psychosocial factors. Mean gestational age at the baseline assessment was 28.2 weeks. Participants were then randomized to control or intervention arms with a 1:1 allocation following a computer-generated schedule stratified by site and parity (first-time parent vs. those with children) using permuted blocks of sizes 2, 4 or 6. Research managerial staff, participants and intervention teams were aware of allocation. Researchers who conducted follow-up assessments were blinded to randomization. Participants were reminded not to disclose their randomization allocation before each follow-up, and researchers reported any breach to the research managerial staff; four breaches of blinding were reported at the 3-year follow-up. At the 2-year home-based assessment, women were invited to re-enroll in the extended follow-up and informed consent was obtained.

The right@home NHV program was structured around the core Miller Early Childhood Sustained Home-visiting framework and training[19,31] and bolstered by five evidence-based strategies for content (sleep, safety, nutrition, regulation, bonding/relationship) and two for the delivery process (video feedback and motivational interviewing strategies).[27,28] Program implementation was enabled using program logic that articulated improved long-term (5-year) parent and child outcomes, together with adaptation processes that ensured the program had fidelity to the evidence and worked in the real-world health system.[27] The program logic was centered around confident parenting and child developmental outcomes, with anticipated associated maternal mental health benefits. Mothers in the intervention group were offered 25 nurse home visits (mean 23.2 home visits received), commencing antenatally and delivered mostly by the same nurse trained in the right@home NHV model of care.[28,29] Most intervention group women (75.6%) also received

one or more home visits by a social care practitioner (mean 1.7 visits),[28] who provided brief counselling interventions and/or case management as needed. In contrast, the usual CFH service includes six (Tasmania) or nine (Victoria) free nurse consultations up to 2 years (mean 7.6 consultations received)[26], with some limited program flexibility depending on family need.

Outcomes/measures (Table 1): All maternal mental health outcomes were collected via self-report at the 3-year home-based follow-up assessment, in interviews with researchers blinded to randomization allocation. Measures were selected to include mental health symptoms and positive aspects of mental health,[32-34] rather than mental ill health only. Maternal mental health symptoms were measured using the Depression Anxiety and Stress Scales (DASS)[35] and positive mental health measures of personal wellbeing[33] and self-efficacy[34] were also assessed (see Table 1 for details). The DASS Total Symptom scores and Depression, Anxiety and Stress Subscales were each reverse-scored to aid interpretation, such that higher scores represent better mental health. Reversed DASS subscale scores were also dichotomized to reflect poorest mental health symptom severity (study-defined as lower 15% of scores according to population reference ranges[36]) versus better mental health (upper 85% of scores) to estimate the impact of NHV on mental health morbidity. The measures are not diagnostic tools and therefore have no agreed minimum clinically important difference.

Statistical analyses: The initial RCT sample size was calculated to detect a minimum effect size (ES) of 0.3 standard deviations (SD) in the primary parent responsivity outcome. A target sample size of 714 participants was estimated to provide 80% power, with 5% significance level, accounting for clustering by care provider in the intervention group and site of care provision for usual care. This estimate allowed for 40% attrition to 2-year follow-up. A final sample size of 722 participants was achieved. The sample size achieved at the 3-year follow-up was 495 (68.6%), which retained 80% power to detect a minimum ES of 0.3

SD on continuous measures of maternal mental health. For all women retained at 3 years, baseline characteristics of those in the intervention and usual care group were compared using chi-square tests (categorical measures) and t-tests (continuous measures) to assess differences arising due to attrition.

In line with the published statistical analysis plan used at age 2 years,[26] between-group comparisons of mental health outcomes at 3 years were made following intention to treat linear (continuous outcomes) and logistic (binary outcomes) regression models. Initially, these models included families who had participated in the 3-year follow-up and completed the mental health outcome measures i.e. complete case data. Regression models were adjusted for the stratification factors used during randomization: parity and study site; and additional baseline covariates: family's Socio-Economic Index for Areas (SEIFA) score,[37] maternal education, maternal age at child's birth, parity, antenatal risk, maternal self-efficacy and maternal mental health, as well as child sex and age at the 3-year assessment. All regression analyses accounted for effects of nurse clustering.[29] Adjusted results are presented to ensure treatment effect estimates are corrected for chance imbalances in baseline covariates, appropriate confidence intervals are estimated and statistical power is most efficient.[38] Adjusted results are reported as mean differences, standardized effect sizes (ES) or odds ratios (OR) with 95% Confidence Intervals (CI).

Multiple imputation techniques were used to evaluate the sensitivity of the findings based on complete cases to sample attrition. Multiple imputation provided estimates of program effects which included all mothers who were initially randomly assigned. 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.[39] Data were analyzed using Stata version 15 for Windows (Stata Corp, College Station, TX).

Ethical approval: right@home was approved by Human Research Ethics Committees: Royal Children's Hospital (HREC 32296); Peninsula Health (HREC/13/PH/14); Ballarat Health Services (HREC/13/BHSSJOG/9); Southern Health (HREC 13084X); and Northern Health (HREC P03/13) in Victoria, and University of Tasmania (HREC H0013113); all Australian. The ethics-approved study protocol included processes for responding to participant or child safety concerns.

RESULTS

Of 5586 women screened, 1427 (25.5%) were eligible (Figure 1). Of these, 722 (50.6%) enrolled in the trial. Of 722 enrolled, 558 (77.3%) re-enrolled in the extended follow-up and 495 (68.6%) provided data at 3-year follow-up. Table 2 presents the baseline characteristics for women who participated at 3 years compared to women lost to follow-up. The women participating in the 3 year follow up, across both the intervention and usual care group, had slightly better mental health at baseline, were more likely to have completed high school, and were less likely to have reported a drug problem or history of family violence. Amongst those retained, comparison of baseline characteristics between the intervention and usual care group showed minimal differences.

Table 3 presents the descriptive statistics of the maternal mental health outcomes and the adjusted complete case analyses. Compared to usual care, benefits of the intervention were evident for mental health in the DASS Total Score (ES: 0.25, 95% CI: 0.12 to 0.38), and consistently across the Depression, Anxiety and Stress subscales. These benefits translated to higher odds of better mental health (better 85% of symptom scores relative to norms) for Depression (OR:1.68, 95% CI: 1.08 to 2.60), Anxiety (OR:1.38, 95% CI: 0.92 to 2.08) and Stress (OR: 2.09, 95% CI: 1.28 to 3.42). Similarly, program benefits were evident

in better personal wellbeing (ES: 0.16, 95% CI: 0.04 to 0.29) and not lacking self-efficacy (OR: 1.60, 95% CI: 1.19 to 2.16).

Results of the multiple imputation analyses (Table 4) are similar to the complete case analyses in estimated effects, confirming that the use of complete case analyses had not led to bias due to attrition between the treatment groups. Estimates had slightly wider confidence intervals because the imputation of a large proportion of the study outcomes increased the uncertainty of estimation, thus these analyses using multiple imputation are considered the more conservative.[39]

DISCUSSION

Benefits of the right@home NHV program were evident for maternal mental health and wellbeing outcomes at 1-year post intervention completion (child age 3 years). Our findings align with results from three previous US NHV studies showing small-to-modest effect sizes for maternal mental health from child age 2 to 4 years (ES: 0.1 to 0.6 for maternal depression symptoms and parenting stress).[21-23] We found similar-sized benefits for maternal depression, anxiety and stress symptoms (ES: 0.17 to 0.25), but note the additional positive benefits on personal wellbeing (ES 0.16) and self-efficacy (OR: 1.60).

These findings also align favorably with programs that directly target maternal mental illness. Psychosocial and psychological interventions delivered by nurses, physicians, psychologists, researchers or lay people have shown similarly modest positive benefits in the antenatal and first year postpartum periods (ES: 0.06 to 0.16).[40,41] However, these benefits have either not been observed or assessed beyond child age 1-year, nor were they delivered specifically to women experiencing adversity.

Despite substantial research and policy attention paid to maternal mental health, and its known importance for children's development, there are comparatively few published data

on maternal mental health beyond the first year postpartum.[8,17] An Australian population cohort of first-time mothers reported depression increasing with child age, with a peak at 4 years.[17] Within our study, mothers receiving usual care also reported worse mental health symptoms from 2 to 3 years.[26] In contrast, our findings for intervention mothers suggest that the right@home NHV program may have prevented or postponed this decline in mental health. These findings deliver on the initial aspiration of the program as a salutogenic prevention intervention embedded in healthcare for women who may benefit from additional support, rather than an intervention responding to crisis or illness.[28]

The strengths of our findings lie in the trial's rigorous design and research collaboration. Implementation of the NHV program and the research evaluation were led by different institutions. Outcome assessments were completed by researchers who were blinded to intervention status. The trial is also strengthened by the high retention of study participants in both groups (69% over a 4-year study duration), despite the substantial adversity experienced by participants. For context, by 2-year follow-up the UK Building Blocks study retained 71% of their cohort for self-reported outcomes,[42] ProKind retained less than 50%,[43] and the French CAPEDP retained only 31% of their original cohort.[44] Although those lost to follow-up reported slightly more adversities at baseline, participant characteristics at 3 years remained balanced between the trial arms. In addition, multiple imputation methods were implemented to confirm estimates made using complete data. Compared to the results of the complete cases analyses, multiple imputation methods provided a more conservative estimation of program effects in which benefits for maternal mental health were still evident. Given the large, multi-site design of the trial, high participant retention and confirmation using multiple imputation, we believe our findings should generalize to pregnant women experiencing adversity, in similar health care systems.

There are several limitations. The multiple self-reported mental health measures are likely to represent overlapping constructs. However, this was to encompass both the positive aspects of mental health and symptoms of mental ill health, i.e. both positively and negatively framed items.[32-34] While mental health was examined using both continuous and dichotomized symptom scores across multiple domains of the DASS, this allowed us to estimate the impact of NHV on a scale of mental health symptoms as well as rates of dichotomized mental health morbidity. The DASS is not a diagnostic tool; however, it is one of the only broad-spectrum, self-report mental health measures and is frequently used in research with clinical and population-level cohorts.[36] We reported effect sizes to enable comparability with previous NHV programs and psychological interventions which have reported mental health outcomes using different measures. Although participation in the NHV program in general may have influenced how women reported their mental health (aside from the true benefit), we expect any potential response bias would be minimal given the measures were collected 1-year after the intervention ended. A further limitation of the current study is that the exclusion criteria mean findings may not generalize to non-English speaking women or women with severe intellectual disability.

Given the crucial role that maternal mental health plays in optimal health of mothers and their children,[8,11-13] addressing inequities in maternal mental health can generate substantial societal and mental health benefits.[3,5] To realize this goal the most efficient and equitable approach is to integrate mental health care into existing health services within a prevention and early intervention paradigm.[1] Although economic data are not presented in this paper, we note that self-reported use of health services following the intervention, from child age 2 years, was similar between the intervention and usual care groups. Future research will examine the cost-consequences of the right@home NHV program outcomes, including maternal mental health benefits, identified at 3-years. Our findings provide

evidence to support NHV as a potential platform to achieve substantial benefits through maternal mental health.[6] Interventions for the prevention of postnatal depression have been estimated to save $23.3 million over 5 years in Australian mental health expenditure.[5] While these estimates focus predominantly on intervention effects in the antenatal and first year postpartum, the similar benefits identified at 3 years postpartum suggest an additional advantage in focusing policy on maternal mental health beyond the first year.

CONCLUSION

The right@home NHV program lead to emerging benefits for maternal mental health and wellbeing at child age 3-years, a year after the intervention ended. These findings show that a NHV program that is designed for women experiencing adversity can lead to later benefits to mental health, even when implemented within existing CFH services. While vital for addressing the established mental health burden, the benefits of NHV delivered through existing health care infrastructure may be most critical as the economic and psychosocial stressors of the COVID-19 pandemic emerge for families with young children. At scale there may be real potential to reduce inequities in maternal mental health.

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Table 1. Description of maternal mental health outcome measures

Item	Description
Mental health symptoms	Depression, Anxiety and Stress Scales (DASS).[35] 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 stress. Three subscales (7 items each): Depression, Anxiety and Stress, examined as continuous scores of mental health symptoms. DASS scores were reversed so that higher scores indicate better mental health, ranging from 0-21. Reversed DASS subscale scores were also dichotomized to reflect poorest mental health symptom severity (study-defined as lower 15% of scores according to population reference ranges[36]) versus better mental health (upper 85% of scores). DASS subscales are strongly correlated with other self-report mental health measures in Australian postpartum women, such as the Edinburgh Postnatal Depression Scale (EPDS, Pearson's correlation(r)=0.84), and the anxiety and depression subscales of Beck Depression Inventory (BDI-II; r=0.82 and 0.86, respectively).[45]
Personal wellbeing	Personal Wellbeing Index.[33] 8 items assessing satisfaction with specific life domains, rated using a 10-point scale ("no satisfaction at all" to "completely satisfied"). Higher scores indicate better wellbeing, ranging from 0-80.
Self-efficacy	3 items assessing mother's self-efficacy or locus of control, which aimed to capture how the mother felt about her life in general including the extent to which she felt that she gets what she wants out of life, felt in control and can run her own life, drawn from the UK Millennium Cohort Study.[34] Each item reflected the presence versus absence of self-efficacy and were used to form a single dichotomous item reflecting 'any lack of self-

Item	Description
	efficacy’ versus ‘no lack of self-efficacy’.

Table 2. Baseline characteristics according to follow-up status (i.e. retained or lost in right@home study) at child age 3 years.

Baseline characteristics (pregnancy)	**Intervention (N = 363)**		**Control (N = 359)**		
	Retained (N=255)	**Lost (N=108)**	**Retained (N=240)**	**Lost (N=119)**	**p-value** [a]
Mother					
Age (years), mean (SD)	27.6 (5.9)	27.1 (6.4)	28.3 (6.4)	26.9 (6.2)	0.22
DASS (reversed – higher scores indicate better mental health)					
Total Score, mean (SD)	51.2 (9.7)	49.8 (11.1)	51.5 (8.8)	50.8 (10.4)	0.69
Depression Scale, mean (SD)	18.0 (3.5)	17.7 (4.0)	18.2 (3.1)	17.9 (3.6)	0.42
Anxiety Scale, mean (SD)	17.5 (3.4)	17.1 (3.5)	17.7 (3.1)	17.2 (3.7)	0.49
Stress Scale, mean (SD)	15.7 (4.0)	15.0 (4.8)	15.6 (3.9)	15.7 (4.3)	0.77
DASS (dichotomized - within 85th percentile score of better mental health according to norms)					
Depression Scale	82.7	81.5	86.7	79.0	0.23
Anxiety Scale	59.2	50.9	61.2	52.9	0.64
Stress Scale	80.8	77.8	80.0	83.2	0.83
Education status					
Did not complete high school	21.3	33.7	26.5	22.3	0.43
Completed high school / vocational training	67.0	58.7	63.2	66.0	
Completed a university degree	11.7	7.6	10.3	11.7	
Marital status					
Single / not living with partner	29.0	26.9	22.9	31.1	0.54
Married / living with partner	69.4	70.4	75.4	66.4	

Baseline characteristics (pregnancy)	Intervention (N = 363)		Control (N = 359)		
	Retained (N=255)	Lost (N=108)	Retained (N=240)	Lost (N=119)	p-value [a]
Separated / divorced	1.6	2.8	1.7	3.5	
Currently unemployed	62.8	73.2	62.9	74.0	0.97
Family income from benefit or pension	42.4	47.2	41.3	42.9	0.26
Ever had a drug problem	12.2	18.5	13.0	24.6	0.78
Experienced domestic violence in past year	10.7	15.9	10.6	13.5	0.97
Total adversity risk count (from screening), mean (SD)	3.0 (1.3)	3.5 (1.4)	3.2 (1.2)	3.3 (1.2)	0.10
Child					
First born	38.8	34.3	34.6	40.3	0.33
Female	57.3	46.9	45.8	41.9	0.01
Family					
SEIFA Index of Social Disadvantage Quintile					0.55
1 (most disadvantaged)	44.2	45.2	39.8	40.9	
2	6.8	9.6	8.7	8.7	
3	39.4	32.7	39.0	36.5	
4	6.4	11.5	10.0	7.8	
5 (least disadvantaged)	3.2	1.0	2.6	6.1	
Language other than English	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 Intervention N =351-363, Control N= 345-359 due to missing data.

Table 3. Adjusted complete case regression analyses comparing the two trial arms on maternal mental health outcomes at child age 3 years.

	Intervention		Control (Usual care)		Comparative statistic [b]: Intervention compared to Control				
Outcome	**N**	**Summary** [a]	**N**	**Summary** [a]	**Statistic** [b]	**(95% CI)**	**p-value**	**ES**	**(95% CI)**
Depression, Anxiety and Stress Scale (DASS) (reversed – higher scores indicate better mental health)									
Total Score	251	54.15 (8.38)	236	51.77 (9.45)	2.23	(1.08, 3.39)	0.001	0.25	(0.12, 0.38)
Depression Scale	252	18.52 (3.22)	236	17.88 (3.45)	0.67	(0.26, 1.09)	0.003	0.20	(0.08, 0.32)
Anxiety Scale	252	18.98 (2.72)	236	18.36 (3.13)	0.51	(0.15, 0.88)	0.008	0.17	(0.05, 0.30)
Stress Scale	253	16.53 (3.67)	236	15.54 (4.10)	0.90	(0.35, 1.46)	0.002	0.23	(0.09, 0.37)
Depression, Anxiety and Stress Scale (DASS) (dichotomized – within 85th percentile score of better mental health according to norms)									
Depression Scale [c]	252	222 (88.10%)	236	195 (82.63%)	1.68	(1.08, 2.60)	0.020		
Anxiety Scale [c]	252	214 (84.92%)	236	184 (77.97%)	1.38	(0.92, 2.08)	0.12		
Stress Scale [c]	253	229 (90.51%)	236	193 (81.78%)	2.09	(1.28, 3.42)	0.003		
Personal Wellbeing	247	58.77 (12.93)	228	56.07 (12.56)	2.11	(0.47, 3.76)	0.014	0.16	(0.04, 0.29)
Self-efficacy [c,d]	249	192 (77.11%)	233	157 (67.38%)	1.60	(1.19, 2.16)	0.002		

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.

N=Number of participants included in the analysis; CI= Confidence Interval; ES= Effect Size (Cohen's d).

[a] Summary statistics are mean (SD) except where specified as dichotomous where n and %; [b] The comparative statistic is mean difference for continuous outcomes (intervention minus control) and odds ratio for dichotomous outcomes (relative odds for intervention compared with receiving usual care); [c] Outcome is dichotomous (%); [d] 'No lack of self-efficacy' vs 'Any lack of self-efficacy'.

Table 4. Adjusted multiple imputed regression analyses comparing the two trial arms on maternal mental health outcomes at child age 3 years.

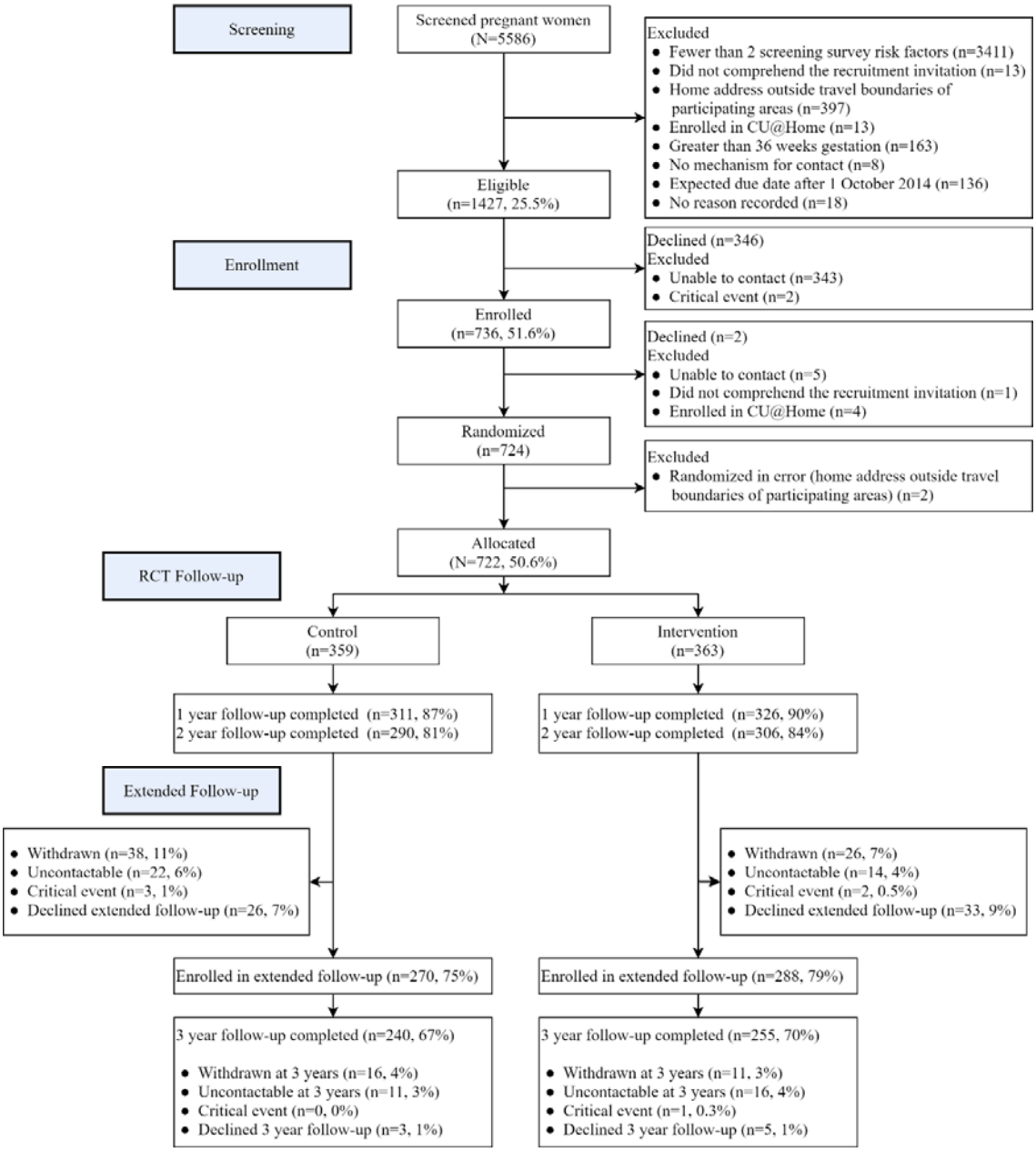
Outcome	**Intervention**		**Control (Usual care)**		**Comparative statistic [b]: Intervention compared to Control**				
	N	**Summary [a]**	**N**	**Summary [a]**	**Statistic [b]**	**(95% CI)**	**p-value**	**ES**	**(95% CI)**
Depression, Anxiety and Stress Scale (DASS) (reversed – higher scores indicate better mental health)									
Total Score	363	53.79	359	51.74	1.85	0.05 ; 3.65	0.045	0.18	0.00 ; 0.36
Depression Scale	363	18.51	359	17.89	0.59	-0.05 ; 1.24	0.069	0.16	-0.01 ; 0.34
Anxiety Scale	363	18.82	359	18.31	0.40	-0.28 ; 1.07	0.23	0.12	-0.08 ; 0.32
Stress Scale	363	16.46	359	15.54	0.86	0.07 ; 1.65	0.035	0.20	0.02 ; 0.38
Depression, Anxiety and Stress Scale (DASS) (dichotomized - within 85th percentile score of better mental health according to norms)									
Depression Scale [c]	363	91.74	359	88.58	1.53	1.05 ; 2.24	0.028		
Anxiety Scale [c]	363	89.53	359	85.52	1.40	1.00 ; 1.94	0.047		
Stress Scale [c]	363	93.39	359	88.02	1.95	1.20 ; 3.16	0.007		
Personal Wellbeing	363	58.95	359	56.23	2.37	-0.59 ; 5.34	0.10	0.17	-0.04 ; 0.37
Self-efficacy [c,d]	363	75.68	359	65.44	1.74	1.26 ; 2.40	0.001		

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.

N=Number of participants included in the analysis; CI= Confidence Interval; ES= Effect Size (Cohen's d).

[a] Summary statistics are mean (SD) except where specified as dichotomous where n and %; [b] The comparative statistic is mean difference for continuous outcomes (intervention minus control) and odds ratio for dichotomous outcomes (relative odds for intervention compared with receiving usual care); [c] Outcome is dichotomous (%); [d] 'No lack of self-efficacy' vs 'Any lack of self-efficacy'.

Figure 1. Participant CONSORT diagram



Screening

Screened pregnant women (N=5586)

Excluded
- Fewer than 2 screening survey risk factors (n=3411)
- Did not comprehend the recruitment invitation (n=13)
- Home address outside travel boundaries of participating areas (n=397)
- Enrolled in CU@Home (n=13)
- Greater than 36 weeks gestation (n=163)
- No mechanism for contact (n=8)
- Expected due date after 1 October 2014 (n=136)
- No reason recorded (n=18)

Eligible (n=1427, 25.5%)

Enrollment

Declined (n=346)
Excluded
- Unable to contact (n=343)
- Critical event (n=2)

Enrolled (n=736, 51.6%)

Declined (n=2)
Excluded
- Unable to contact (n=5)
- Did not comprehend the recruitment invitation (n=1)
- Enrolled in CU@Home (n=4)

Randomized (n=724)

Excluded
- Randomized in error (home address outside travel boundaries of participating areas) (n=2)

Allocated (N=722, 50.6%)

RCT Follow-up

Control (n=359)

Intervention (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%)

Extended Follow-up

- Withdrawn (n=38, 11%)
- Uncontactable (n=22, 6%)
- Critical event (n=3, 1%)
- Declined extended follow-up (n=26, 7%)

- Withdrawn (n=26, 7%)
- Uncontactable (n=14, 4%)
- Critical event (n=2, 0.5%)
- Declined extended follow-up (n=33, 9%)

Enrolled in extended follow-up (n=270, 75%)

Enrolled in extended follow-up (n=288, 79%)

3 year follow-up completed (n=240, 67%)

- Withdrawn at 3 years (n=16, 4%)
- Uncontactable at 3 years (n=11, 3%)
- Critical event (n=0, 0%)
- Declined 3 year follow-up (n=3, 1%)

3 year follow-up completed (n=255, 70%)

- Withdrawn at 3 years (n=11, 3%)
- Uncontactable at 3 years (n=16, 4%)
- Critical event (n=1, 0.3%)
- Declined 3 year follow-up (n=5, 1%)