Cover page

Title: Effectiveness of a home-based peer support program for Chinese mothers with low breastfeeding self-efficacy to increase the exclusivity and duration of breastfeeding: a randomized controlled trial.

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Background Information

The World Health Organization's (WHO) Global Strategy for Infant and Young Child Feeding, which aims to improve rates for breastfeeding recommends that national governments develop a network of community-based mother-to-mother breastfeeding support groups and 'lay and peer counsellors' to enhance existing service [1]. Professional health workers can help improve breastfeeding practices. In resource limited-settings, lack of health workers hinders effective breastfeeding and emotional support. Therefore, we have to depend on peer support to provide knowledge, experience, emotional or practical help. When mothers participate in groups of social activities or receive one-on-one counseling from another mother in the community, they can communicate with each other and exchange knowledge among themselves. Such one on one or group peer support for mothers allow them to support each other, helps in decision making and subsequently empower them [2]. Thus, these interventions have potential to improve breastfeeding practices and child wellbeing [3]. Such interventions have therefore been considered as sustainable alternative to counseling in primary health care settings [4]. These are potentially lower cost interventions compared to those provided by professional health care workers [5]. Recently updated Cochrane review based on 52 RCTs including 37 high income countries indicate that extra support was likely to be more effective in settings with high initiation rates, when delivered face-to-face when offered proactively and on an on-going scheduled basis and tailored to the needs of the population [6].

Peer counselling is being introduced worldwide in supporting mothers' needs for successful maintenance of breastfeeding. Findings from a Cochrane review suggest that postnatal care at home may reduce infant health service utilization in the weeks following the birth, and that more home visits may encourage more women to exclusively breastfeed [7]. In high resource settings healthy women and babies are frequently discharged from hospital within one or two days of birth, potentially home visits in the first few days of the birth by healthcare professions or trained support workers offer opportunities for assessment of the mother and new born, health education, infant feeding support, emotional and practical support.[8-11] By having existing trained peer counsellors (PC) by La Leche League (HK) from our previous project, we propose to conduct a (web-based) home-based peer support programme for mothers who intend to breastfeed but have a low self-efficacy in breastfeeding. We understand mothers are often housebound and find it difficult to attend group support or seek help during the first month postpartum which is the critical period in sustaining exclusive breastfeeding and are at high risk in developing postpartum depression. Peer supporters help women overcome their breastfeeding problems, and women report improved mental health through increased self-esteem, confidence and well-being [12].

In Hong Kong around 20% of women are affected by mental illness either during pregnancy or in the 12 months after giving birth. These include anxiety, depression and postpartum psychosis. Any of these can have a profound effect on breastfeeding and it is important that families can access support at this critical time. There is evidence that breastfeeding can have a preventive effect on mental illness developing. Mothers who plan, but unable to breastfeed their babies are more likely to suffer from postnatal depression. A large scale research study in the UK showed that mothers who planned to breastfeed and who actually went on to breastfeed were around 50% less likely to become depressed that mothers who had not planned to, and who did not, breastfeed. Mothers who planned to breastfeed but who did not go to breastfeed were over twice as likely to become depressed as mothers who had not planned to, and who did not breastfeed [13]. Due to the nature of the study's design, it cannot prove that not breastfeeding raises the risk of postnatal depression. However, it highlights the need to support new mothers who want to breastfeed but are unable to do so. Around 20% of women develop postnatal depression during pregnancy or in the 12 months after giving birth which has long-term sequelae on the family and the infant's psychosocial development.

A Cochrane Review of support for breastfeeding mothers aimed at what kind of support can be provided to help mothers solve any problem concluded that trained volunteers and doctors and nurses had a positive impact on breastfeeding. Factors that may have contributed to the success for women who

exclusively breastfed were face-to-face contact, volunteer support, and specific schedule of four to eight contacts are more likely to succeed with women practicing exclusive breastfeeding [14]. A systematic review indicated that community based peer support for mothers is effective in increasing the duration of exclusive breastfeeding, moreover mothers are more likely to exclusively breastfeed when they receive peer support one on one or through a mother's group [15]. Therefore a feasibility randomized controlled trial (RCT) of home-based breastfeeding peer support programme was conducted by our team to determine if a future definitive RCT could be conducted to improve breastfeeding outcomes among new mothers who intend to breastfeed but have low self-efficacy on breastfeeding. Participants were recruited on a postnatal ward, eighty-five mothers were approached and 20 were screened eligible and randomly allocated into the two arms (with peer support intervention versus usual care). A higher percentage of mothers' exclusively breastfed at 1 month (44% versus 33%), 2 months (43% vs 25%) and 4 months postpartum (50% vs 33%) in the peer support arm compared to usual care. Views on the program from qualitative interviews from the participants after the intervention were positive and met their expectation. The advantages of the intervention stated by all participants were they have a point of contact in which they have someone to speak to directly about their problems. Volunteer's response is quicker and the process is faster compared with 'usual maternity care'. Peer support provided more emotional support and care which relieves pressure for first-time mothers. Participants feel more comfortable to speak with the volunteers compared to health professionals as they found nurses in hospital and clinics were too routine and more concerned with scientific or quantitative issues. These findings from the feasibility study demonstrate that women value peer supporters as mothers with similar experiences who can relate to their own situation through a shared language. Therefore, a home-based peer support intervention is recommended for the proposed study.

Summary of known and potential risks and benefits

As intervention involves peer support (face-to-face) and no invasive procedures will be involved, risks to women and their infants are likely to be minimal. In terms of confidentiality and anonymity, analysis will take place on anonymous data. Personal identifiable data will be held separately from the anonymous data used for analysis.

Benefits include women gaining in awareness of the value of breastfeeding for their own and for their infant's health, and feeling supported in this aspect of caring for their infants.

1 Objectives and Purpose

The aim of the proposed study is to evaluate the effectiveness of a (web-based) home-based breastfeeding peer support program in improving breastfeeding practices among women with low breastfeeding self-efficacy.

2 Design

This is a two armed blinded randomized controlled trial. 442 women will be recruited from four hospitals. Trained peer counsellors will provide home based (web based due to 5th Covid wave) one-to-one breastfeeding intervention sessions to the participants.

Study Procedure

1. Recruitment:

   Mother-infant pairs will be recruited from a hospital that has an average of 300+ deliveries per month. Eligible participants will be approached and invited to join the study in antenatal clinics. Women who agree to participate and sign the consent form will be invited to complete the following forms available both in Chinese or English version:

   a. Demographic Data Collection Form
   b. Breastfeeding Self-efficacy and Attitude Data Collection Form

Research assistant will complete the following form from participants' medical records:

   a. Maternal and Birth Data Collection Form

This study includes two study arms:

a. Home-based peer support programme (web-based) and standard usual care

b. Control group will be standard usual care

Participants will be randomized following completion of the baseline data. Block randomization procedures with random block sizes of 2, 4 or 6 will be used. An independent research assistant who will not participate in participant recruitment, data collection and analysis will generate the allocation sequence using the statistical software Stata 14. Allocation sequences will be kept in sequential numbered, opaque, sealed envelopes. Outcome assessors will be blinded to the treatment allocation. The research assistant will draw the first sealed envelope from the box and participants will be allocated to that intervention group.

2. Telephone follow-up call:
   The participants will receive follow-up telephone calls at one, two, four and 6 months postpartum. Each follow-up call will take approximately 15 minutes.

   The following forms will be completed by a research assistant in the telephone follow-ups:

   One month follow-up:
   a. One-Month Follow-up Data Collection Form

   Two months follow-up:
   a. Two-Month Follow-up Telephone Data Collection Form
   b. Breastfeeding Self-efficacy and Attitude Data Collection Form

   Four months follow-up:
   a. Four-Month Follow-up Telephone Data Collection Form
   b. Breastfeeding Self-efficacy and Attitude Data Collection Form

   Six month follow-up:
   a. Six-Month Follow-up Telephone Data Collection Form

   These data collection forms will be completed if needed:
   b. Weaning Data Collection Form (if participants' babies have been weaned)
   c. Return to Work Data Collection Form (if participants have return to work)

Data Sources

Data collection will consist of: (1) baseline demographic data will include data such as education, income, employment, family composition, antenatal education, (2) maternal and infant data which will include data on the mother's previous obstetrical history, delivery data and basic infant health data.

Study Outcome

Primary outcome: Infant feeding status.

Key Measures

- **Infant Feeding Status:** Patterns of breast milk feeding as assessed at each follow up point will be classified according to existing World Health Organization definitions. Infants will be considered exclusively breastfed if they receive no solids, no non-breast milk, or no water or other liquids (other than vitamins or medications). Non-exclusively breastfed infants supplemented with infant-formula or other milk substitutes can, if required, be further classified as high partial breastfeeding (>80% of feeds are breast milk), medium-partial breastfeeding (20 to 80% of feeds are breast milk), low partial breastfeeding (<20% of feeds are breast milk). Infant feeding patterns will also be categorized according to definitions that include both the type and mode of infant feeding: (1) direct breastfeeding only, (2) expressed breast milk only, (3) direct breastfeeding and expressed breast milk feeding, (4) direct breastfeeding and formula feeding, (5) expressed breast milk feeding and formula feeding, (6) direct breastfeeding, expressed breast milk feeding, and formula feeding, and (7) formula feeding only. We will compare the overall duration of any and exclusive breastfeeding among participants in the (web-based) home-based peer support programme to the control group which received standard post-natal care only.

- **Breastfeeding Self-efficacy:** Maternal breastfeeding self-efficacy will be measured using the Breastfeeding Self-Efficacy Scale Short-Form (BSES-SF) (Chinese and English version). The BSES-SF consists of 14 items measured on a 5-point Likert scale that begin with the phrase "I can always." On the scale 1 indicates "not at all confident" and 5 indicates "always confident. Total scale scores range from 14 to 70 with higher scores indicting greater breastfeeding confidence and self-efficacy. We will administer the BSES-SF in baseline period and at 2 and 4 months postpartum. We will compare the scores among intervention and control groups. Permission to use the BSES-SF has been granted by the authors of both the original and Hong Kong Chinese versions.
- **Edinburgh Postnatal Depression scale:** Participant's postpartum depression symptoms will be measured by EPDS, Chinese version. It is an instrument consisting of 10 simple and easily understood items, with rating on a scale from 0 to 3, yielding a total range of 0 to 30. EPDS was developed by Cox et al (1987) and has been widely used for the assessment of postnatal depressive symptoms, but it is not a diagnostic scale for depression, rather a screening tool for those vulnerable to developing depression. The Chinese version of EPDS has been validated and shown to have high sensitivity in detection on postnatal depression. To evaluate the postpartum depressive symptoms, pre (1 month postpartum) and post (2 months postpartum) EPDS will be compared between the two groups.

3 Selection and Withdrawal of Subjects

Study population

To be eligible for inclusion in the RCT, participants must be (1) 18 years of age or older, (2) primiparous mothers, (3) intention to breastfeed, (4) low breastfeeding self-efficacy score (between 14 and 32), (5) singleton pregnancy, (6) term infant (37-42 weeks gestational), (7) Cantonese speaking, (8) HK resident and (9) mother with no serious medical or obstetrical complications.

Participants will be excluded from the study if they fail to meet these criteria and/or if their baby: (1) is <37 weeks gestation, (2) has an Apgar score <8 at five minutes, (3) has a birthweight <2500 grams, (4) has any severe medical conditions or congenital malformations, (5) is placed in the special care baby unit for more than 48 hours after birth, or (6) is placed in the neonatal intensive care unit at any time after birth.

4 Treatment of Subjects

The team members have successfully trained 60 PCs from our previous project. The training programme comprised of 20 hours of classroom teaching and practical sessions at Queen Elizabeth Hospital and the Maternal Child Health Centres (MCHCs). The training programme was conducted by UNICEF and La Leche League covering topics such as (1) why breastfeeding is important, (2) how to assure good start of breastfeeding, (3) how to help mother breastfeeding (4) communication skills, (5) common breastfeeding problems, (6) diet and hygiene, (7) maternal illness and needs, (8) local support and role of peer counsellors. The peer counsellors was assessed by their trainers after completing the training programme. Those who pass the assessment can then carry out volunteer work using train the trainer approach with supervision from La Leche League in MCHCs. Additional training workshop will be arranged for the PCs on solving problems of exclusive breastfeeding and correct breastfeeding technique by team leaders.

The intervention will be based on the PC programme previously conducted in our project except it will be home based (web based) peer support programme by trained PCs. In order to ensure the quality and consistency of intervention, additional training tailored to issues that may encouter in (web-based) home-based contacts will be provided to peer counsellors before the study.

The (web-based) home-based PC programme comprises of two schedule of two contacts during first month postpartum, one contact during 2 months postpartum, one contact during 4 months and one contact during 6 months postpartum, when mothers are most likely to experience difficulties with breastfeeding, and thereafter as needed. Both control and intervention groups will receive the same standard antenatal and postpartum care and a breastfeeding information leaflet. The control group will not receive home based PC programme but a breastfeeding information leaflet so the subjects will be blinded to the nature of the interventions.

5 Assessment of Efficacy

This study aims to assess effectiveness of the peer support intervention. The assessment of efficacy of the intervention will be undertaken at 1 month, 2 months, 4 months and 6 months postpartum using the criteria specified in the study outcomes.

6 Assessment of Safety

This research involves a patient support intervention and we do not anticipate any patient safety issues. The person(s) carrying out the intervention will be trained and with experience in supporting breastfeeding women. However, as a precaution, both the delivery of the intervention and participant outcomes will be closely monitored by the PI and the study investigators

7 Statistic

Data Analysis

To compare the baseline characteristics between the two study groups, t-tests will be used for continuous variables and chi square test for categorical variables. Intention to treat analysis will be conducted. The primary outcome analyses will compare the proportions of participants in the two study groups exclusively breastfeeding at 1, 2, 4 and 6 months postpartum using chi square tests. To control for confounding factors, multiple logistic regression models will be used if required to compare breastfeeding rates between groups at the study follow up points. The secondary outcome analyses will use an independent 2-sample t tests to examine the breastfeeding self-efficacy scores and EPDS scores between the two study groups at baseline and at 1 and 3 months postpartum. To control for confounding factors, multiple linear regression models will be used to compare the scores between the groups at 3 months.

Where appropriate, each estimate will be accompanied by a 95% confidence interval and a 5% level of significance will be used in all statistical tests except where specified. The analysis will be performed using the Stata version 14.0 statistical software.

8 Direct Access to Source Data/Documents

Once data are collected, only the PI will have access to named data which will be kept locked in the PIs office in the School of Nursing. Access to the study data will be available for study related monitoring, audit and regulatory inspection by appropriate bodies. It will also be available for IRB review as appropriate.

9 Quality Control and Quality Assurance

As part of the usual review process in the department, data analysis will be reviewed by the study team to ensure it is appropriate, accurate and correctly interpreted.

10 Ethics

The main ethical considerations for this study are to ensure confidentiality to the participants and to ensure that the participants feel free to either participate in the study or to not participate in the study. The following measures will be taken to address these concerns:

- Participation is the study will be completely voluntary and potential participants will be assured that they will not suffer any consequences of lower standards of care for not participating.
- Participants will be also informed that they may withdraw from the study at any time without any repercussions.
- Informed written consent will be obtained from all participants.
- No specific identifiers (such as name, telephone number, or address) will be included in the data used for analysis or be available to the study team other than the PI. Other study information will not be specific enough, either singly or in combination, to uniquely identify an individual.

This study complies with the principles of the 1996 Declaration of Helsinki.

11 Data Handling and Record Keeping

Anonymised data will be analysed within the School of Nursing. All data collection forms will contain a study ID number only. The only data which will be able to link the participant with the study data are the consent form. All signed consent forms will be kept in the PI's office in a locked filing cabinet.

12 Financing and Insurance

This research does not involve any invasive intervention or medical procedure. The only data collected will be biographical and health related data using questionnaires, data collection sheets, or interviews.

13 Publication Policy

Papers approved by the study team will be published in appropriate peer reviewed journals.

References:

1. Borra, C., M. Iacovou, and A. Sevilla, *New Evidence on Breastfeeding and Postpartum Depression: The Importance of Understanding Women's Intentions.* Maternal and Child Health Journal, 2015. **19**(4): p. 897-907.
2. World Health Organization, *Global strategy for infant and young child feeding*. 2003, World Health Organization: Geneva.
3. Younes, L., et al., *The effect of participatory women's groups on infant feeding and child health knowledge, behaviour and outcomes in rural Bangladesh: a controlled before-and-after study*. J Epidemiol Community Health, 2015. **69**(4): p. 374-81.
4. Lewycka, S., et al., *Effect of women's groups and volunteer peer counselling on rates of mortality, morbidity, and health behaviours in mothers and children in rural Malawi (MaiMwana): a factorial, cluster-randomised controlled trial.* Lancet, 2013. **381**(9879): p. 1721-35.
5. ZA, B., et al., *Global experience of community health workers for delivery of health related millennium devleopment goals: A systematic review, country case studies, and recommendations for scaling up*. 2010.
6. Morrow, A.L., et al., *Efficacy of home-based peer counselling to promote exclusive breastfeeding: a randomised controlled trial.* Lancet, 1999. **353**(9160): p. 1226-31.
7. Renfrew, M.J., et al., *Support for healthy breastfeeding mothers with healthy term babies.* Cochrane Database of Systematic Reviews, 2012(5).
8. Yonemoto, N., et al., *Cochrane in context: Schedules for home visits in the early postpartum period.* Evid Based Child Health, 2014. **9**(1): p. 100-2.
9. Carabin, H., et al., *Does participation in a nurse visitation programme reduce the frequency of adverse perinatal outcomes in first-time mothers?* Paediatr Perinat Epidemiol, 2005. **19**(3): p. 194-205.
10. Donovan, E.F., et al., *Intensive home visiting is associated with decreased risk of infant death.* Pediatrics, 2007. **119**(6): p. 1145-51.
11. Lassi, Z.S., B.A. Haider, and Z.A. Bhutta, *Community-based intervention packages for reducing maternal and neonatal morbidity and mortality and improving neonatal outcomes.* Cochrane Database Syst Rev, 2010(11): p. CD007754.
12. Shaw, E., et al., *Systematic review of the literature on postpartum care: effectiveness of postpartum support to improve maternal parenting, mental health, quality of life, and physical health*. Birth, 2006. **33**(3): p. 210-20.
13. Wade, D., S. Haining, and A. Day, *Breastfeeding peer support: are there additional benefits?* Community Pract, 2009. **82**(12): p. 30-3.
14. McFadden, A., et al., *Support for healthy breastfeeding mothers with healthy term babies.* Cochrane Database of Systematic Reviews, 2017(2).
15. Shakya, P., et al., *Effectiveness of community-based peer support for mothers to improve their breastfeeding practices: A systematic review and meta-analysis.* PLoS One, 2017. **12**(5): p. e0177434.
16. Morse, J.M. and B. Doberneck, *Delineating the concept of hope.* Image J Nurs Sch, 1995. **27**(4): p. 277-85.
17. Penrod, J. and J.M. Morse, *Strategies for assessing and fostering hope: the hope assessment guide.* Oncol Nurs Forum, 1997. **24**(6): p. 1055-63.
18. Thomson, G., N. Crossland, and F. Dykes, *Giving me hope: women's reflections on a breastfeeding peer support service.* Matern Child Nutr, 2012. **8**(3): p. 340-53.
19. Dennis, C.L. and S. Faux, *Development and psychometric testing of the breastfeeding self-efficacy scale.* Research in Nursing & Health, 1999. **22**(5): p. 399-409.
20. Ip, W.Y., et al., *Translation and validation of the Hong Kong Chinese version of the breastfeeding self-efficacy scale—short form.* Research in Nursing and Health, 2012.
21. Cox, J.L., et al., *Validation of the Edinburgh postnatal depression scale (EPDS) in non-postnatal women.* Journal of Affective Disorders, 1996. **39**(3): p. 185-189.
22. Lee, D.T.S., et al., *Detecting postnatal depression in Chinese women - Validation of the Chinese version of the Edinburgh Postnatal Depression Scale.* British Journal of Psychiatry, 1998. **172**: p. 433-437.
23. StataCorp, *Stata statistical software: release 14.1 [program]*. 2015, StataCorp LP: College Station, Tx.