Maternal & Child Nutrition

DOI: 10.1111/mcn.12249

Original Article

Breastfeeding booklet and proactive phone calls for increasing exclusive breastfeeding rates: RCT protocol

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Abstract

Breastfeeding is associated with infant and maternal health benefits and considerable potential savings to health services. Despite this, only 37% of infants globally are exclusively breastfed for 6 months. Interventions are needed to improve breastfeeding rates. The aim of this study is to determine whether written breastfeeding information in pregnancy and proactive breastfeeding-focused support phone calls, provided by a health professional educated in breastfeeding management, increase exclusive breastfeeding rates at 3 months compared with general birth-related information with proactive support calls or standard care.

This is a single-centre, randomised, controlled, three-arm, superiority study with blind outcome assessment. Eligible participants will include primigravidae with singleton pregnancies who speak Croatian, attending six primary care obstetric practices. We estimate a total sample size of 459, with computer generated stratified randomisation of 153 women per arm. Participants in the intervention and active control groups will receive booklets in pregnancy, phone calls 2 weeks later, and 2, 6 and 10 weeks after birth. The primary outcome will be the proportion of women exclusively breastfeeding at 3 months. Secondary outcomes will compare: infant feeding practices and attitudes, social support, breastfeeding difficulties, breastfeeding self efficacy and utilisation of breastfeeding support services. Follow-up at 6 months will compare exclusive and any breastfeeding and utilised support services. Analysis will be by intention to treat. This trial will contribute to future evidence syntheses identifying the most effective forms of breastfeeding support.

Keywords: exclusive breastfeeding, pregnancy, randomised controlled trial, protocol, proactive support.

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Introduction

Breastfeeding is associated with health benefits for both the infant and mother (Horta *et al*. 2007; Hoddinott *et al*. 2008; Eidelman *et al*. 2012) and considerable potential savings to health services (Renfrew *et al*. 2012b; Pokhrel *et al*. 2015). Any breastfeeding (exclusive breast milk or mixed breast and formula milk) reduces the risk of gastrointestinal infection by 64% (effect lasts for 2 months after stopping breastfeeding) and reduces the risk of otitis media by 23% (Eidelman *et al*. 2012). Exclusive breastfeeding for >4 months reduces the risk of hospital admission for lower respiratory tract infections in the first year by 72%; for 3–4 months it reduces the risk of allergic disease by 27% in low-risk populations, and up to 42% in infants with a positive family history (Eidelman *et al*. 2012). Meta-analyses found that any breast milk feeding is associated with a 58% reduced risk of necrotizing enterocolitis (NEC), with reduced mortality and improved neurodevelopmental and educational outcomes. Longer term follow-up shows that breast milk is associated with reduced blood pressure levels and reduced risk of metabolic syndrome in adolescence (Horta *et al*. 2007). For mothers there is a reduced risk of breast and ovarian cancers. The relative risk of breast cancer is estimated to decrease by 4.3% for every 12 months of breastfeeding (Collaborative Group on Hormonal Factors in Breast Cancer, 2002).

Many countries have conducted intervention studies to try and improve breastfeeding rates. A 2012 Cochrane review (52 studies; 56 451 mother-infant pairs; 21 countries) found that additional professional

or lay support after birth can increase both the duration of any and exclusive breastfeeding, with proactive contacts recommended (Renfrew *et al.* 2012). For antenatal interventions, a 2012 Cochrane Systematic Review included 19 studies with 8506 women and concluded that no specific individual or group education in pregnancy can be recommended (Lumbiganon *et al.* 2012).

A 2013 Cochrane review of telephone support identified eight trials aiming to improve breastfeeding outcomes at 6 weeks, 3 and 6 months. Results were inconsistent between trials for any or exclusive breastfeeding at 6 weeks, whereas at 3 and 6 months women receiving telephone support were more likely to be exclusively breastfeeding (three trials with 411 women). We undertook a detailed review of how the delivery of the telephone support interventions was reported in the studies included in the Cochrane review (Lavender *et al.* 2013). Telephone support was delivered by health professionals in five trials (Bloom *et al.* 1982; Bunik *et al.* 2007; Rasmussen *et al.* 2011; Hoddinott *et al.* 2012b; Hoddinott *et al.* 2012a; Simonetti *et al.* 2012) by trained volunteers in three trials (Mongeon & Allard 1995; Dennis 2003; Meglio *et al.* 2009) and by both in one trial (Pugh *et al.* 2002). Interventions differed in the number of individuals delivering the intervention (single person to several), the additional training provided, the frequency (daily or monthly), length (5 min to 30 min) and duration of calls (for <2 weeks < several months) and whether calls were patient centred or used structured protocols. Whether calls were proactive or reactive was poorly reported and only the FEST pilot trial reported audio-recording call content and analysing intervention content (Hoddinott *et al.* 2012b; Hoddinott *et al.* 2012a). A literature and clinical trial registries search for this application identified two more recent trials not included in the Lavender *et al.* 2013 Cochrane review (Lavender *et al.* 2013). A Hong Kong trial randomised 722 primiparous women into three groups: (i) standard care; (ii) additional support while in hospital; and (iii) weekly post-discharge telephone calls lasting 20–30 min for 4 weeks delivered by four research nurses (Fu *et al.* 2014). Any breastfeeding increased from 67.3% to 76.2% at 1 month: odds ratio (OR) 1.63 (95%CI 1.10 to 2.41) and exclusive breastfeeding increased from 16.9% to 28.4% at 1 month: OR 1.89 (95%CI 1.24 to 2.90). A Danish randomised controlled trial (RCT) randomised 226 obese women, with one lactation consultant providing structured telephone calls over 6 months (Carlsen *et al.* 2013). The intervention increased exclusive breastfeeding at 3 months: OR 2.45 (95% CI: 1.36, 4.41; $P = 0.003$) and for partial breastfeeding at 6 months: OR 2.25 (95% CI: 1.24, 4.08; $P = 0.008$). A narrative review of interventions to increase exclusive breastfeeding concluded that postnatal interventions of long duration appeared to be the most effective (Skouteris *et al.* 2014).

The evidence for what communication, behaviour maintenance techniques or style is associated with improved breastfeeding outcomes is sparse as few studies have assessed intervention fidelity (Renfrew *et al.* 2012; Lavender *et al.* 2013; Skouteris *et al.* 2014). A qualitative meta-synthesis of women's breastfeeding experiences recommends a tailored person-centred approach (Schmied *et al.* 2011).

WHO recommends exclusive breastfeeding for 6 months; however, global rates are estimated at around 37% (UNICEF website). In Croatia, despite high initiation rates (>94%), only 14% of mothers exclusively breastfeed till 6 months (Zakarija-Grkovic 2012). Hence, in the most recent 'National Program for the Protection and Support of Breastfeeding in the Republic of Croatia (2013-6)', the following targets for *exclusive breastfeeding* have been set: 95% within

Key messages

- Exclusive breastfeeding rates decline most rapidly in the first few months after birth, hence the need for interventions to slow down this trend.
- We will test the hypothesis that the provision of written materials in pregnancy and proactive, supportive phone calls after birth will have a positive impact on exclusive breastfeeding rates at 3 months.
- To minimise the Hawthorn effect, there is an active control group with an attention matched general birth intervention delivered by the same professional, as well as a standard care group.
- We will use recognised behaviour change techniques and a mother-centred approach.

the first 48 h, 70% at 3 months and 40% at 6 months. Interventions to achieve these targets must be sought and trialled. The most commonly utilised is the UNICEF/WHO Baby-Friendly Hospital Initiative (BFHI) which has provided some initial promising results. A before-after study conducted in Croatia found that education of hospital maternity staff (Step 2 of BFHI) resulted in a doubling of exclusive breastfeeding rates during the first 48 h post-birth (Zakarija-Grkovic *et al.* 2012). Further research is required to find the most appropriate methods for sustaining breastfeeding, following discharge from hospital.

Participants and methods

Aim and hypothesis

The primary aim of this three arm study is to determine whether breastfeeding information in pregnancy, combined with proactive breastfeeding-focused support phone calls (intervention), increase exclusive breastfeeding rates at 3 months more than general birth-related information and support calls (active control) or standard care (control). The three arms are described in detail below. We hypothesise that women who receive a breastfeeding information booklet in pregnancy, in addition to proactive breastfeeding-focused telephone support at 2, 6 and 10 weeks post birth, will be more likely to be exclusively breastfeeding at 3 months in comparison to mothers who receive general written information and proactive birth related telephone support or standard care. We have chosen exclusive breastfeeding at 3 months as our main outcome because we believe that this will more accurately reflect the efficacy of the intervention than at a later period. It has also been noted that exclusive breastfeeding rates drop most rapidly in the first few months after birth hence we are interested in finding an intervention that will slow down this trend. Finally, because many mothers in Croatia introduce solids before 6 months, 3 months will provide a more accurate reflection of exclusive breastfeeding rates.

The secondary aim is to evaluate the effectiveness of the above mentioned breastfeeding intervention on the proportion of mothers providing any breast milk at 3 and 6 months postnatal age. In addition, the effect of the breastfeeding-focused intervention on maternal attitudes towards infant feeding, breastfeeding self-efficacy and prevalence of breastfeeding problems will be assessed at 3 months. We hypothesise that proactive, breastfeeding focused support in pregnancy and during the first 10 weeks after birth will increase the proportion of women who are breastfeeding at 3 and 6 months as well as improve attitudes towards infant feeding and breastfeeding self-efficacy in mothers. Finally, we expect the number of breastfeeding problems encountered by women during the first 3 months postpartum to be less among those who received breastfeeding-focused as opposed to only general information and support.

Definitions

In our study exclusive breastfeeding will refer to mothers who provide breast milk only to their infants, regardless of how it is given. If the infant is provided with any other fluids or food in addition to breast milk, in the 24 h prior to data collection, with the exception of vitamins, minerals and medicines, then the mother will be classified as breastfeeding with complementary foods, i.e. practicing 'any breastfeeding'. We have chosen the 24-h recall period because it is considered more difficult for mothers to have accurate recall of their infants' diets over longer periods of time (Hector 2011)

Trial design

This is a single-centre, randomised, controlled, three-arm, superiority study with blind outcome assessment being conducted in the County of Split-Dalmatia, Croatia, among women expecting their first baby. Within the County, women will be recruited from six sites.

Setting and participants

The County of Split-Dalmatia has a population of 454 798 and is currently serviced by two maternity hospitals: a tertiary referral hospital in the administrative centre, Split, with 4396 births in 2013 (20% caesarean rate), and a small local hospital in the town of Sinj, where 108 uncomplicated deliveries took place in the

same year. The perinatal mortality rate was 3.1/1000 live births in 2013.

Eligible participants will include primigravidae, with a singleton pregnancy, attending six (three public, three private) primary care obstetric practices between 20 and 32 weeks gestation who speak and write Croatian and are planning to reside in the County of Split-Dalmatia for at least 1 year from recruitment. Women will be recruited from the city of Split (four practices), and from the towns of Omis and Makarska (one practice each). Practices with experienced staff and high patient turnover were selected.

Exclusion criteria will include inability to communicate in Croatian by phone, planning to leave the County of Split Dalmatia within 1 year of giving birth and severe medical or psychiatric problems, identified by the primary care obstetrician, where being a participant in research might cause distress. Informed, written consent will be obtained from all women willing to participate. We have chosen first time mothers only, because numerous studies indicate that primiparity is associated with shorter breastfeeding duration and exclusivity (Agboado *et al.* 2010; Al-Sahab *et al.* 2010; Erkkola *et al.* 2010; Hauck *et al.* 2011). In addition, women who have a positive initial breastfeeding experience are more likely to breastfeed subsequent children, hence our focus on primiparas (Hure *et al.* 2013).

Standard care

In Croatia, routine antenatal care consists of women attending a primary care obstetrician and gynaecologist (O&G) of their choice (public or private) at monthly intervals until 28 to 30 weeks of pregnancy, after which they are seen every 3 weeks until 36 weeks and then weekly thereafter. In some cities, women are also seen by the local maternity hospital staff after 37 weeks of pregnancy while in other settings women only attend hospital for complications in pregnancy. Written information, on any topic, is not routinely provided to women during pregnancy, although some O&Gs hand out commercially sponsored promotional gift packs, which do not contain formula samples but are not Code compliant because they advertise breast milk substitutes (Shubber 1998). Currently, the average hospital stay is three days following a normal delivery and six days following a Caesarean section (verbal communication with hospital staff). After discharge, women are visited by their local community nurse once a week for the first 2 weeks, the first visit occurring within 72 h. At 1 month, parents take their child to their chosen primary care paediatrician, and at 6 weeks the mother sees her primary care O&G for a routine check-up. Physicians in Croatia do not receive any training in providing breastfeeding support. All visits to public providers are free of charge.

Current available breastfeeding support in the County of Split-Dalmatia consists of the option of attending any of four antenatal courses (covering a wide range of topics intended for both parents-to-be including: antenatal care, oral health, exercise in pregnancy, giving birth, the BFHI, newborn care, breastfeeding, psychological adjustment, legal rights and responsibilities) (UNICEF 2010) and giving birth in one of two Baby-Friendly hospitals. After discharge from hospital, mothers with infant feeding issues have the option of attending one of four breastfeeding support groups (two led by community nurses, one by a La Leche League leader and one by peer supporters), calling a hotline staffed by trained lay volunteers, calling a hotline staffed by trained counsellors, seeing a private physician/IBCLC and attending a 'Breastfeeding-Friendly' paediatric primary care practice (Zakarija-Grković & Pavičić Bošnjak 2013).

Recruitment procedure

Practice staff, in each of the six participating sites, will assess all expectant women for eligibility, using a standard screening form, and if eligible, will inform them, verbally and in writing, about the study. If women agree to participate they will be assigned a unique identification number which will be used at randomisation and on all questionnaires. Prior to commencement of the study, practice staff will be briefed on the use of the screening forms and study protocol. Monthly quality control meetings will be conducted with practice staff to review recruitment procedures and questionnaire compliance. A 6-month recruitment period is anticipated.

Randomisation and blinding

A list of included women will be forwarded by the practice staff to DP conducting the intervention. Eligible women will not be told by practice staff what the three different groups are; instead they will be informed that a study on infant feeding is being conducted by researchers from the University of Split School of Medicine. Randomisation of each participant to one of the three arms will be carried out according to a computer pre-generated random number list (Urbaniak & Plous 2013) for each of the six participating sites. Stratified randomisation will be conducted, based on some current known predictors of exclusive breastfeeding, namely smoking status and level of education, (Onah *et al.* 2014) to ensure good balance of participant characteristics in each group. This way 12 sequence lists will be provided for each of the six sites. The person performing the intervention will not be blinded to group allocation. Outcome data will be collected by study participants. These self-completed, coded questionnaires will then be sent to the University of Split School of Medicine, where they will be entered into a database by a medical student, unaware of group allocation.

Intervention

The intervention in this study is breastfeeding focused support in the form of printed educational material (booklet) and four proactive telephone calls. The booklet contains information based on Session 3: 'Promoting Breastfeeding During Pregnancy' of the UNICEF/WHO 20-hour Course for Maternity Staff (UNICEF & WHO 2006). Using a question and answer format, it provides evidence based information in a way that is easy to understand, including the importance of exclusive breastfeeding for the mother as well as the baby, the importance of skin-to-skin contact immediately after the birth, the importance of giving the baby colostrum, the importance of good positioning and attachment (with illustrations provided), the importance of rooming-in/keeping baby nearby, the importance of baby-led feeding, the importance of continuing breastfeeding after 6 months while giving other foods, knowing when baby is getting enough milk and the risks of not breastfeeding, including additional costs involved and the effect on the environment. In addition to the breastfeeding booklet, mothers in the intervention group will also receive a general, pregnancy booklet (described below).

The written materials and telephone support aim to provide women with the information, confidence and support required to successfully breastfeed their babies using recognised behaviour change techniques (Michie *et al.* 2013) (Table 1). The first call (during pregnancy) will begin with a general question about the woman's pregnancy, to check that she is not distressed. Next she will be asked whether she has received the booklet and read it. If she has not read it, we will ascertain her intention to read the booklet in the future, including any reasons for not reading it. If she intends to read the brochure soon, the possibility of arranging a convenient time to call her again once she has read the brochure will be discussed. All calls will be logged. We will focus on the booklet content, by asking the woman to explain what she found most interesting and offering her the opportunity to clarify any information. If the woman's comments reveal that she knows a lot about breastfeeding, the caller will reflect and reinforce the woman's

Table 1. Behaviour change technique (BCT) intervention components

	Intervention components		
	Antenatal written information	Antenatal phone support	Postnatal phone support
BCT components	Health consequences	Shaping knowledge	Feedback on behaviour
	Social and environmental consequences	Goal setting	Problem solving
	Emotional consequences	Commitment	Instruction on how to breastfeed
	Persuasive argument	Boost self-confidence	Boost self-efficacy
	Pros and cons	Social support (emotional)	Social support (emotional)

knowledge. Next, the woman will be asked about her breastfeeding plans and goals and invited to discuss her beliefs and feelings about breastfeeding. These will be acknowledged and she will be encouraged to pursue her breastfeeding goals. She will be informed about the WHO recommendations for infant feeding, specifically exclusive breastfeeding for 6 months followed by continued breastfeeding, with adequate complementary foods, until 2 years of age. Finally, the woman will be asked if she has any other concerns or questions.

Subsequent phone calls (at 2, 6 and 10 weeks postpartum) will focus on the mother's individual worries and concerns about breastfeeding her baby with the aim of acknowledging her struggles, providing relevant advice and encouragement to continue pursuing her goals. Communication skills, as described in Session 2: 'Communication Skills', UNICEF/WHO 20-h course for maternity staff, will be employed throughout all phone calls, including: using open questions, expressing interest and reflecting back, empathising, avoiding words which sound judging, accepting what a mother thinks and feels, recognising and praising what is right, providing relevant information using suitable language and making suggestions rather than commands.

If, during the telephone conversation it becomes evident that a woman is at risk of post-partumdepression or other significant complications in the postpartum period, she will be encouraged to attend her family doctor or primary care gynaecologist. If there is any suggestion that the infant is at risk, the mother will be directed to her paediatrician. If the mother is experiencing difficulties with breastfeeding that cannot be resolved over the phone, she will be directed to breastfeeding support groups and health care providers with a special interest in breastfeeding.

To avoid bias in treatment effect because of differential expertise of care providers, and to ensure continuity of care, the intervention will be administered by one person only. All interventions will be conducted by DP, a registered nurse with 15 years of clinical experience, of which 2 years were spent working in a primary care obstetric practice, and who completed a 90-h breastfeeding course for health care professionals, in 2012, which covered the 'Core Curriculum for Lactation Consultant Practice' (2012).

Comparison groups

1. Active control group

To minimise the Hawthorne effect in the intervention group, described as 'a positive emotional effect because of the perception of a sympathetic or interested observer' (McCarney *et al.* 2007), we will actively include one control group of mothers as well, by offering them the same support (attention matching), in the form of a booklet and four proactive telephone calls. The same principles will be applied, the only difference being in the content of the booklet and telephone conversations. The active control group will be sent a general booklet on pregnancy, taken from the internet and modified for the purpose of the study with the authors' approval, which covers the following topics: antenatal visits, exercise in pregnancy, social security benefits, antenatal courses, paternal involvement, visits by the community nurse, what to take to the hospital and registering the birth of the baby. The first phone call (during pregnancy) will start with the same questions but will focus on the content of the pregnancy booklet, whereas subsequent calls will focus on parenting issues unrelated to breastfeeding. At all times the same communication guidelines and format will be adhered to. We will aim for calls to be of similar length in both groups. If control mothers seek help with breastfeeding issues, they will be directed to local support groups, as described in the intervention arm.

2. Standard care group

The standard care group will not receive any written materials in pregnancy nor telephone support phone calls at any stage, as is the routine procedure currently in Croatia. The standard care pathway, as described above, will apply.

Schedule

The schedule for the implementation of the interventions will be as follows: within 72 h of randomisation, the participants in the intervention and active control groups will be sent printed educational materials to their home address via the post. Two weeks later these

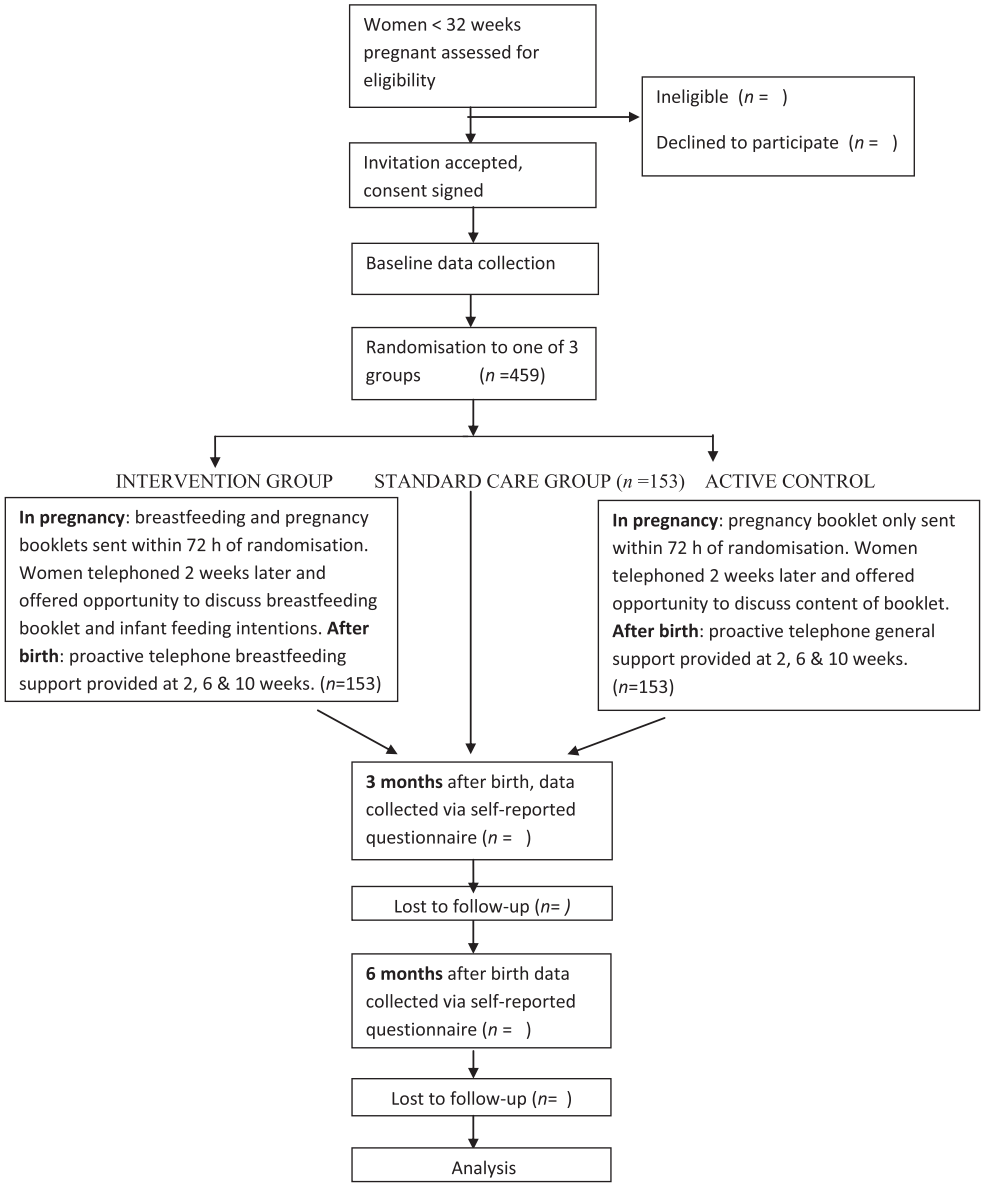

Fig. 1. RCT flow diagram.

women will be contacted by phone to discuss the booklet. After the birth, participants in the intervention and active control groups will receive telephone support in the second, sixth and 10th week (Fig. 1 flowchart). A call log will be kept with start time, end time, woman spoken to/call unanswered recorded. If a participant cannot be reached by phone after three attempts, a text message will be sent. We will also note if an onward referral was made and what the mother's main concerns or comments were related to. All phone calls will be audiotaped, with the mother's permission and her ID number will be stated at the beginning of the call. A researcher independent from the research team will select a 10% random sample of phone calls to be assessed for fidelity, i.e. to check for adherence to the study protocol.

Table 2. Time schedule for baseline data collection and outcome measurements

Measures	Pregnancy (baseline)	3 months post-birth	6 months post-birth
Maternal sociodemographic data	+		
Maternal infant feeding intentions	+	+	
Birth demographics (gestation, sex, weight, delivery type, NICU admission)		+	
Social Support, SS-A	+	+	
Infant feeding attitudes, IIFAS	+	+	
Breastfeeding practices (exclusive, predominant, partial, non)		+	+
Breastfeeding difficulties		+	
Breastfeeding Self-Efficacy, BSES		+	
Accessed breastfeeding support	+	+	+

Data collection (Table 2)

Baseline

Women who consent to participate will be asked by the practice staff to complete the following baseline questionnaires while attending the practice: Iowa Infant Feeding Attitude Scale (De La Mora *et al.* 1999) (IIFAS), Social Support Appraisal Scale (Vaux *et al.* 1986) and a survey on infant feeding intentions, sociodemographic factors and accessed breastfeeding support.

The IIFAS is a validated tool used to assess attitudes towards infant feeding (De La Mora *et al.* 1999) It has been translated into Croatian and used in a variety of settings, with a Cronbach alpha of 0.6–0.73, indicating acceptable reliability (Zakarija-Grkovic & Burmaz 2010) (Marinović Guić 2007). The IIFAS covers various dimensions of infant feeding (cost, nutrition, convenience, bonding) within its 17 statements, and respondents are asked to indicate the extent to which they agree with each statement on a five-point Likert scale ranging from 1 = 'strongly disagree' to 5 = 'strongly agree'. IIFAS scores range from 17 to 85, with a higher score indicating a more positive attitude toward breastfeeding.

Social support will be measured using the Social Support Appraisal Scale (SS-A), a 23-item instrument designed to tap the extent to which the individual believes that he or she is loved by, esteemed by and involved with family, friends and others. This instrument is also graded on the five point Likert type scale, and the score is calculated by summing the points for each question. Based on the obtained score, subjective social support is classified as low (<33 points), medium (<64 points) and high (>65 points).

Sociodemographic data will include: place of residence, age, cohabitation, level of education, employment, home ownership, number of people per household, due date, infant feeding intentions, pacifier use intentions, smoking status and body mass index.

At 3 months

Questionnaires for data collection will be sent via the post by the interventionist to all mothers, with an envelope addressed to the research team for returning the completed forms.

The primary outcome collected will be exclusive breastfeeding at 3 months. The following secondary outcomes will be collected: any breastfeeding, infant feeding attitudes, maternal infant feeding intentions, social support, breastfeeding difficulties, breastfeeding self efficacy, utilisation of breastfeeding support services and birth demographics (infant gestational age at birth, sex, birth weight, delivery type, NICU admission). The Breastfeeding Self-Efficacy Scale–Short Form (BSES-SF) was developed to measure breastfeeding self-efficacy, an important predictor of breastfeeding outcomes. It has been translated into Croatian and found to have good reliability and validity with a Cronbach alpha of 0.86 (Pavicic Bosnjak *et al.* 2012).

At 6 months

Data on exclusive and any breastfeeding and utilised support services will be collected from mothers via self-reported postal questionnaires. At all stages of data

collection, women in each trial arm will be asked which breastfeeding support services they contacted and how often. All data will be entered by a member of the research team blind to group allocation.

Sample size

A priori power analysis has been calculated to determine an adequate sample size for the study. Prior data indicate that the exclusive breastfeeding rate in Croatia at 3 months postpartum is 34% (Zakarija-Grkovic *et al.* 2012). We anticipate an improvement in exclusive breastfeeding rates between the standard care group and the intervention of at least 15%, which yields a necessary sample size of 146 per group. Based on earlier research conducted in Split (Zakarija-Grkovic *et al.* 2012), we estimate that the drop-out rate will be up to 5%, therefore requiring an additional seven women per group. In total we will aim for a sample size of 153 women per arm, that is, our final estimate sample size to be recruited is 459.

Data analysis

Descriptive statistics, with accompanying 95% CI, will be calculated for all variables. In order to assess whether randomization resulted in equal groups, based on the distribution of data we will analyse baseline data using ANOVA or Kruskal–Wallis test for the continuous variables, and Chi-square tests for the categorical variables. To study the differences between the arms on the primary outcome measure (the proportion of mothers who exclusively breastfeed 3 months after discharge) a Chi-square test will used, with alpha error set to 0.05. The analysis will be made with per intention to treat method. As attendance at support groups is theoretically available to all mothers as part of usual care pathway, we will check the attendance rates for the three arms and explore its effect on the primary outcome. The internal consistency and reliability of secondary outcomes (Vaux *et al.* 1986; De La Mora *et al.* 1999; Zakarija-Grkovic *et al.* 2012) will be estimated with Cronbach's alpha and exploratory factor analysis used to check for dimensionality. Distribution of the secondary outcomes will be assessed for normality and their values reported using 95% confidence intervals. Pre-post changes in secondary outcomes will be tested using repeated measures ANOVA or Friedman test. Exclusive breastfeeding and its relation to secondary outcomes will be analysed by logistic regression, with variables being tested using an automated (stepwise) process. All data will be analysed using MedCalc Software (Ostend, Belgium). Reporting of the results of the study will adhere to the CONSORT statement (Schulz *et al.* 2010). We plan to communicate our results with all practices involved in recruitment of participants, relevant professional bodies in the form of published papers and conference proceedings.

Ethical considerations

Prior to seeking written consent, practice staff will provide all eligible mothers with a plain language information sheet outlining the general purpose and course of the study. A decision not to participate, or withdrawal from the study at any stage, will not jeopardise patient care. All patient data will be kept in locked computers, accessible only to study personnel. Ethics approval has been obtained from the Institutional Review Board of the University of Split School of Medicine (no.: 2181-198-03-04-13-0027). The trial was registered on ClinicalTrials.gov, a protocol registration system, on 22 November 2013, under the identifier number: NCT01998087. No monetary or material support has been received for this study.

Discussion

In this protocol we outline a method of providing perinatal breastfeeding support, based on written, plain language information and proactive telephone calls, that is tailored to women's needs, with the aim of empowering and enabling women to reach their breastfeeding goals.

We are aware of two other published protocols for RCTs of telephone support. Ericson *et al.* will be trialling the effectiveness of proactive vs. reactive person-centred, telephone calls to Swedish breastfeeding mothers of preterm infants (Ericson *et al.* 2013). They hypothesise that proactive, daily (from day 1 until day 14 after discharge) telephone support, offered by

members of their NICU-based breastfeeding support team, will increase the proportion of mothers who are exclusively breastfeeding 8 weeks after discharge. The other study, being conducted in Melbourne, Australia, will assess the effectiveness of proactive, telephone peer support vs. usual care for breastfeeding primiparous women (Forster *et al*. 2014). Peers, recruited from the community, will make two telephone calls within the first ten days postpartum, then weekly telephone calls until week twelve, with continued contact until 6 months postpartum. The study team hypothesise that the telephone peer support will increase the proportion of infants receiving any breast milk at 6 months by 10% compared with usual care (from 46% to 56%).

Both of the above studies intend to investigate a postnatal intervention. In our study, we will have both an antenatal as well as a postnatal component to our intervention The antenatal period is an ideal opportunity to promote breastfeeding and prepare expectant couples for the challenges of parenthood. Antenatal preparation alone, though, has been shown to be insufficient for facing the realities of breastfeeding, hence the need for ongoing postnatal support (Dyson *et al*. 2005). In our study we will also aim to provide continuity of care by having one researcher delivering the intervention and the active control. By doing so, we are controlling for personality effects and communication style, which are potential confounders in any verbal support intervention.

This will be the first Croatian RCT to test the effectiveness of perinatal breastfeeding support, thus addressing the challenge to find effective measures for increasing the proportion of infants who are breastfed for at least 6 months. This trial will contribute to future evidence syntheses identifying the most effective forms of breastfeeding support.

Acknowledgements

We would like to thank Professor Matko Marušić for his ongoing support and assistance with study conception, and Dr Varja Đogaš, from the Department of Psychological Medicine, for helping format the interview schedule for the telephone intervention. We would also like to thank Stephan Dombrowski, Senior Lecturer in Health Psychology, University of Stirling, for providing advice on behaviour maintenance techniques.

Source of funding

None.

Conflict of interest

The authors declare that they have no conflicts of interest.

Contributions

DP conceived the study. IZG, DP and PH designed the study protocol. MM determined the study sample size. IZG wrote the initial draft of the manuscript. PH, MM and DP contributed to the initial draft of the manuscript and approved the final version.

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