The RUBY study - Ringing Up about Breastfeeding early: a multi-site randomised controlled trial of telephone peer support for breastfeeding

Danish Association of Certified Lactation Consultants
ODENSE Feb 2020
Researchers and collaborating organisations

<table>
<thead>
<tr>
<th>Principal Researchers</th>
<th>Judith Lumley Centre</th>
<th>Prof Della Forster</th>
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<tr>
<td></td>
<td></td>
<td>Prof Helen McLachlan</td>
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<td></td>
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<td>Dr Mary-Ann Davey</td>
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<td></td>
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<td>Assoc Prof Lisa Amir</td>
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<td></td>
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<td>Prof Rhonda Small</td>
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<tr>
<td>Deakin University</td>
<td></td>
<td>Dr Lisa Gold</td>
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<td>University of Toronto</td>
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<td>Prof Cindy-Lee Dennis</td>
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<thead>
<tr>
<th>Associate researchers</th>
<th>Australian Breastfeeding Association (ABA)</th>
<th>Kate Mortensen</th>
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<tr>
<td></td>
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<td>Nanette Shone</td>
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<td>Royal Women’s Hospital</td>
<td>Anita Moorhead</td>
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<td>Fiona McLardie-Hore</td>
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<td></td>
<td>Western Health</td>
<td>Patrice Hickey</td>
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<td>Jenny Tenni</td>
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<td>Monash Health</td>
<td>Prof Chris East</td>
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<td>La Trobe University</td>
<td>Dr Touran Shafiei</td>
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<td>Heather Grimes</td>
</tr>
</tbody>
</table>

Funding

Felton Bequest, Royal Women's Hospital, La Trobe University
Topics covered in this talk

The RUBY randomised controlled trial (RUBY: Ringing Up about Breastfeeding early)

• Background of RUBY study and previous evidence
• Study aims and methods
• Intervention fidelity (process evaluation)
• Primary study outcomes

Women’s views of receiving telephone-based peer support
• Based on PhD candidate’s work (Fiona McLardie-Hore)

Women’s views of providing telephone-based peer support
• Based on PhD candidate’s work (Heather Grimes)
Background

- Breastfeeding offers significant health and economic benefits
- Effective strategies to increase breastfeeding maintenance in high-income countries have proven complex
- Breastfeeding **duration** in most high-income countries remains shorter compared to low-income countries
- Socially disadvantaged babies are more likely to **have poorer health outcomes**, as well as being less likely to be breastfed
Background

• Increasing global breastfeeding rates is fundamental to achieving United Nations Sustainable Development goals by 2030

• In Australia breastfeeding rates had not changed for 15-20 years until recently . . .
  
  • Breastfeeding is now slightly higher, but the issue is the *increasing gap between families in lower and higher income groups*

We have the ‘Australian National Breastfeeding Strategy 2019 and beyond’
Breastfeeding initiation and duration in Australia

Percent

21.3% stopped by 1 month completed

Completed months

Initiation

Australian National Infant Feeding Survey 2010, Australian Institute of Health and Welfare
Breastfeeding initiation and duration, by income

*Australian National Infant Feeding Survey 2010. Australian Institute of Health and Welfare*
Evidence before we started RUBY study

- Limited evidence on how to maintain breastfeeding in countries with intermediate to high breastfeeding initiation.

- Many strategies aimed at increasing breastfeeding duration have *not* been successful.

- The peer support studies with positive outcomes – have limited relevance to the Australian (and Danish) context.

- 2 RCTs relevant ...
  
  - UK study of access to lay breastfeeding support network: no impact (approach *not proactive*) (Graffy et.al, 2004)
  
  - Canadian study of *proactive* telephone support by peers who had breastfed, and trained to provide support: 14% difference in breastfeeding at 3 months, 81% compared to 67% in the control group (Dennis et.al, 2004)
Proactive support

RUBY was the first Australian RCT to test the effectiveness of a proactive approach to peer support for breastfeeding.

A proactive approach here means women did not have to seek support for breastfeeding – the support was actively provided by peer volunteers – other mothers who had breastfed themselves (more details later).

Often the women who are most likely to cease breastfeeding early are also the ones who do not seek support and advice.

This is what was provided in the RUBY study – support that did not have to be asked for proactive support.
Evidence pre-RUBY publication: Cochrane review 2017 (McFadden)

- 73 studies in 29 countries of differing income levels and different breastfeeding initiation and duration
- Overall conclusion: breastfeeding support increases duration and exclusivity of breastfeeding to six months
  - Support likely to be more effective in settings with high initiation
  - Support by professional or lay/peer supporters, or combination of both likely to be effective
  - Face-to-face support more likely to increase breastfeeding than telephone support

*But effect size varied greatly between trials and settings*

3 predominantly telephone support studies found NO difference in any or only breastfeeding at 6 months
Cochrane review (pre-RUBY publication)

Telephone support... no difference in any breastfeeding or only breastfeeding at 6 months.

### Analysis 3.1. Comparison 3 All forms of support versus usual care: SUBGROUP ANALYSIS - type of support, Outcome 1 Stopping any breastfeeding before last study assessment up to 6 months.

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Support</th>
<th>Usual care</th>
<th>Risk Ratio M-H</th>
<th>Weight</th>
<th>Risk Ratio M-H</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n/N</td>
<td>n/N</td>
<td>Random 95% CI</td>
<td></td>
<td>Random 95% CI</td>
</tr>
<tr>
<td>I Predominantly telephone support</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dennis 2002</td>
<td>25/132</td>
<td>43/126</td>
<td>0.6 % 0.36 [0.56, 0.85]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bunik 2010</td>
<td>116/161</td>
<td>113/180</td>
<td>2.6 % 0.99 [1.33]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Di Meglio 2010</td>
<td>33/38</td>
<td>40/40</td>
<td>2.9 % 0.76 [0.99]</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Subtotal (95% CI)</strong></td>
<td><strong>331</strong></td>
<td><strong>346</strong></td>
<td><strong>6.1 % 0.87 [0.65, 1.17]</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total events: 174 (Support), 196 (Usual care)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heterogeneity: Tau² = 0.05; Chi² = 14.04, df = 2 (P = 0.00089); I² = 86%</td>
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<td></td>
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</tbody>
</table>

### Analysis 3.2. Comparison 3 All forms of support versus usual care: SUBGROUP ANALYSIS - type of support, Outcome 2 Stopping exclusive breastfeeding by last study assessment up to 6 months.

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Support</th>
<th>Usual care</th>
<th>Risk Ratio M-H</th>
<th>Weight</th>
<th>Risk Ratio M-H</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n/N</td>
<td>n/N</td>
<td>Random 95% CI</td>
<td></td>
<td>Random 95% CI</td>
</tr>
<tr>
<td>I Predominantly telephone support</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Di Meglio 2010</td>
<td>38/38</td>
<td>40/40</td>
<td>2.7 % 0.40 [0.39, 0.41]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bunik 2010</td>
<td>161/161</td>
<td>189/180</td>
<td>5.6 % 0.99 [1.01]</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Subtotal (95% CI)</strong></td>
<td><strong>199</strong></td>
<td><strong>220</strong></td>
<td><strong>5.6 % 1.00 [0.99, 1.01]</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total events: 199 (Support), 220 (Usual care)</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Heterogeneity: Tau² = 0.0; Chi² = 0.0; df = 1 (P = 1.00); I² = 0.0%</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Test for overall effect: Z = 0.0 (P = 1.0)</td>
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</tbody>
</table>
Primary aim of RUBY study

To determine whether
• proactive peer support
• provided in the postnatal period
• by telephone
• increased the proportion of infants who were breastfed for at least six months
Secondary aims

To determine if the intervention:

- Increases mean duration of breastfeeding
- Increases exclusive breastfeeding at 6 months

To evaluate the cost effectiveness of peer support

We also

- Explored the views and experiences of mothers participating in the trial
- Explored the views and experiences of volunteers providing telephone support
- Collected data on other outcomes e.g. infant and maternal health outcomes, health service use
Study design

Two-arm, multi-site randomised controlled trial

Stratified by site

Sites chosen with aim of including women from lower socio-economic circumstances (all in Melbourne, Australia):

- Monash Health – Clayton Campus
- Royal Women’s Hospital – Parkville Campus
- Western Health – Sunshine Campus
Study participants

INCLUSION CRITERIA
First baby
Singleton
Public admission
Able to speak English
Intention to breastfeed

EXCLUSION CRITERIA
Serious maternal illness
Infant staying in hospital after mother’s discharge
Antenatal member of Australian Breastfeeding Association

Forster et al. BMC Pregnancy and Childbirth 2014, 14:177
http://www.biomedcentral.com/1471-2393/14/177

STUDY PROTOCOL
Ringing Up about Breastfeeding: a randomised controlled trial exploring early telephone peer support for breastfeeding (RUBY) – trial protocol

Della A Forster¹², Helen L McLachlan¹³, Mary-Ann Davey¹, Lisa H Amir¹*, Lisa Gold¹, Rhonda Small¹, Kate Mortensen⁵, Anita M Moorhead², Heather A Grimes¹⁶ and Fiona E McLardie-Hore²
Sample size

**Aim:** to detect 10% in proportion of infants receiving *any breast milk* at six months

**Baseline estimate for control group:** rate of *any breastfeeding* at six months in Victoria, Australia, at start of study i.e. 46%

**Detecting improved or worse outcomes:** wanted to not miss

- a 10% *increase* in breastfeeding from 46% in the control group to 56% in the intervention group; or

- a 10% *decrease* in breastfeeding from 46% in the control group to 36% in the intervention group

**Considerations:** allowed 20% loss to follow up and for potential effect of ‘clustering’…so **needed 1152 women in total**
Recruitment

Eligible women recruited in postnatal wards of trial sites

- Recruitment done by research midwives employed for the study
- Women were approached, the study explained, then asked if they would like to participate

Once women consented to participate

- Background questionnaire completed
- Data was collected from medical record
- Randomised to either peer support or usual care
Usual care

- Postnatal stay 48 hours for vaginal birth, 72 hours after caesarean birth
- Access to hospital breastfeeding services
- 1-2 home visits from hospital midwives
- Maternal and Child Health Nurse support in the community
Intervention

• Usual care, *plus* telephone support from a peer volunteer
• Volunteer called the new mother 4 - 6 days after birth then 3 - 4 days after the initial call

Subsequent calls

• Weekly for first 12 weeks after birth
• Three to four weekly from 12 weeks to 6 months
• New mother could contact volunteer between scheduled calls
Providing peer support: the RUBY call schedule

<table>
<thead>
<tr>
<th>Contact Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial contact</td>
<td>Volunteer rings the new mother within 4-6 days of birth</td>
</tr>
<tr>
<td>Second contact</td>
<td>Volunteer rings new mother within 3-4 days after the initial call</td>
</tr>
<tr>
<td>Subsequent calls</td>
<td>Weekly for first 12 weeks after birth</td>
</tr>
<tr>
<td></td>
<td>Three to four weekly from 12 weeks to six months after birth</td>
</tr>
</tbody>
</table>

*New mother could contact volunteer between scheduled calls*
Volunteer selection

‘Peers’ were women who:

- had breastfed for at least six months
- had a positive attitude to breastfeeding
- were not breastfeeding experts
- attended a RUBY training session
Recruitment of volunteers

• Main method - posts on Australian Breastfeeding Association web page and Facebook (like La Leche League in Denmark)

• Volunteers expressed interest via email or phone message

• Followed up by volunteer coordinator, who screened for eligibility

• Successful applicants invited to attend training session
Recruitment of volunteers (2)

The best success was via the consumer breastfeeding association, the Australian Breastfeeding Association (ABA) as shown here.

![RUBY volunteer enquiries diagram](image-url)
Volunteer (peer) training

Delivery of training

- women who volunteered had 4 hours training
- training included groups of up to 20 women
- delivered by volunteers from ABA
- some information from research team

Training focus

- beliefs, values and respecting those of others
- positive language and confidence building
- active listening, empathy
- encouraging and supporting new mothers
- normal baby behaviour
Expectations of the volunteers

- Make regular telephone contact with the mother according to the RUBY call schedule
- Focus on emotional wellbeing, breastfeeding and parenting issues
- Refer women to existing services if required
- Record details of calls in a RUBY call log
- NOT to be a professional counsellor or support

Volunteers reimbursed $50 for each woman supported to cover call costs
Initiating contact between peer volunteers and postpartum women

- First time mothers recruited in postnatal units of participating hospitals at least 24 hours after birth
- Mothers randomised to receive ‘usual care’ or to receive peer support (‘intervention’ group)
- Research midwife emailed intervention mothers’ contact details to volunteer coordinator
- Volunteer coordinator allocated each mother (research participant) to a peer volunteer mother:
  - she received limited information – the woman’s study ID, her first name, her phone number, and her baby’s name and date of birth
  - she commenced support according the RUBY call schedule

Example of information:
Study ID: 3139
Rhiannon, phone 0427 412 571
Baby boy, “Jack", DOB 11/12/15
Data collection – research participants

Demographic data:
• questionnaire at recruitment, before randomisation

Obstetric/neonatal medical outcomes:
• from maternal and neonatal medical records

Outcome data:
• by telephone at 6 months postpartum

Economic evaluation:
• resource use data - medical record and women's self-reported use of health care and resources by 6 months postpartum

Experiences of receiving peer support (women in intervention only):
• mail out survey exploring women’s views and experiences
• face to face interviews about receiving peer support
Ringing Up about Breastfeeding: a randomised controlled trial exploring early telephone peer support for breastfeeding (RUBY) – trial protocol

Della A Forster1,3, Helen L McLachlan1,3, Mary-Ann Davey1, Lisa H Amir1, Lisa Gold4, Rhonda Small1, Kate Mortensen5, Anita M Moorhead2, Heather A Grimes6 and Fiona E McLardie-Hore2

Abstract

Background: The risks of not breastfeeding for mother and infant are well established, yet in Australia, although most women initiate breastfeeding many discontinue breastfeeding altogether and few women exclusively breastfeed to six months as recommended by the World Health Organization and Australian health authorities. We aim to determine whether proactive telephone peer support during the postnatal period increases the proportion of infants who are breastfed at six months, replicating a trial previously found to be effective in Canada.

Design/Methods: A two arm randomised controlled trial will be conducted, recruiting primiparous women who have recently given birth to a live baby, are proficient in English and are breastfeeding or intending to breastfeed. Women will be recruited in the postnatal wards of three hospitals in Melbourne, Australia and will be randomised to peer support or to ‘usual’ care. All women recruited to the trial will receive usual hospital postnatal care and infant feeding support. For the intervention group, peers will make two telephone calls within the first ten days postpartum, then weekly telephone calls until week twelve, with continued contact until six months postpartum. Primary aim: to determine whether postnatal telephone peer support increases the proportion of infants who are breastfed for at least six months. Hypothesis: that telephone peer support in the postnatal period will increase the proportion of infants receiving any breast milk at six months by 10% compared with usual care (from 46% to 56%). Outcome data will be analysed by intention to treat. A supplementary multivariate analysis will be undertaken if there are any baseline differences in the characteristics of women in the two groups which might be associated with the primary outcomes.

Discussion: The costs and health burdens of not breastfeeding fall disproportionately and increasingly on disadvantaged groups. We have therefore deliberately chosen trial sites which have a high proportion of women from disadvantaged backgrounds. This will be the first Australian randomised controlled trial to test the effectiveness and cost effectiveness of proactive peer telephone support for breastfeeding.

Trial registration: Australian and New Zealand Clinical Trials Registry ACTRN12612001024831.

Keywords: Breastfeeding, Exclusive breastfeeding, Breastfeeding rates, Peer support, Telephone, Australia
Participants assessed for eligibility
n = 13,637

Ineligible women n = 10,212 (75%)

Eligible women
n = 3425/13637 (25%)

Missed n = 992 (29%)

Eligible women approached
n = 2433/3425 (71%)

Undecided & lost to follow
n = 300 (12%)
Declined n = 973 (40%)

Randomised n = 1157/2433 (48%)
Participant flow chart (2)

Randomised n= 1157/2433 (48%)

Peer support intervention n=577 (50%)

Six month interview completed n=501/574 (87%)

Peer support survey completed n=360/501 (72%)

Post randomisation exclusion n=3

Usual care n=580 (50%)

Six month interview completed n=515/578 (89%)

Post randomisation exclusion n=2
<table>
<thead>
<tr>
<th>Participant characteristics</th>
<th>Intervention (n=574)</th>
<th>Usual care (n=578)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maternal age (mean, sd)</td>
<td>31.0 sd 5.0</td>
<td>31.2 sd 4.7</td>
</tr>
<tr>
<td>Degree or higher</td>
<td>370 64</td>
<td>404 70</td>
</tr>
<tr>
<td>Household income pre-tax ($AUS) (n=507/517)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Less than $1400/week</td>
<td>181 35</td>
<td>185 35</td>
</tr>
<tr>
<td>Pension or benefit (n=571/577)</td>
<td>37 6</td>
<td>26 4</td>
</tr>
<tr>
<td>Born in Australia</td>
<td>275 48</td>
<td>243 42</td>
</tr>
<tr>
<td>English first language</td>
<td>349 60</td>
<td>354 61</td>
</tr>
<tr>
<td>Smoked pre-pregnancy</td>
<td>77 13</td>
<td>74 13</td>
</tr>
<tr>
<td>Participant characteristics 2</td>
<td>Intervention (n=574)</td>
<td>Control (n=578)</td>
</tr>
<tr>
<td>------------------------------</td>
<td>----------------------</td>
<td>-----------------</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td><strong>Onset of labour - spontaneous</strong></td>
<td>296</td>
<td>52</td>
</tr>
<tr>
<td><strong>Epidural /spinal for labour analgesia</strong></td>
<td>314</td>
<td>55</td>
</tr>
<tr>
<td><strong>Caesarean birth</strong></td>
<td>162</td>
<td>28</td>
</tr>
<tr>
<td><strong>Body mass index (n=539/559)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Underweight (&lt; 18.5)</td>
<td>30</td>
<td>5</td>
</tr>
<tr>
<td>Normal range (18.5 – 24.99)</td>
<td>362</td>
<td>67</td>
</tr>
<tr>
<td>Overweight (25 – 29.99)</td>
<td>91</td>
<td>17</td>
</tr>
<tr>
<td>Obese (&gt; 30)</td>
<td>57</td>
<td>11</td>
</tr>
<tr>
<td>Participant characteristics 3</td>
<td>Intervention (n=574)</td>
<td>Control (n=578)</td>
</tr>
<tr>
<td>------------------------------</td>
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<td>-----------------</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td><strong>Gestation wks</strong> (mean, sd) n=574/574</td>
<td>39.5</td>
<td><em>sd</em> 1.2</td>
</tr>
<tr>
<td><strong>Birthweight grams</strong> (mean, sd) n=573/578</td>
<td>3394</td>
<td><em>sd</em> 453</td>
</tr>
<tr>
<td><strong>Mother’s self-report</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skin to skin immediately after birth</td>
<td>531</td>
<td>93</td>
</tr>
<tr>
<td>Problems related to feeding</td>
<td>258</td>
<td>45</td>
</tr>
<tr>
<td>Desire to breastfeed very strong</td>
<td>489</td>
<td>85</td>
</tr>
<tr>
<td>Confident in ability to breastfeed</td>
<td>239</td>
<td>41</td>
</tr>
<tr>
<td>Baby had any formula since birth</td>
<td>127</td>
<td>22</td>
</tr>
<tr>
<td>Plans to breastfeed 6 mths or longer</td>
<td>435</td>
<td>76</td>
</tr>
</tbody>
</table>
Intervention fidelity

• 233 volunteers provided support to new mothers
• Each mother received an average of 6 calls (verbal contacts)
• Each volunteer supported an average of 2 mothers (range 0 to 11)
• The mean time to first telephone contact was 7 days after birth (SD 4.4 days)
• 40% of mothers had between 7 – 20 connections
• 2,396 calls made in total
# Intervention fidelity

<table>
<thead>
<tr>
<th>Duration of support</th>
<th>n  (%)  (n=582)</th>
<th>Number of calls</th>
</tr>
</thead>
<tbody>
<tr>
<td>Never made contact</td>
<td>60 (10%)</td>
<td>-</td>
</tr>
<tr>
<td>Up to 4 weeks</td>
<td>154 (26%)</td>
<td>2 (1-5)</td>
</tr>
<tr>
<td>4 weeks to &lt; 8 weeks</td>
<td>59 (10%) ###</td>
<td>4 (1-9)</td>
</tr>
<tr>
<td>8 weeks to &lt; 12 weeks</td>
<td>49 (9%)</td>
<td>7 (3-14)</td>
</tr>
<tr>
<td>12 weeks to &lt; 16 weeks</td>
<td>38 (7%) ###</td>
<td>7 (1-13)</td>
</tr>
<tr>
<td>16 weeks to &lt; 20 weeks</td>
<td>25 (4%)</td>
<td>7 (3-15)</td>
</tr>
<tr>
<td>20 weeks to 26 completed weeks</td>
<td>196 (34%) ###</td>
<td>11 (1-24)</td>
</tr>
</tbody>
</table>

# Data derived from peer volunteer call logs (n=419). If not submitted, from field notes collected directly by the volunteer coordinator at the time contact was ceased. ## 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 (%).

**Note:** data derived from 419/582 (73%) returned call logs (some mothers allocated second volunteer)
Intervention fidelity

- 26 weeks completed: 34%
- Up to 20 weeks: 4%
- Up to 16 weeks: 7%
- Up to 12 weeks: 9%
- Up to 8 weeks: 10%
- Up to 4 weeks: 27%
- Never established contact: 10%
## Duration of calls

<table>
<thead>
<tr>
<th>Length of calls (minutes)</th>
<th>Number (n=2402)</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 - 5</td>
<td>408</td>
<td>17</td>
</tr>
<tr>
<td>6 - 10</td>
<td>673</td>
<td>28</td>
</tr>
<tr>
<td>11 - 15</td>
<td>456</td>
<td>19</td>
</tr>
<tr>
<td>16 - 20</td>
<td>312</td>
<td>13</td>
</tr>
<tr>
<td>21 - 25</td>
<td>216</td>
<td>9</td>
</tr>
<tr>
<td>26 - 30</td>
<td>144</td>
<td>6</td>
</tr>
<tr>
<td>31 - 35</td>
<td>48</td>
<td>2</td>
</tr>
<tr>
<td>36 - 40</td>
<td>72</td>
<td>3</td>
</tr>
<tr>
<td>41 - 45</td>
<td>24</td>
<td>1</td>
</tr>
<tr>
<td>More than 46</td>
<td>48</td>
<td>2</td>
</tr>
</tbody>
</table>

Data derived from returned peer volunteer call logs (n=358/518, 69%)

Median duration of calls was 12 minutes (n = 2402 calls)
Topics discussed during calls

- Tongue-tie
- Nipple/breast thrush
- Nipple shield
- Oversupply
- Baby unwell
- Mastitis
- Mother’s health problem
- Engorgement
- Not enough milk
- Nipple pain/damage
- General concern/anxiety
- Positioning and attachment
- Expressing
- Supply and demand
- Feed frequency
- Normal infant behaviour
- General breastfeeding information

Number of calls
<table>
<thead>
<tr>
<th>Referrals made by volunteers during calls ( (n = 2331) )</th>
<th>( n )</th>
<th>( (%)^* )</th>
</tr>
</thead>
<tbody>
<tr>
<td>No referrals made</td>
<td>1658</td>
<td>71.1</td>
</tr>
<tr>
<td>Australian Breastfeeding Association</td>
<td>378</td>
<td>16.2</td>
</tr>
<tr>
<td>Maternal and Child health</td>
<td>254</td>
<td>10.9</td>
</tr>
<tr>
<td>General practitioner</td>
<td>116</td>
<td>4.9</td>
</tr>
<tr>
<td>Hospital lactation service</td>
<td>57</td>
<td>2.4</td>
</tr>
<tr>
<td>Private lactation consultant</td>
<td>51</td>
<td>2.2</td>
</tr>
<tr>
<td>Hospital service e.g. emergency department</td>
<td>11</td>
<td>0.5</td>
</tr>
<tr>
<td>Other (s)(^+)</td>
<td>133</td>
<td>5.7</td>
</tr>
</tbody>
</table>

*Respondents could tick more than one option so could add to > 100%*

+Referrals included in ‘Other’ included to specific websites, neonatal sleep related resources, pharmacists and hospital drug information call-lines, health professionals such as paediatricians, local government resources such as maternal and child health clinics or breastfeeding drop in centres and mothers’ groups
## Outcomes

<table>
<thead>
<tr>
<th></th>
<th>Intervention (n=501)</th>
<th>Control (n=515)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td><em><em>Breastfeeding</em> at 6 months</em>*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any breast milk</td>
<td>376</td>
<td>75.1</td>
</tr>
<tr>
<td>Only breast milk</td>
<td>268</td>
<td>54.0</td>
</tr>
<tr>
<td>If not giving breast milk - age at ceasing in weeks (mean, sd) (n=135/172)</td>
<td>13.3</td>
<td>sd 8.1</td>
</tr>
<tr>
<td><strong>Edinburgh Postnatal Depression Score</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Score &gt;12 (n=485/504)</td>
<td>57</td>
<td>5.8</td>
</tr>
</tbody>
</table>

* Breast milk feeding
# Breast milk feeding at 6 months – primary outcome

<table>
<thead>
<tr>
<th></th>
<th>Intervention (n=501)</th>
<th>Control (n=515)</th>
<th>Adj. RR*</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any breast milk*</td>
<td>376 75.1</td>
<td>354 68.7</td>
<td>1.10</td>
<td>1.02, 1.18</td>
</tr>
<tr>
<td>Only breast milk*</td>
<td>268 53.5</td>
<td>249 48.4</td>
<td>1.10</td>
<td>0.97, 1.23</td>
</tr>
</tbody>
</table>

* Adjusted for breastfeeding intention, formula given (prior to recruitment), site, EPDS, born in Australia. NB: may include solid foods and non-milk fluids
Duration any breast milk feeding – survival analysis

* Adjusted HR 0.77, 95% CI 0.61, 0.97   (censored at 26 weeks):

* Adjusted for breastfeeding intention, formula given (prior to recruitment), site, EPDS, born in Australia. NB: may include solid foods and non-milk fluids
## Reasons for ceasing breastfeeding before 6 months

<table>
<thead>
<tr>
<th>Reasons (if ceased before 6 months postpartum)</th>
<th>Peer support</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>(n=125/161)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Felt not enough milk/ did not know if enough milk</td>
<td>91 (73%)</td>
<td>119 (74%)</td>
</tr>
<tr>
<td>Difficulties attaching baby to the breast</td>
<td>29 (23%)</td>
<td>22 (14%)</td>
</tr>
<tr>
<td>Baby didn’t put on enough weight</td>
<td>18 (14%)</td>
<td>17 (11%)</td>
</tr>
<tr>
<td>Baby lost interest/looking around/ stopping &amp; starting</td>
<td>13 (10%)</td>
<td>14 (9%)</td>
</tr>
<tr>
<td>Had to return to work</td>
<td>12 (10%)</td>
<td>22 (14%)</td>
</tr>
<tr>
<td>Feeling run down/tired/exhausted</td>
<td>10 (8%)</td>
<td>22 (14%)</td>
</tr>
<tr>
<td>Did not want to breastfeed/ or breastfeed any longer</td>
<td>10 (8%)</td>
<td>10 (6.2%)</td>
</tr>
<tr>
<td>Mental health-stressful/anxiety</td>
<td>7 (6%)</td>
<td>14 (8%)</td>
</tr>
<tr>
<td>Mastitis</td>
<td>6 (5%)</td>
<td>6 (4%)</td>
</tr>
<tr>
<td>Advice from health professional</td>
<td>5 (4%)</td>
<td>3 (2%)</td>
</tr>
<tr>
<td>Nipple pain</td>
<td>5 (4%)</td>
<td>14 (9%)</td>
</tr>
<tr>
<td>Taking medication</td>
<td>2 (2%)</td>
<td>8 (5%)</td>
</tr>
<tr>
<td>Other</td>
<td>25 (20%)</td>
<td>39 (24%)</td>
</tr>
</tbody>
</table>
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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f Australian Breastfeeding Association, Level 3, Suite 2150 Albert Road, South Melbourne, Victoria 3205, Australia
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h Monash University and Midwifery, Monash University and Monash Health, Australia

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Telephone intervention
Peer volunteer
Community-based

ABSTRACT

Background: Breastfeeding rates are suboptimal internationally, and many infants are not receiving any breast milk by six months of age. Few interventions increase breastfeeding duration, particularly where there is a 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 it would be a potentially sustainable model in many settings. We aimed to determine whether proactive telephone-based peer support during the neonatal 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 part of 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 12612001-024831.

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. Funding: The Felton Bequest, Australia, philanthropic donation and La Trobe University grant.

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Mothers’ perspectives of peer support
Exploring the outcomes, views and experiences of women receiving proactive telephone peer support for breastfeeding

Fiona McLardie-Hore: PhD candidate and RUBY study coordinator

Supervisors
Della Forster, Helen McLachlan, Touran Shafiei

Breastfeeding outcomes
Women’s views and satisfaction with support
Women’s experience of receiving support
Economic analysis
RUBY data collection

Recruitment interview prior to randomisation
- participant characteristics
- intended duration of BF
- confidence in ability to breastfeed
- partner & family/friends support for breastfeeding
- obstetric and neonatal outcomes

Six month postpartum telephone interview
- feeding outcomes
- mother and baby health data including health service use
- Edinburgh Postnatal Depression Score

Peer support mail out survey
- Nature of contact
- discussions with peer
- Positive/negatives of support
- Peer support evaluation inventory
Women’s views and experience of support
Views and experiences postal survey

RUBY study
Exploring your views and experiences of telephone support

Thank you for being a part of the RUBY study.

As with the other questionnaires for the study, we are interested in your views and experiences no matter what they are — there are no right or wrong answers.

If there are any questions you would prefer not to answer just skip these and move on to the next question.

1. What things did you talk about with the volunteer mother? (Tick all that apply)
   - Baby eating and the breast
   - Baby behaviour
   - Lactation
   - She taught me where to get help
   - Selling my baby
   - My milk supply
   - How often to feed my baby
   - Feeding pain or breast pain
   - She reassured me
   - Baby sleep patterns
   - Support from my family
   - Baby care
   - She gave me emotional support
   - My emotional wellbeing
   - Other (please describe)

2. We want to know how helpful you found these calls. Overall on a scale of: 1 (Not at all helpful) to 5 (Very helpful) how would you describe the telephone support you received?
   - Not at all helpful
   - 1
   - 2
   - 3
   - 4
   - 5
   - Very helpful

3. Was there anything you found particularly positive (helpful) about these calls?
   - No
   - Yes (please describe)

4. Was there anything you found particularly negative (not helpful) about these calls?
   - No
   - Yes (please describe)

Directions:
In answering the following questions, please think about your peer support experience. The following questions ask you to pick a number which best describes your feelings. While you may not find an answer that exactly matches your feelings, please indicate the number which comes closest to how you feel.

Example: My peer listened to me talk about my feelings or concerns

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree

When answering these questions think specifically about the conversations you had with your peer volunteer:

In general, my peer:

1. Listened to me talk about my feelings or concerns
2. Helped me find that I was not alone in my situation
3. Gave me practical advice
4. Helped me feel that what I was going through was “normal”
5. Gave me a way to express my feelings
6. Offered advice about how I was doing
7. Told me that I did something well
8. Assisted me to solve the problems or concerns
9. Offered support at a personal level of mine
10. Helped me with practical information
11. Helped me feel that I was not alone in my situation
12. Told me what was useful for my current situation
13. Helped me to find a way to do things
14. Helped me to understand what was going on
15. Told me that help was available when I needed it

PS_Survey_V5: 02/10/2013
<table>
<thead>
<tr>
<th>Participant characteristics</th>
<th>Respondents (n=360)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maternal age at recruitment (years) mean (SD)</td>
<td>31.9 (sd 4.6)</td>
</tr>
<tr>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Married or living with partner</td>
<td>349 96.9</td>
</tr>
<tr>
<td>Education level graduate degree or higher</td>
<td>256 71.3</td>
</tr>
<tr>
<td>Household weekly income pre-tax ($AUD) Less than $1400</td>
<td>83 23.0</td>
</tr>
<tr>
<td>Born in Australia</td>
<td>192 53.3</td>
</tr>
<tr>
<td>English as first language</td>
<td>245 68.1</td>
</tr>
<tr>
<td>Baby had formula since birth, before recruitment</td>
<td>62 17.2</td>
</tr>
<tr>
<td>Plans to breastfeed 6 months or more</td>
<td>281 78.1</td>
</tr>
<tr>
<td>Level of breastfeeding support from family and friends</td>
<td></td>
</tr>
<tr>
<td>No support</td>
<td>4 1.1</td>
</tr>
<tr>
<td>A little support</td>
<td>33 9.2</td>
</tr>
<tr>
<td>Moderate support</td>
<td>62 17.2</td>
</tr>
<tr>
<td>A lot of support</td>
<td>261 72.5</td>
</tr>
</tbody>
</table>
## Women’s experience of peer support

<table>
<thead>
<tr>
<th>Outcome</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Top 3 topics discussed with the volunteer (n=341)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Milk supply</td>
<td>259</td>
<td>76</td>
</tr>
<tr>
<td>Baby behaviour</td>
<td>251</td>
<td>74</td>
</tr>
<tr>
<td>Baby attaching to the breast</td>
<td>246</td>
<td>72</td>
</tr>
<tr>
<td>Described support as helpful/very helpful (n=330)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>261</td>
<td>79</td>
</tr>
<tr>
<td>“Overall I was satisfied with my peer support experience”</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- agree/strongly agree (n=151*)</td>
<td>140</td>
<td>93</td>
</tr>
</tbody>
</table>

* Low response due to ‘Peer support experience inventory’ introduced late to survey
Women’s positive experience of receiving peer support (based on comments from 279 women)
How did you feel about the frequency of calls? n=332

- About right: 85%
- Too often: 10%
- Not often enough (I would have liked more calls): 5%

Average length of calls n=332

- 0-5 minutes: 10%
- 6-10 minutes: 13%
- 11-20 minutes: 33%
- Longer than 20 minutes: 32%
- It varied: 13%

Frequency and length of calls

ringing up about breastfeeding
Other contact with peer volunteer mother

- 40% of women (n=188) contacted the peer between scheduled calls (reactive contact)
- Of these, 20% made only one contact and 29% made two
- 59% who did make contact did so via text message (n=201/341, 59%) as well as telephone
Reason for other contact with peer

Reason for contact

- Return call: 60%
- Breastfeeding advice: 40%
- Touchbase/update: 20%
- Help with breast problem: 10%
- Advice re baby behaviour: 5%
- Needed support/reassurance: 5%
- Share baby photos: 5%
- Advice re baby health: 5%
- Thank the volunteer: 5%
- Advice re referral on: 0%
Survey of volunteer mothers
Motivation to volunteer

Volunteer Functional Inventory (VFI) used as a quantitative measure exploring volunteer mothers’ views (Clary et al., 1998)

Volunteers rated the extent to which they ‘Strongly agreed’ to ‘Strongly disagreed’ with a series of 19 statements using a 7-point scale

- 94.5% ‘Agreed’ or ‘Strongly agreed’ that they were doing something for a cause that was important to them
- 64.9% ‘Agreed’ or ‘Strongly agreed’ that their volunteer experience would be personally fulfilling
Conclusions

• Interest in volunteering to provide peer support was high.
• Volunteers' were motivated by a strong belief in the value of breastfeeding support.
• Extensive training of volunteer peers wasn’t required but they would value ongoing education.
• Though sometimes challenging, volunteers were satisfied with their experience of supporting a new mother.

Volunteers perceived peer support to be beneficial for new mothers and a worthwhile experience.
RUBY RCT summary

Proactive telephone peer support in the postnatal period associated with babies more likely to receive any breast milk at six months of age

Weaker evidence of an association with babies receiving breast milk only

Women found telephone breastfeeding support from a peer helpful and they were satisfied with the experience

Though sometimes challenging, volunteers’ were satisfied with their experience of supporting new mothers
Thank you to the Australian Breastfeeding Association

Thank you to the extremely hard working research midwives, and most importantly to the mothers and volunteers who most generously gave their time to participate in the RUBY study

Thank you to the Felton Bequest and La Trobe University for funding the project
A brief look at some of our other breastfeeding research
Key areas of breastfeeding research

1. Studies with overall breastfeeding focus
   - large RCTs e.g. ABFAB, DAME, RUBY, DOMPERIDONE
   - large cohort studies MILC
   - other focused work – BF in public, expressing and transporting EBM

2. Other studies that also measure/include breastfeeding
   - large RCTS COSMOS, group antenatal care
   - other large studies – Your Views Matter, Baggarrook
   - studies on perinatal mental health – IVY, DAISY

3. Capacity building
   - scholarship positions
   - inception of BF journal club
   - some operational funding always set aside for BF research
“Woman’s Journey” (Baggarrook Yurrongi) – example of breastfeeding research integrated with model of care research
Trials to increase breastfeeding rates

**ABFAB:** NHMRC-funded

- 3 armed RCT of education in late pregnancy
- Practical skills/Family attitudes/Standard care
- No difference in breastfeeding rates at 6 months
  
  (Forster et al. *Birth* 2004)

**SILC (Supporting Infant feeding in Local Communities):** State Government funded

- 3 armed cluster RCT in 10 local government areas
- Early MCHN home visits/visits & breastfeeding drop-in centres/standard care
- No difference at 6 months
  
  (McLachlan et al. *BMJ Open* 2016)
Studies that address problems women have with breastfeeding

Most common:

- Nipple and breast pain
- Low milk supply (“Not enough milk”)
- Concerns about medications while breastfeeding

Lisa Amir leads this work
Physical and breastfeeding problems

Women with multiple physical and breastfeeding problems across first 8 weeks experienced poorer mood at 8 weeks postpartum.

Strength of study:

- Prospective cohort design
- Rigorous adjustment for confounders.


Photo: Ahn Nguyen, Unsplash
Mastitis

Definition:
At least two breast symptoms:
- Breast pain
- Lump
- Redness

At least one systemic symptom:
- Fever
- Flu-like symptoms (myalgia, headache, lethargy, nausea, dizziness)

Incidence and determinants of mastitis

17% (206/1193) women had at least one episode in 6 months postpartum in Melbourne
(Amir et al BMC Public Health 2007)

20% (70/346) of participants developed mastitis in first 8 weeks postpartum

Increased risk of developing mastitis if they reported:
• nipple damage (RR 2.17, 95 % CI 1.21, 3.91)
• over-supply of breast milk (RR 2.60, 95 % CI 1.58, 4.29)
• nipple shield use (RR 2.93, 95 % CI 1.72, 5.01) or
• expressing several times a day (RR 1.64, 95 % CI 1.01, 2.68)
(Cullinane et al BMC Family Practice 2015)
Women's experience of lactational mastitis

‘I have never felt worse’

BACKGROUND
Mastitis is a common problem for breastfeeding women in the postpartum period.

METHODS
Ninety-four breastfeeding women participating in a case control study of mastitis provided a free text comment about their experience of mastitis. Women were recruited from the emergency department, wards or breastfeeding clinics of
Case-control study of mastitis

Free-text item:

“We are interested in your experience of mastitis. Please describe how you have been feeling and how mastitis has affected you”.

Amir LH, Lumley J. *Aust Fam Physician* 2006; 35(9): 745-47
Writing for GPs – showing what women share on social media

Recognising and managing mastitis

Mastitis is a concern for breastfeeding women and their doctors. GPs want to know which antibiotics to prescribe and when to start and stop them. Families may worry about the safety of antibiotics for the baby, whether mastitis will recur and whether the mother should be advised to stop breastfeeding and begin feeding her baby with infant formula.

**Diagnosis of mastitis**
A diagnosis of mastitis can be made if a woman has symptoms that include breast pain (a constant ache), an area of the breast

**Figure 1.** A social media post describing a new mother’s experience of mastitis. The post attracted more than 800 ‘likes’ and many comments from women with similar experiences. Courtesy Remi Peers.

**Figure 2.** The mother in Figure 1 commented, “Despite the roadblocks that can arise at the start of breastfeeding, it does get easier, and it is possible to go on to have a happy and healthy breastfeeding relationship after experiencing mastitis.”

Courtesy Remi Peers.
Breastfeeding women need medications

It is common for breastfeeding mothers to take medications. Systematic review found postpartum women reported use of medications varies widely: from 34 to 100%.

**Medicines and breastfeeding women: projects**

**GP survey**

“Decision-making is a spectrum from a straightforward decision, such as treatment of mastitis, to a complicated one requiring multiple inputs and consideration. GPs use more information seeking and collaboration in decision-making when they perceive the problem to be more complex, for example, in postnatal depression.”

Jayawickrama, Amir, Pirotta *BMC Research Notes* 2010

**Pharmacist survey**

**Content of pharmacology text books**

**Delphi study of pharmacology experts**

“The most important parameters about the infant were the age and health of the child, and those of the medicine were the safety profile and experience of use in infants. . . . Although clinicians and lay people would appreciate a simple classification scheme, in practice, decision-making about the safety of medicines for breastfeeding women is complex.”

Amir, Ryan, Barnett *Breastfeed Med* 2015
Identifying design solutions to increase women’s comfort with breastfeeding in public

A/Professor Lisa Amir
Judith Lumley Centre
Breastfeeding in public projects

2016 project: City of Bendigo and City of Melbourne, Victoria, Australia

2018 project: Royal Women’s Hospital, Melbourne

Part 1
- Survey of attitudes towards breastfeeding in public

Part 2
- Focus groups and interviews focusing on experiences of the physical environment when breastfeeding in public
- Targeting under-represented groups
  - Indigenous women
  - CALD women
  - Women with disabilities
Breastfeeding standees
Thank you for having me in Denmark for your conference!!!

Our collaborators: epidemiologists, statisticians, midwives, nurses, Lactation Consultants, maternal and child nurses, GPs, paediatricians, O&Gs, psychiatrists, pharmacists, microbiologists, other scientists, social scientists, planners, urban designer, psychologists, physiotherapists, Australian Breastfeeding Association, health services, and other community groups.

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