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Research Paper

Proactive Peer (Mother-to-Mother) Breastfeeding Support by Telephone (Ringing up About Breastfeeding Early [RUBY]): A Multicentre, Unblinded, Randomised Controlled Trial

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ABSTRACT

Background: Breastfeeding rates are suboptimal internationally, and many infants are not receiving any breast milk at all by six months of age. Few interventions increase breastfeeding duration, particularly where there is relatively high initiation. The effect of proactive peer (mother-to-mother) support has been found to increase breastfeeding in some contexts but not others, but if it is shown to be effective would be a potentially sustainable model in many settings. We aimed to determine whether proactive telephone-based peer support during the postnatal period increases the proportion of infants being breastfed at six months of age.

Methods: RUBY (Ringing Up about Breastfeeding earlY) was a multicentre, two-arm un-blinded randomised controlled trial conducted in three hospitals in Victoria, Australia. First-time mothers intending to breastfeed were recruited after birth and prior to hospital discharge, and randomly assigned (1:1) to usual care or usual care plus proactive telephone-based breastfeeding support from a trained peer volunteer for up to six months postpartum. A computerised random number program generated block sizes of four or six distributed randomly, with stratification by site. Research midwives were masked to block size, but masking of allocation was not possible. The primary outcome was the proportion of infants receiving any breast milk at six months of age. Analyses were by intention to treat; data were collected and analysed masked to group. The trial is registered with ACTRN, number 12612001024831.

Findings: Women were recruited between Feb 14, 2013 and Dec 15, 2015 and randomly assigned to peer support ($n = 574$) or usual care ($n = 578$). Five were not in the primary analysis [5 post-randomisation exclusions]. Infants of women allocated to telephone-based peer support were more likely than those allocated to usual care to be receiving breast milk at six months of age (intervention 75%, usual care 69%; Adj. RR 1·10; 95% CI 1·02, 1·18). There were no adverse events.

Interpretation: Providing first time mothers with telephone-based support from a peer with at least six months personal breastfeeding experience is an effective intervention for increasing breastfeeding maintenance in settings with high breastfeeding initiation.

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Abbreviations: ABA, Australian Breastfeeding Association; ACTRN, Australian New Zealand Clinical Trials Registry number; Adj. RR, Adjusted relative risk; AUD, Australian dollar(s); CI, Confidence interval; HR, Hazard ratio; RCT, Randomised controlled trial; RR, Relative risk; RUBY, **R**inging **U**p about **B**reastfeeding earl**Y**; sd, Standard deviation.

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Research in context

Evidence before this study

The evidence on how to maintain breastfeeding in countries such as Australia with intermediate to high breastfeeding initiation was limited before the RUBY started, and most strategies aimed at increasing the duration of breastfeeding were ineffective. Overall, pre-RUBY, peer support provided in the postnatal period seemed likely to reduce the risk of not breastfeeding, particularly if the support included at least five contacts; however the evidence suggested that in *high-income countries*, peer support might have limited effect.
A more recently updated systematic review on support for breastfeeding found increased evidence of the value of face-to-face support from health professionals to increase breastfeeding, but no positive association between (predominantly) telephone-based peer support and increased breastfeeding maintenance http://www.ncbi.nlm.nih.gov/pubmed/28244064. To capture any further evidence since the conduct of these systematic reviews, we searched PubMed and CINAHL Plus on April 5, 2018 for trials reported in 2016 through 2018 that compared proactive telephone-based peer support to increase breastfeeding, using search terms ((((breastfeeding or breast feeding or breast fed or breastfed [MeSH Terms])) AND (random* or controlled[MeSH Terms])) AND (*phone[Title/Abstract]) AND support[Title/Abstract] AND ("2016/01/01"[PDAT]: "2018/04/05"[PDAT]) (PubMed) and "TX (breastfeeding or "breast feeding" or breastfed or "breast fed") AND TX *phone* AND TX controlled AND support NOT TX HIV 2016-2018" (CINAHL Plus). We identified only two study protocols and two feasibility studies; that is, no further evidence to date.

Added value of this study

This is the largest study to date (to our knowledge) exploring if proactive telephone-based peer support is associated with increased breastfeeding at six months, and the number of participants is more than the total previously included in this specific meta-analysis (i.e. of telephone-based peer support) in the relevant Cochrane review. We found a positive association with assignment to proactive telephone-based peer support and the proportion of infants receiving breast milk at six months.

Implications of all the available evidence

Our large adequately powered RCT provides evidence that proactive volunteer lay support can improve the prevalence of breastfeeding to six months in primiparous women – an important finding given how difficult it is to increase breastfeeding maintenance, particularly in settings with high breastfeeding initiation. This intervention has great potential for widespread implementation at a population level. The research team included investigators from the leading consumer organisation for breastfeeding in Australia, the Australian Breastfeeding Association, and the intervention was deliberately co-designed so that it could be scaled up with very little additional infrastructure.

1. Introduction

Knowledge about the benefits of breastfeeding for both women and children has expanded in the last decade [1], and the global economic cost associated with the proportion of infants not being breastfed has been quantified [2]. Not breastfeeding is associated with poorer outcomes for infants [3] and women [4] in both low and high income countries [1], yet breastfeeding duration is shorter in most high income countries compared with low income countries [1].

Australia has high breastfeeding initiation, with 96% of infants commencing breastfeeding; however by six months of age only 60% of infants are receiving any breast milk, and only 15% are exclusively breastfed to five months [5]. Infants in low income Australian families are less likely to initiate breastfeeding and more likely to have a shorter duration; 93% of infants in families in the lowest income quintile commence breastfeeding, and by four months only 52% are receiving any breast milk, compared with infants in families in the highest income quintile, whose rates are 98% and 77% respectively [5]. These findings suggest a further increase in health inequities among socially disadvantaged infants already at risk of poorer health outcomes [6], and that interventions need to be in place to prevent early breastfeeding cessation. In Victoria, the second most populous state in Australia, the most recent report (2014/2015 data) shows the overall rate of any breastfeeding at six months as 50% [7], with marked disparities across the state; of the 78 local government areas, some have overall rates of any breastfeeding at six months as low as 38%, while others are up to 64% [8]. Strategies to support breastfeeding maintenance in countries such as Australia need therefore to focus on the groups least likely to initiate and continue breastfeeding.

When this study was designed there was limited evidence on how to maintain breastfeeding in countries with intermediate to high breastfeeding initiation such as Australia [9]. A more recent 2017 Cochrane review (which included 73 studies from 29 countries) found breastfeeding support is likely to be more effective in settings with high initiation, that both lay and professional support are beneficial, and that face-to-face support is associated with better outcomes than telephone-only support [10]. The two sub-analyses of predominantly telephone-based support showed no evidence of effect, however of the 27 studies that explored telephone-based support, details of whether the support was lay or professional, or proactive or not was not clear in all cases. There was also no sub-analysis of proactive support (initiated by someone other than the woman herself) versus reactive support (provided in response to a request or question from the woman) [10]. The effect of peer or lay support versus professional support was difficult to interpret due to the different timing of outcome measurements and whether it was *exclusive* or *any* breastfeeding being assessed [10]. Another systematic review included only peer support interventions aimed at increasing breastfeeding continuation, and found peer support was a) more likely to be effective in low and middle income settings than high income countries; b) more effective if the number of planned peer-to-mother contacts were ≥ 5; and c) was more effective if initiated postnatally rather than antenatally and continued postnatally [11].

One of the randomised controlled trials (RCTs) included in both the reviews found a large effect: a Canadian study of proactive telephone-based support by trained peers with breastfeeding experience found a 14% difference in any breastfeeding at three months – 81% of those allocated to the peer support group were breastfeeding compared to 67% in the control group [12]. It was this study which underpinned the trial reported here, undertaken in the Australian context.

The objective of the Ringing Up about Breastfeeding (RUBY) trial was to determine whether peer (mother-to-mother) support, provided during the postnatal period by telephone, using a proactive approach, increased the proportion of infants who received breast milk for at least six months [13]. In this paper, we present the primary and secondary outcomes.

2. Methods

2.1. Study Design

We conducted a two-group, unblinded randomised controlled trial, recruiting women from three public hospitals in the state of Victoria,

Australia, all of which provide care for relatively disadvantaged women. Ethics approval was obtained from the following Human Research Ethics Committees (reference number in brackets): Royal Women's Hospital (12/25); La Trobe University (12-082); Monash Health (12251B); and Western Health (12/WH/107).

2.2. Participants

Women were eligible for inclusion if they were first time mothers, admitted as public patients to the postnatal units of the participating hospitals, were proficient in English and were intending to breastfeed. They were excluded if they had a serious physical or medical illness, had a multiple birth, were a member of the Australian Breastfeeding Association (ABA)[1] prior to the baby's birth (indicative of high motivation to breastfeed and high self-efficacy), or the infant remained in hospital after the mother's discharge. Further detail is provided in the published protocol [14].

Research staff aimed to offer trial participation to all eligible women during their inpatient stay at one of the trial sites, after the birth of their baby, and prior to discharge from hospital, which was approximately 48 h postpartum or less. Before randomisation took place, women who agreed to participate provided written consent and completed a baseline questionnaire which included questions about planned breastfeeding duration, family support for breastfeeding, infant feeding since birth, and demographic characteristics.

2.3. Randomisation and Masking

Women were randomly allocated (1:1) to either the usual care group or intervention group that consisted of usual care plus proactive telephone-based support from a peer volunteer. Randomisation was carried out by a computerised random number generator in variable block sizes of four to six (to avoid selection bias), and was stratified by site. The allocation sequence was generated and administered by the Clinical Epidemiology and Biostatistics Unit at Murdoch Children's Research Institute. The program was accessed by research staff who entered the details of the trial hospital and the woman's birth date, then a randomised allocation was immediately generated, and the woman was informed of the outcome. Recruitment staff were masked to block size. Staff on the postnatal wards were not aware of group allocation. Outcome data collection was masked to group allocation. The research team were masked to group allocation, and remained masked at all stages until the end of the primary data analysis. All data cleaning and variable generation took place before trial group data were added, then trial groups were relabelled by an independent researcher so that those conducting the analysis could not identify the groups during the analysis. Data were presented to the Data Monitoring Committee for an interim analysis in unlabelled study groups.

2.4. Procedures

2.4.1. Usual Care

In Australia breastfeeding support is a priority in the postnatal period both in hospital and in the community and all women in the study had access to the usual supports for breastfeeding. The standard postpartum hospital stay at all sites was up to 48 h after vaginal birth and 72 h after caesarean section, with each site providing access to hospital specialist breastfeeding services by lactation consultants if needed. Women were offered one to two postnatal visits in the home from a hospital midwife within the first week after discharge from hospital, after which a Maternal and Child Health Nurse (MCHN) service was provided in the community.[2] All women could also access the ABA telephone helpline service, staffed by trained volunteer breastfeeding counsellors. This free service is available 24 h a day seven days per week, but is reliant upon the breastfeeding mother accessing the service herself; that is, reactive rather than proactive, and does not provide continuity between the counsellor and the mother.

2.4.2. Intervention

In addition to usual care, all women allocated to the intervention group received proactive telephone-based support from a peer volunteer. Participant details were provided to the peer volunteer coordinator, who allocated the next available peer to provide support to the mother. Peers were provided with the woman's first name and phone number, and were requested to initiate contact. Peers made an initial telephone call to the new mother 24 to 48 h after hospital discharge, i.e. four to six days after the birth, with a follow-up call three to four days after the initial call. Subsequent calls were to be made each week for the first twelve weeks after birth, then three to four weekly between twelve weeks and six months. The calls focused on the new mother's wellbeing and breastfeeding experience, with volunteers referring the mother to existing support services as required. The participant was able to contact the peer volunteer between the scheduled calls as needed.

Women were eligible to be peer volunteers if they had breastfed a baby until at least six months of age and were not breastfeeding experts (defined as no more than eight hours of breastfeeding training as a professional or counsellor). The majority of peers were recruited via online posts requesting expressions of interest on the ABA Facebook page. Recruitment of the peer volunteers occurred between December 2012 and May 2015. During this time, 24 training sessions were conducted, taking place every 4 to 8 weeks, and including 4 to 17 participants in each. The volunteer coordinator screened potential volunteers for eligibility, and volunteers were required to commit to being available to support at least one mother for six months. All attended a four-hour training session conducted by the RUBY research team in conjunction with an ABA educator. The sessions, adapted from the ABA training course for counsellors, focussed on active listening, respecting beliefs and values of others, positive language, empathy, building confidence, baby behaviour, and encouraging and supporting new mothers. Emotional wellbeing was a focus, along with breastfeeding and parenting issues, and peers were encouraged to refer women to existing services (such as ABA, MCHN, general practitioner) as required. The volunteer coordinator provided ongoing supervision of the peer volunteers, and kept in regular contact by phone and email; contact was made after the initial peer-participant matching, and was then monthly, with additional contact as needed.

2.4.3. Data collection

Demographic data (including maternal age, education, marital status, maternal country of birth, and smoking) were collected by questionnaire at recruitment and prior to randomisation, and obstetric and neonatal medical data were collected from the medical record at the time of recruitment. Women in the intervention group were also mailed questionnaires regarding their experience of receiving peer support after completing the six-month telephone interview conducted by the research assistant. Peer volunteers were asked to log details of all contacts with their allocated mother(s) (e.g. call length, discussion

[1] The Australian Breastfeeding Association is a non-profit, volunteer organisation, and the leading consumer breastfeeding advocacy group in Australia, providing resources, education and support to families.

[2] In Victoria, Australia the MCHN service is a universal free service with a health professional who is both a Registered Nurse and Registered Midwife and who holds a Postgraduate Diploma in Community Child Health. The MCHN service supports maternal health and wellbeing and children's health and development from birth until school age, as well as providing parenting support. Women are allocated one home-based visit in the first two weeks after discharge plus at least 4 clinic visits over the first 6 months, at no cost. Visits are scheduled as 30 min and explicitly include breastfeeding as a topic, and participation rates are 95% up to 8 weeks [15].

content), and were reimbursed $50 AUD for each woman supported to cover costs of calls.

2.5. Outcomes

The primary outcome was the proportion of infants receiving *any breast milk* at six months of age. This outcome was collected six months post birth by a telephone interview conducted by trained research assistants masked to group assignment.

The questions used to describe infant feeding were "In the last 24 hours, how have you been feeding your baby?" and "We would also like to know all the different ways you have been feeding your baby since birth?" (both questions had a list of pre-coded mutually exclusive response options [14] the research assistants completed), in conjunction with a series of questions to explore when (and if) solids were commenced, when breast milk feeding had ceased (if it had), and when (and if) other fluids had been commenced. The research group developed and have reported on these outcome measures extensively in previous breastfeeding studies [16–20].

Secondary outcomes were the proportion of infants receiving breast milk only at six months (defined as breast milk being the only milk provided in the last 24 h, but not excluding solid foods; thus not to be misinterpreted as the proportion exclusively breastfeeding to six months as recommended by the World Health Organization [21]) and time to cessation of breastfeeding, measured by survival analysis, censored at six months postpartum (both outcomes by self-report at six-month interview). Other outcomes not included in this paper (due to the large amount of data this would include) are the cost of the peer support intervention, and cost effectiveness in relation to infant and maternal health outcomes and health service use (medical records and self-report); women's views and experiences (intervention group, self-report); and peer volunteers' views and experiences (online survey and focus groups). These will be reported in other papers. Intervention fidelity was measured using data from peer volunteer call logs (recording details of each contact, or attempted contact, with their allocated participant/s), and women's self-report.

There was no separate Safety Committee; the trial coordinator and volunteer coordinator monitored any potential adverse issues occurring in trial participants or volunteers respectively, and reported to chief investigator team.

2.6. Statistical Analysis

Our primary hypothesis was that proactive peer support provided to women by telephone in the postnatal period would increase the proportion of infants receiving any breast milk at six months by 10% compared with usual care (from 46% to 56%). Secondary hypotheses were that proactive peer support provided by telephone in the postnatal period would increase breastfeeding duration (i.e. decrease early cessation of breastfeeding) and increase exclusive breastfeeding at six months. We based our sample size calculations on the rate of any breast milk feeding in Victoria at the time the study was conceived, which was 46% [22]. Allowing for a 10% difference in either direction (i.e. up to 56% or down to 36%) with 80% power and alpha 0.05, we needed 822 women (411 per group). Allowing 20% loss to follow-up meant we needed to recruit 1028 women. We received advice that there was potential for within-peer clustering, so allowed for this in our sample size calculations [14]. We assumed an overall average breastfeeding rate of 56% in the intervention arm, and calculated our final sample size required as 1152 (576 per trial group) [14]. This sample size also ensured adequate power to detect clinically important differences in exclusive breastfeeding at six months and duration of breastfeeding.

Collection of data, including data on eligible non-participants, was undertaken in accordance with the requirements of the CONSORT guidelines for reporting of randomised trials [23]. All analyses were by intention to treat, undertaken in Stata Version 14. The primary outcome was calculated as event numbers and percentages (by trial arm), and compared using relative risks (RR) with 95% confidence intervals (CIs), with usual care as the reference group. In order to account for the stratification variable (site), and for two additional factors which may have impacted on the outcomes based on the scientific literature, and which did differ between groups (i.e. breastfeeding intention and formula given [prior to recruitment]), multivariate analysis was performed. Predicted probabilities of the outcomes were estimated using marginal standardisation after logistic regression (using the margins command). The predicted probabilities were then used to derive the adjusted risk ratios (Adj. RR) using the nlcom command in Stata 14. The comparison of those receiving breast milk only at six months was calculated the same way. As detailed below in the results, a total of 230 peers supported a mean of two mothers, so although planned for, we did not consider it necessary to adjust for a cluster effect; however further analysis was conducted to confirm if taking potential clustering into effect made a difference to the estimated Adj. RRs. Volunteer mother ID codes were used to denote clusters. Control mothers were each allocated an individual ID in this variable so they were each considered as a single cluster, as recommended in a recent paper [24]. There was no change in point estimates; so the Adj. RRs do not include adjustment for cluster.

Survival analysis was used to explore time to cessation of any breast milk feeding, with the outcome censored at six months postpartum. The Cox proportional hazards model was used to estimate a hazard ratio (HR) for risk of cessation of any breast milk feeding, adjusted for breastfeeding intention and formula given (prior to recruitment), with the proportional hazards assumption checked and confirmed. All primary and secondary outcomes are presented as adjusted results.

Intervention fidelity variables are presented as numbers and percentages, with mean and standard deviation used where appropriate. Cost-effectiveness data and women's views of receiving and providing the intervention will be reported elsewhere. A Data Monitoring Committee oversaw the study. The trial is registered with the Australian New Zealand Clinical Trials Registry: ACTRN 12612001024831.

3. Results

Between Feb 14, 2013 and Dec 15 2015, we recruited and randomised 1157 women to the trial: 577 to telephone-based peer support and 580 to usual care (Fig. 1). Of the 13,637 women assessed for eligibility, the most common reason for ineligibility was multiparity (6672 [65%] of 10,212). Of those eligible and approached, 1157 [48%] of 2433 agreed to participate. Randomisation by site was as follows (number assigned to peer support/number assigned to usual care): Royal Women's Hospital, $n = 382/382$; Monash Health, $n = 113/114$; Sunshine Hospital, $n = 82/84$. Five women (three in the peer support group and two in usual care) were found to be ineligible after randomisation and subsequently excluded; one woman from each trial arm was found to have had a postpartum haemorrhage >1000 ml, one woman in usual care was an antenatal member of the ABA, and in the intervention arm one participant was multiparous and one participant's infant remained in the neonatal special care unit following maternal hospital discharge. Overall, 1152 women were available for the primary analysis (574 in the peer support group and 578 in the usual care group). At six months 501 women (87%) in the peer support group and 515 in the usual care group (89%) completed the telephone interview.

Baseline characteristics were similar between groups (Table 1). A higher proportion of infants of women assigned to usual care had received infant formula prior to recruitment (28% compared with 22%) and more women assigned to usual care planned to breastfeed for six months or more (81% compared with 76%).

A total of 230 peer volunteers (of 246 trained) provided support to new mothers. The volunteers were matched with mothers a mean of 3.2 days postpartum (sd 2.97 days), with 85% matched within four days of birth. The mean time to the first telephone contact was 7 days

after birth (sd 4.4 days), with 73% receiving a call within a week of giving birth. Participation in the program wasn't necessarily continuous, as volunteers were able to take breaks from supporting participants based on their own personal or family needs. The peer volunteer participation intensity is therefore more accurately measured by how many mothers each volunteer was allocated and supported. Peers supported a mean of 2 mothers (range 0 to 11). The number of participants supported at any one time by a peer depended on the peer's availability and the needs of her currently supported mothers. Each mother received six calls on average (defined here as spoken verbal contacts between mother and volunteer), and for the 64% whose support continued beyond four weeks, the median number of calls was higher with increasing duration of participation, with a median of 11 calls for those whose support continued for 20 weeks or more (Table 2). One-third of the volunteer/participant pairs ($n = 196$) maintained contact for the planned 26 weeks, including two volunteer/participant pairs who communicated almost solely by text message, and 209 volunteer/mother pairs (36%) had contact for less than four weeks (including 61 pairs where no contact was made). Known reasons for discontinuing contact before six months (once established) included: [1] the volunteer no longer being able to contact the mother ($n = 195/319$, 61%); [2] the mother having ceased breastfeeding ($n = 35/319$, 11%); [3] the mother requesting to discontinue calls (29/319, 9%); [4] the volunteer being unable to continue to provide support ($n = 19/319$, 6%); and [5] other varied reasons ($n = 44$). Where contact was never established ($n = 61$), the most common reason was the volunteer being unable to contact the mother ($n = 38/61$, 62%) due to telephone difficulties (change of number, phone no longer working) or no response. One woman requested not to receive support, and two indicated they were too busy to participate. In the other 20 instances, it is not known why support did not commence. Of the 2112 calls recorded on returned call logs, 294 calls were initiated by the participant (not the peer); however it is not known if this was women reactively seeking support in these instances, as the call may have been pre-planned by an exchange of text messages.

More infants of women assigned to proactive telephone-based peer support were receiving any breast milk at six months of age (376 [75%] of 501 assigned to peer support vs 354 [69%] of 515 assigned to usual care; Adj. RR 1·10; 95% CI 1·02, 1·18) (Table 3). There was weaker evidence of an association with infants receiving only breast milk (Adj. RR 1·10; 95% CI 0·97, 1·23). Women in the peer support group had a 23% lower risk of ceasing breast milk feeding than those in the usual care group (Adj. HR 0·77; 95% CI 0·61, 0·97, censored at 26 weeks) (shown graphically in Fig. 2). Adjusting for a potential peer clustering

Table 1
Participant characteristics.

Characteristic	Intervention ($n = 574$)	Control ($n = 578$)
Maternal age at recruitment (years) mean (SD)	31·0 (5·0)	31·2 (4·7)
Married or living with partner	548 (95%)	537 (93%)
Education level graduate degree or higher	370 (64%)	404 (70%)
Household weekly income pre-tax ($AUD)		
Less than $1000	108 (19%)	104 (18%)
$1000 to $1999	200 (35%)	187 (32%)
$2000 or more	199 (35%)	226 (39%)
Declined to answer	67 (12%)	61 (11%)
Pension or benefit ($n = 507/517$)	37 (7%)	26 (5%)
Born in Australia	275 (48%)	243 (42%)
English as first language	349 (61%)	354 (61%)
Smoked pre-pregnancy	77 (13%)	74 (13%)
Maternal BMI pre-pregnancy ($n = 539/559$)		
Underweight (<18.5)	29 (5%)	30 (5%)
Normal range (18.5–24.99)	362 (67%)	365 (65%)
Overweight (25–29.99)	91 (17%)	113 (20%)
Obese (≥30)	57 (11%)	51 (9%)
Onset of labour - spontaneous	296 (52%)	286 (50%)
Epidural analgesia for labour	255 (44%)	246 (43%)
Caesarean birth ($n = 573/577$)	162 (28%)	160 (28%)
Baby gestation at birth (weeks) ($n = 574/575$) mean(SD)	39·5 (1·2)	39·4 (1·2)
Birthweight (grams) mean (SD)	3395 (453·7)	3380 (486·4)
Infant skin-to-skin immediately after birth	531 (93%)	535 (93%)
Infant admitted to neonatal/special care nursery	33 (6%)	41 (7%)
Received infant formula since birth, before recruitment	127 (22%)	164 (28%)
Plan to breastfeed six months or more	435 (76%)	468 (81%)

Data are n (%) or mean (SD). BMI = body mass index. Different n given where $n <$ column n.

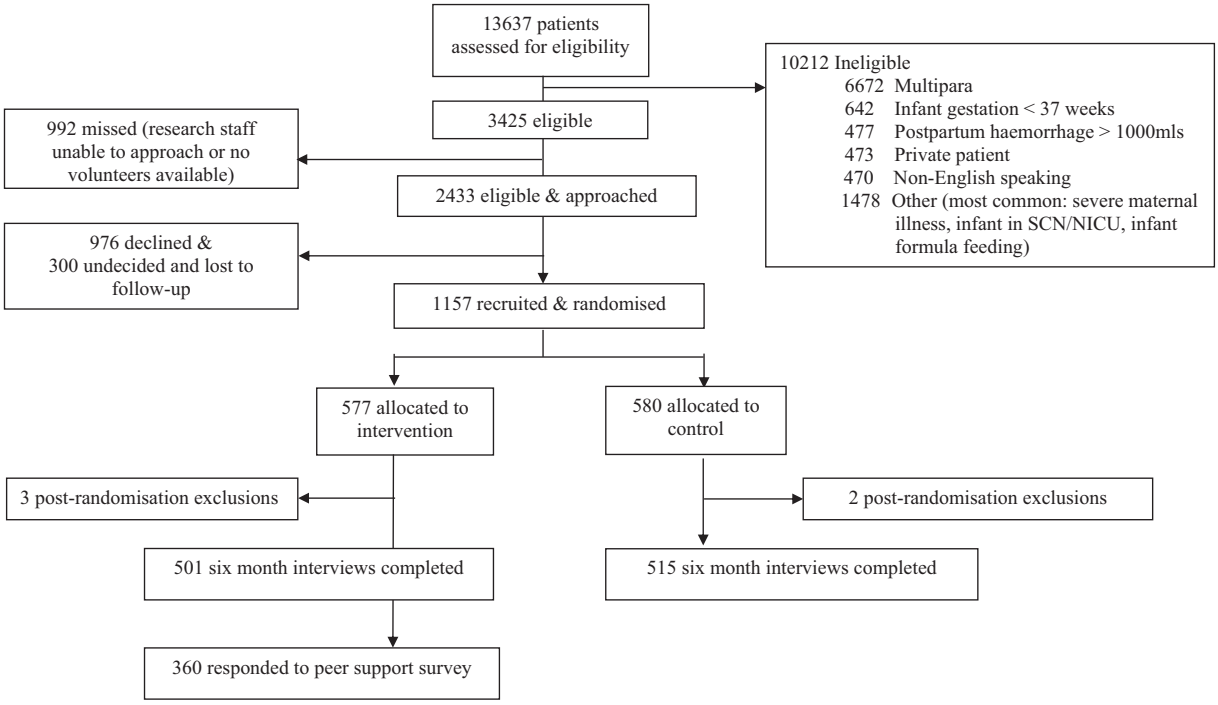


Fig. 1. Participant flow chart.

effect made no difference to the point estimates, so none of the results are presented adjusted for cluster.

Other infant feeding outcomes are reported in Table 4. The reasons reported for ceasing breastfeeding by six months were similar in the two groups. Self-reported difficulties encountered with breastfeeding were also similar in each group (401 women in peer support group [80%] experienced difficulties as did 429 in the usual care group [83%]), as were a number of other infant feeding outcomes. Sources of infant feeding advice or help are also shown (Table 4).

4. Discussion

We found that infants of first time mothers assigned to receive proactive telephone-based peer support for breastfeeding in the six months following birth were more likely to be receiving any breast milk at six months of age compared with women assigned to usual care. Women in the peer support group also had a longer duration of breastfeeding (censored at six months). There was weak evidence of an effect on infants receiving breast milk as their only milk feeding at six months of age.

The RUBY peer support intervention was planned to be delivered over a period of six months; however, of the women allocated to the intervention group, only one third of participant/volunteer pairs maintained contact for this length of time, and in one in ten cases, peer volunteers could not establish contact with mothers they had been allocated to support. Despite this, and with the varied 'dose' of peer support received, the intervention tested increased the proportion of women breastfeeding at six months – a finding similar to the Canadian RCT on which the current trial was modelled [12].

Our study adds important data to the most recent Cochrane review of breastfeeding, "Support for healthy breastfeeding mothers with healthy term babies", that concluded support provided predominantly by telephone is not more effective than usual care in increasing any breast milk feeding up to six months [10]. Our finding that infants of women in the intervention group were more likely to be receiving some breast milk at six months of age provide data from a significant number of women to add to the next update of this meta-analysis. In particular, the data will support further analysis of proactive (compared to reactive) telephone-based support, as well as lay versus professional support. Similarly, our findings will add to any update of the systematic review of peer support for breastfeeding continuation by Jolly et al. [11]; two out of the three key findings of that review are supported by our findings – that breastfeeding continuation was increased by peer support provided in the postnatal period only, and with at least 5 planned contacts. Our findings additionally demonstrate the potential for peer support to improve breastfeeding outcomes in a high-income setting. Given similar proportions of women in each group reported experiencing a breastfeeding problem, this trial also provides evidence that one underlying mechanism of peer support is the peers assisting women to persevere through their difficulties and continue to breastfeed.

There is increasing literature on the importance of social relationships in both maintaining good health and in treating disease [25], and social support theory suggests that social connectedness and supportive interpersonal relationships are associated with more favourable health outcomes [26]. Dennis suggests that peer support is embedded in the social relationship construct, and that the peer support in the health context is a 'created' social relationship designed with a health outcome in mind [25]. Based on this, and Dennis' original peer support RCT [12], the peer volunteers in the RUBY study were trained to provide 'informational, emotional and appraisal' support in the created social relationship, which we consider to be the underlying mechanism aimed at facilitating wellbeing and social connectedness, and leading to improved breastfeeding outcomes. Using their experiential knowledge and training, the peers were able to offer a range of suggestions and strategies on parenting and feeding issues faced by the new mothers, with volunteer training emphasising the need to support the mother to come to her own decisions, and to refer the mother on for professional support as needed. Volunteers had been trained to provide emotional support through active listening, expressions of empathy and caring.

With health agencies under increasing pressure to deliver care in an efficient and cost-effective manner, a peer support intervention for breastfeeding women, such as that tested in our study, could greatly assist agencies wishing to 'protect, promote and support' breastfeeding. When contemplating the implementation and sustainability of a program of telephone-based peer support for breastfeeding, agencies should take this model into consideration; peer support offers a low-cost opportunity for long-term support across the first six months postpartum. In this 'real world' trial, where 10% of participants chose not to engage with their allocated peer supporter, and only one third of the relationships lasted the planned potential six months, the intervention resulted in a 6% absolute increase in breast milk feeding at six months. While this was less than the 14% increase reported in the similar Canadian study [12], our findings showed an increase sustained to six months (the Canadian study measured infant feeding to only three months), and that women in the peer support group had a 23% lower risk of ceasing breast milk feeding than those in the usual care group, so we consider that further implementation of this model is a viable option for scale-up, and one that is not overly burdensome on peer volunteers. If applied to the Australian context, with more than 300,000 births per year [27], a 6% increase in breast milk feeding would translate to at least 18,000 more infants receiving breast milk to at least six months, with all the benefits that confers.

The findings of our study should be interpreted in context – we had a selected group of primiparous women from three public maternity facilities in Melbourne, Australia. It is not possible to say if the results would be the same in a different population. In light of the increasing gap in breastfeeding duration between the most and least disadvantaged groups in Australia [28], we deliberately chose these sites given they provide care to relatively disadvantaged women, although no measures of social circumstance were applied to trial eligibility criteria. Compared to all women giving birth in Australia, the women in this study were of a similar age (31 years vs 30.5 years for all women), had a similar rate of onset of spontaneous labour (51% vs 48% nationally); and were less likely to be overweight or obese (28% vs 45%) or have a caesarean birth (28% vs 34%) (although the national figures include multiparous women) [27]. The women who participated were less likely to have an average weekly household income less than $1000 AUD (19% vs 32% nationally [although the latter includes all age groups]) [29].

It was not possible to mask the participants to trial arm due to the nature of the intervention, however the investigators were masked to trial arm at all stages of data collection, data cleaning and primary analysis. Breastfeeding rates in both trial arms were higher than national figures (the most recent showing that 61% of infants are receiving at least

Table 2
Intervention fidelity.

Peer support provided (intervention group only)		
Length of support	*n* (%) (*n* = 579)	Number of calls[a] median (range) (*n* = 418)
Never made contact	61 (11%)	–
Up to 4 weeks	153 (26%)	2 (1–5)
4 weeks to <8 weeks	58 (10%)[b]	4 (1–9)
8 weeks to <12 weeks	50 (9%)	7 (3–14)
12 weeks to <16 weeks	39 (7%)[b]	6.5 (1–13)
16 weeks to <20 weeks	22 (4%)	7 (3–15)
20 weeks to 26 completed weeks	196 (34%)[b]	11 (1–24)

[a] Data derived from peer volunteer call logs (*n* = 418) and when not submitted, from field notes collected directly by the volunteer coordinator at the time contact was ceased.
[b] In four instances (one each in the 8 and 16 weeks categories and two in the 26 category) only one contact was verbal; multiple texts were recorded for the subsequent support. Data are *n* (%).

Table 3
Infant feeding outcomes at 6 months.

Outcome	Intervention ($n = 501$)	Control ($n = 515$)	RR (or HR)	95% CI	Adj RR (or HR)	95% CI
Primary outcome						
Any breast milk at six months	376 (75%)	354 (69%)	1·09	1·01, 1·18	1·10[a]	1·02, 1·18
Secondary outcomes						
Only breast milk[b] at six months	268 (54%)	249 (48%)	1.11	0·98, 1·25	1.10[a]	0·97, 1·23
Duration of any breast milk feeding (survival analysis, hazard estimate for risk of ceasing, Cox regression)			HR 0·78	0·62, 0·99	HR 0·77[a]	0·61, 0·97

Data are *n* (%), RR (95% CI).
[a] Adj RR – Adjusted for breastfeeding intention, formula given (prior to recruitment), site, HR Hazard Ratio.
[b] May include solid foods and non-milk fluids.

some breast milk at six months of age [5]), suggesting a limitation, as highly motivated women were perhaps more likely to participate in the study; those who were less motivated, or planning a short duration of breastfeeding, may have been more likely to decline participation.

Our large adequately powered RCT provides evidence that volunteer lay support provided by telephone can increase breastfeeding to six months in primiparous women – an important finding given how difficult it is to increase breastfeeding duration. Offering first time mothers telephone-based support from a peer who has herself breastfed for at least six months is a relatively low-cost intervention for increasing breastfeeding maintenance in settings with high breastfeeding initiation. Given the ease with which peer volunteers were recruited, trained and retained in the study, the intervention has potential for widespread implementation at a population level in settings where breastfeeding support organisations such as ABA already exist, and could be scaled up with very little need for extra infrastructure.

Contributors

DAF and LHA conceived the project. All authors contributed to study design, including data collection tools and study processes. DAF, LHA and FM undertook the literature review. DAF, LHA, HLM, MAD, RS and LG wrote the initial funding applications. DAF and FM prepared the data and did the statistical analysis. All authors contributed to data interpretation. DAF and FM wrote the first draft of the manuscript. All authors contributed to manuscript revisions.

Declaration of Interests

We declare there are no competing interests. Funding was received from the Felton Bequest for the study, and a PhD scholarship was provided by La Trobe University.

Data Sharing Statement

Data collected for the study that contributed to this paper, including de-identified individual participant data and a data dictionary defining each field in the set, will be made available to others after publication of the paper for use by other researchers for further analysis unspecified in the RUBY publication plan, with investigator support, after ethical approval including scientific review of a proposal, and with a signed data access agreement.

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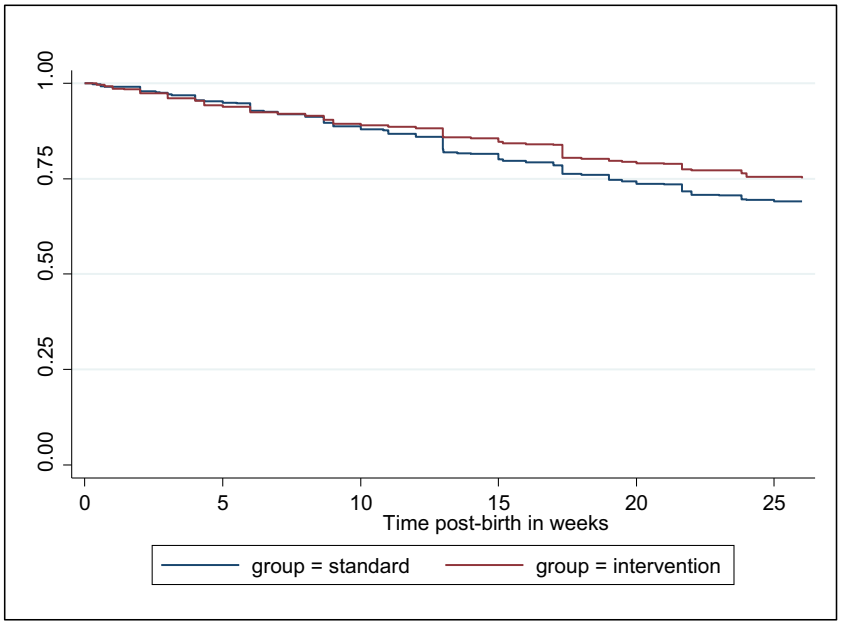


Fig. 2. Breastfeeding maintenance, by trial group (Kaplan–Meier survival estimates, censored at 26 weeks).

Table 4
Other maternal and infant outcomes at 6 months.

Outcome	Intervention ($n = 501$)	Control ($n = 515$)
Other infant feeding outcomes		
Had commenced solids by 26 weeks ($n = 488/508$)	413 (85%)	428 (84%)
Had commenced solids before 21 weeks ($n = 488/508$)	185 (38%)	188 (37%)
Had commenced fluids other than breast milk[a] or formula before 26 weeks ($n = 499/514$)	289 (58%)	294 (57%)
Had commenced fluids other than breast milk[a] or formula before 21 weeks ($n = 495/513$)	121 (24%)	119 (23%)
Self-reported breastfeeding problems (reported at six months)[b]		
Difficulties attaching	199 (40%)	231 (45%)
Milk supply-low	132 (36%)	136 (26%)
Cracked nipples	106 (21%)	123 (24%)
Mastitis	51 (10%)	58 (11%)
Sore/painful nipples	51 (10%)	43 (8%)
Infant tongue-tie	46 (9%)	44 (9%)
Infant excess weight loss	40 (8%)	33 (6%)
Infant inadequate weight gain	35 (7%)	44 (9%)
Infant jaundice/very sleepy	34 (7%)	26 (5%)
Nipple/breast thrush	34 (7%)	33 (6%)
Infant very unsettled/reflux	31 (6%)	36 (7%)
Milk supply - too much	21 (4%)	30 (6%)
Breast refusal	16 (3%)	14 (3%)
Blocked duct	15 (3%)	26 (5%)
Other (e.g. nipple vasospasm, fussy baby, inverted nipples)[c]	123 (25%)	119 (23%)
Reasons for stopping breastfeeding (if ceased before 6 months postpartum) ($n = 125/161$)[b]		
Felt there was not enough milk/did not know if baby had enough milk	91 (73%)	119 (74%)
Unable to get baby to attach/suck/difficulties attaching baby to the breast	29 (23%)	22 (14%)
Baby didn't put on enough weight	18 (14%)	17 (11%)
Baby lost interest/always looking around/stopping & starting feed	13 (10%)	14 (9%)
Had to return to work	12 (10%)	22 (14%)
Feeling run down/tired/exhausted	10 (8%)	22 (14%)
Did not want to breastfeed/did not want to breastfeed any longer	10 (8%)	10 (6%)
Mental health-stressful/anxiety	7 (6%)	14 (8%)
Mastitis	6 (5%)	6 (4%)
Advice from health professional	5 (4%)	3 (2%)
Nipple pain	5 (4%)	14 (9%)
Taking medication	2 (2%)	8 (5%)
Other	25 (20%)	39 (24%)
Maternal characteristics at six months		
EPDS (percentage of women with score ≥ 13) ($n = 485/504$)	34 (7%)	23 (5%)
In paid work, any fraction ($n = 496/512$)	114 (23%)	117 (23%)
Smoking currently ($n = 495/511$)	34 (8%)	30 (7%)
Had sought help or advice on infant feeding since leaving hospital after the birth ($n = 500/514$)	451 (90%)	436 (85%)[d]
Sources of help or advice on infant feeding		
Asked own mother or other family member for infant feeding advice ($n = 446/434$)	111 (25%)	136 (31%)[d]
Used internet sites for advice ($n = 441/426$)	110 (25%)	131 (31%)[d]
Saw lactation consultant at birth hospital ($n = 442/424$)	98 (22%)	127 (30%)[d]
Rang ABA telephone helpline ($n = 441/423$)	96 (22%)	88 (21%)
Saw lactation consultant in local government area of residence ($n = 440/423$)	54 (12%)	74 (17%)[d]
Asked other mothers for infant feeding advice ($n = 444/425$)	75 (17%)	73 (17%)
Read books for advice ($n = 434/415$)	35 (8%)	43 (10%)

Data are *n* (%).
[a] 99% in both groups had received water and 6% intervention/5% control had received fruit juice.
[b] Could have more than one response, thus % can add to more than 100.
[c] Any category with <15 respondents is classified in 'Other' category.
[d] *p*-Value from Chi-square comparison ≤0.05.

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