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Effectiveness of a home-based peer support programme for Chinese mothers with low breastfeeding self-efficacy to increase the exclusivity and duration of breastfeeding: study protocol of a randomised control trial

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ABSTRACT

Introduction Breastfeeding is associated with many health benefits for both women and their newborns. Exclusive breastfeeding has been recommended for at least 6 months to optimise infant growth, development and health. In addition to standard care, community-based peer support is recommended to help mothers improve breastfeeding. A recent survey reveals that the rate of exclusive breastfeeding at 6 months post partum in Hong Kong is low, and half of all breastfeeding mothers never exclusively breastfeed. Taking into account the local practice for women to stay home during the first month post partum and social isolation during and post-COVID-19 pandemic, a home-based peer support programme with the aid of Zoom or Facetime is proposed. This study aims to evaluate the effectiveness of a home-based breastfeeding peer support programme in improving breastfeeding practices and achieving exclusive breastfeeding rate among women with low breastfeeding self-efficacy.

Methods and analysis The study is a two-armed randomised control trial and will include a total of 442 participants. Potential cases will be recruited and screened at four postnatal wards in Hong Kong public hospital. Eligible and consented cases will be randomly allocated into intervention or control groups at a 1:1 ratio. Control group (n=221) will receive standard care, while the intervention group (n=221) will receive home-based peer support as well as standard care. Trained peer counsellors will provide breastfeeding-related support through Zoom or Facetime at 10 days and 1 month post partum. Telephone follow-ups will be conducted at 1 month, 2 months, 3 months and 6 months post partum. Breastfeeding status, mother's breastfeeding self-efficacy and postpartum depression will be assessed and compared between the two arms.

Ethics and dissemination The study has been reviewed and approved by the Institutional Review Board of the University of Hong Kong and Hospital Authority Hong Kong West Cluster (UW 20-564). The findings will be updated in trial registries and disseminated in peer-reviewed journals and academic conferences.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This is a two-armed randomised control trial aiming to include 442 participants.
⇒ As the study focuses on primiparous mothers with low breastfeeding self-efficacy, the finding may not generalise to multiparous mothers or mothers with higher breastfeeding self-efficacy.
⇒ While peer counsellors are all trained and assessed, peer support provided may vary depending on the peer counsellors and the relationship between peer counsellors and the participants.

Trial registration number NCT04621266.

INTRODUCTION

Background

Breastfeeding is associated with many health benefits for both women and their infants. The WHO and UNICEF recommend newborns to be exclusively breastfed for a minimum of 6 months to optimise growth, development and health.[1 2] In terms of infant and later child health, breastfeeding is associated with reduced risk of gastrointestinal infection, otitis media, respiratory tract infection, asthma, allergies, obesity, type I and II diabetes, and sudden infant death syndrome.[3–5] For mothers, breastfeeding is associated with a lower risk of ovarian cancer, breast cancer, type II diabetes, and a reduction in postnatal weight retention.[4 6]

Numerous factors are associated with breastfeeding practice, including breastfeeding self-efficacy, and attitude. These factors not only serve as strong indicators of continued breastfeeding but are also modifiable factors related to the practice.[7 8] Perinatal depression

is also predictive of decreased rate or early termination of breastfeeding.[9 10] On the flip side, breastfeeding was associated with a 14% lower risk of postpartum depression.[9] While approximately 10% of Hong Kong women are affected by perinatal depression and post partum.[11]

A recent survey has revealed that only 22.2% of mothers exclusively breastfeed at hospital discharge in Hong Kong.[12] This falls short of the WHO's global target to achieve 50% exclusive breastfeeding at 6 months post partum in 2025,[1] revealing an important public health concern. With the aim to improve breastfeeding rates, the WHO's Global Strategy for Infant and Young Child Feeding recommends the development of community-based mother-to-mother breastfeeding support groups and peer counsellors (PC) to enhance existing services.[1] Group or one-on-one peer support allows mothers to share knowledge and experience on effective breastfeeding practices and provide emotional or practical help.[13 14] It can be a sustainable and lower-cost alternative to professional care in helping improve breastfeeding practices.[15 16] A systematic review indicated that community-based peer support for mothers is effective in increasing the likelihood and duration of exclusive breastfeeding.[17] Interventions that included face-to-face contact, volunteer support and a specific schedule of four to eight contacts were found to be more likely to succeed in helping women practice exclusive breastfeeding.[18 19] With peer support, which could help them tackle issues related to breastfeeding, women also reported improved mental health through increased self-esteem, confidence and well-being.[20] However, Chinese women who practice 'doing the month' remain homebound during the first month post-birth. A home-based intervention is proposed to offer solution to this ritualistic practice.

Despite the benefits of face-to-face support and volunteer facilitation, the COVID-19 pandemic has become a burden for mothers receiving face-to face support. Multiple studies have indicated a higher rate and severity of postnatal depression and anxiety, as well as a moderate level of fear during the pandemic.[20] Over 61% of the postnatal respondents hesitated to receive face-to face health service due to fear,[21] making it difficult to estimate the effectiveness of a home-based intervention under the pandemic. In order to minimise the impact of COVID-19 pandemic, many face-to-face measures have been switched to online format. Zoom or Facetime, as a cloud-based video communication software, has become two of the major platforms of the population to video call. Breastfeeding classes and support start to be delivered online, and the efficacy of online video-based breastfeeding support has been proven to be effective in achieving higher breastfeeding efficacy and better neonatal outcomes at 1-month follow-up intervals.[22] Even in our pre-COVID-19 pilot study, some participants who received face-to-face sessions expressed a preference for an online format to accommodate their hectic schedules. Thus, our project continued with the online format even after the pandemic situation.[23]

However, the effect of an online video-based peer support programme with a greater scale and longer follow-up duration is still under investigation. Therefore, a home-based peer support programme, using Zoom or Facetime based on participant choice, is proposed to support women who intend to breastfeed but have low self-efficacy in breastfeeding. This could increase the exclusivity and duration of breastfeeding.

Aims

The aim of this study is to evaluate the effectiveness of a home-based breastfeeding peer support programme in improving 6 months exclusive breastfeeding rate among women with low breastfeeding self-efficacy.

The primary hypothesis is that women-infant pairs who received home-based peer support will be exclusively breastfed over a 6-month period. It is also hypothesised that women who received home-based peer support will have higher breastfeeding self-efficacy, and lower postpartum depression symptoms, when compared with those who received only standard care.

METHODS

Trial design

The study adopts a two-armed, randomised controlled trial design, with a superior trial framework. The anticipated duration of the study is from 31 January 2021 to 30 June 2024.

Study setting

The screening and recruitment of study participants will be conducted by a research assistant at the postnatal ward in four public hospitals in Hong Kong. The research nurse will obtain written informed consent from all participants. For the intervention, at least two peer support sessions would be conducted face-to-face pre-COVID-19 or over Zoom or Facetime during and post-COVID-19.

Recruitment

The current study would recruit from four postnatal hospital wards. Women were approached during their stay in the postnatal ward. Eligible participants will be invited to complete the breastfeeding self-efficacy form as screening prior to joining the study and filling in the written consent form. Each participant who consented to participate will have a copy of the consent and info sheet. Each of the participants will be assigned to a study ID for further anonymous data handling.

Sample size

The exclusive breastfeeding rate in Hong Kong was 26.3% at 6 months by the time of project initiation.[24] To calculate the sample size, a power of 80% and a significant level of 5% were used. Assuming a conservative participation rate of 25% based on our pilot study.[23] It is estimated that a sample size of at least 442 participants would be required (n=221 per group), allowing for an attrition rate of 30%.

Patient and public involvement

None.

Inclusion and exclusion criteria

Eligibility of study participants

Individuals attending the four recruiting postnatal clinics are eligible to enter into the study if they (1) 18 years of age or older, (2) are primiparous mothers, (3) intend to breastfeed, (4) have low breastfeeding self-efficacy score in screening (between 14 and 46), (5) have singleton pregnancy and live birth, (6) have term infant (37–42 week gestational), (7) are Cantonese-speaking, (8) are Hong Kong residents and (9) have no serious medical or obstetrical complications.

Individuals will be excluded from the study if they fail to meet these criteria and/or if their infant (1) is below 37 weeks gestation, (2) has an Apgar score below 8 at 5 min, (3) has a birth weight lower than 2500 g, (4) has any severe medical conditions or congenital malformations, (5) has been placed in the special care baby unit for more than 48 hours after birth or (6) has been placed in the neonatal intensive care unit at any time after birth. Participants who are unable to provide written informed consent for any reason will also be excluded from the study.

Eligibility of PC

Individuals who are (1) 18 years of age or older, (2) Cantonese-speaking, (3) have had at least 4 months of breastfeeding experience themselves, (4) have received at least 16 hours of classroom training with two practicums and (5) passed an examination at the end of the training would be eligible to provide intervention as PC.

Assignment of intervention

Allocation

Each of the participants will be assigned to a study ID for further anonymous data handling. The participants will be randomly assigned to either intervention group (home-based peer support provided) or control group (standard care). Before the recruitment began, the randomisation sequence was generated by using STATA (Stata Corp) with simple randomisation by a researcher. The sequence will be password-encrypted, and cannot be assessed by nor disclosed to the researcher who is responsible for recruitment and assessment. The randomised group allocation will be disclosed to the participants by an independent researcher with access to the randomised sequence once the participant is recruited in ward and has completed the baseline assessments.

Blinding

This study adopts an open study design, where participants and the researcher will be notified of their group assignment after the recruitment.

Intervention

The intervention group will receive two home-based peer support sessions and standard care, whereas the control group will receive standard care. An extra home-based peer support session will be provided for the intervention group if needed. Both groups will receive an information leaflet on breastfeeding produced by the Department of Health, Hong Kong.

The intervention in this study is developed based on the conceptual framework by Morse and Doberneck which describes the behavioural manifestation of hope, and The Hope Assessment Guide developed by Penrod and Morse.[25 26] Morse and Doberneck identified seven components of hope in breastfeeding after returning to work: (1) realistic initial assessment of the predicament or threat; (2) the envisioning of alternatives and the setting of goals; (3) a bracing for negative outcomes; (4) a realistic assessment of personal resources and of external conditions and resources; (5) the solicitation of mutually supportive relationships; (6) the continuous evaluation for signs that reinforce the selected goals and (7) a determination to endure.[25] Based on this framework, which enables hope to be assessed in stages, Penrod and Morse's The Hope Assessment Guide describes healthcare strategies to enhance hope in each of the seven stages. These strategies include providing realistic, accurate and timely information; supporting and developing strategies and personal resources, reinforcing signs that encourage home and enhancing the directing energy to endure the situation.[26] The theoretical and practice-based insights from Thomson and colleagues on how breastfeeding peer support services facilitate and encourage hope for women's breastfeeding goals were also incorporated.[27] The peer support programme in this study is developed based on these theoretical frameworks and strategies with the aim to increase and/or sustain exclusive breastfeeding among mothers with low breastfeeding self-efficacy.

Participants in the intervention group will receive two support sessions during the first 6 months of the postpartum period based on their needs. An additional session can be provided on request. The intervention will be provided by trained PC who are recruited and trained by Natural Parenting Network. The training covers various topics including: (1) the importance of breastfeeding, (2) ensuring a good start to breastfeeding, (3) assisting mothers with breastfeeding, (4) communication skills, (5) common breastfeeding problems, (6) diet and hygiene, (7) maternal illness and needs and (8) local support and role of PC. Participants in the training sessions are assessed by their trainers through a standardised exam. Only those who pass the assessment will be included as PC. Furthermore, additional training focused on home-based support is provided to PC by a lactation consultant midwife to address common issues they may encounter during home-support sessions.

Two home-based peer support sessions were conducted within 10 days post partum and 1 month post partum, respectively. A third meeting can be arranged within 6 months post partum on request before completing the 6 month follow-up. Each meeting will be scheduled individually by the peer counsellor. The sessions will be

recorded for later analysis. During the session, the peer counsellor will share their experiences and skills with the mother to address any questions or challenges she may encounter during her breastfeeding journey. The content of the intervention may vary depending on the specific challenges and questions faced by each participant. Participants have the right to refuse the intervention at any time if they wish to discontinue. No harm to the participants is anticipated. Participants are also allowed to seek other professional support, and such information will be recorded during the follow-up assessments.

Baseline and follow-up procedures

Study data will be collected by research nurses or research assistants using questionnaires. Baseline assessments will be conducted in person during recruitment, and maternal and birth data will be extracted from participants' medical records. Follow-up assessments will be completed through phone interviews at 1 month, 2 months, 4 months and 6 months post partum. The schedule of enrolment, intervention and assessments for participants is summarised in figure 1.

	STUDY PERIOD						
	Enrolment	**Allocation**	**Post-allocation**				**Close-out**
TIMEPOINT**	***Postnatal***		***10 days post-partum***	***1-month post-partum***	***2-month post-partum***	***4-month post-partum***	***6-month post-partum***
ENROLMENT:							
Eligibility screen	X						
Informed consent	X						
Allocation		X					
ASSESSMENTS:							
Breastfeeding Attitude	X				X	X	
Infant feeding patterns				X	X	X	X
Breastfeeding self-efficacy scale short-form (BSES-SF)	X				X	X	
Edinburgh Postnatal Depression Scale (EPDS)	X			X	X		
Weaning data				*(if / when applicable)*			
Return to work data				*(if / when applicable)*			
INTERVENTIONS:							
Intervention group	Information leaflet		Home-based peer support session	Home-based peer support session			± Home-based peer support session upon request
Control group	Information leaflet						

Figure 1 Schedule of enrolment, intervention and assessmentf for participants.

Baseline assessments will include demographic data, breastfeeding self-efficacy and participants' attitudes towards breastfeeding. Breastfeeding self-efficacy will be assessed using the 14-item Breastfeeding Self-Efficacy Scale Short-Form (BSES-SF),[28] while breastfeeding attitude will be assessed using the 17-item Breastfeeding Attitude scale.[29]

Follow-up assessments will be conducted at 1 month, 2 months, 4 months and 6 months post partum. At each timepoint, infant feeding status and breastfeeding support will be assessed. Breastfeeding self-efficacy and attitude will be assessed at 1 month post partum. Postpartum depression will be assessed at 1 month and 2 months post partum. Data on breastfeeding support will also be collected, including whether the mother sought professional support, the type of professional support received, and a brief evaluation of the home-based breastfeeding support for participants in the intervention group.

In addition to the outcome measures, weaning and return-to-work data will be collected if applicable. Return-to-work data will be collected if participants have returned to work prior to the follow-up interview. This will include duration of the return to work, working hours per week and details about expressing breast milk at the workplace. Weaning data will be collected from participants when applicable.

Outcome measures

Primary outcome

The primary outcome measure is the proportion and duration of exclusive breastfeeding between the two groups. Infant feeding status will be classified using the existing WHO definitions.[30] 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).[30] 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%–80% of feeds are breast milk), low partial breastfeeding (<20% of feeds are breast milk). Infant feeding patterns will also be categorised based on the type and mode of infant feeding, including: (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.[30] The participants' infant feeding status will be followed up at 1, 2, 4 and 6 months post partum. The proportion and duration of exclusive and any breastfeeding will be compared between the two groups.

Secondary outcomes

The study includes two secondary outcome measures: participants' breastfeeding self-efficacy and postpartum depression. Breastfeeding self-efficacy will be assessed using the BSES-SF.[7 28] The scale consists of 14 items, and participants will rate each item on a 5-point Likert scale, indicating their level of confidence in various aspects of breastfeeding. The scale ranges from 1 (indicating 'not at all confident') to 5 (indicating 'always confident'). The total scale score ranges from 14 to 70, with higher scores indicating greater breastfeeding confidence and self-efficacy. The recommended cut-off score in the Hong Kong Chinese versions is applied after rounding up to the nearest integer 46.[28] Permission to use the scale has been granted from the authors of both the original and Hong Kong Chinese versions.[7 28] The BSES-SF will be administered at baseline and 1 month post partum, and the scores will be compared across the two groups.

Postpartum depression will be measured using the Chinese version of the Edinburgh Postnatal Depression Scale (EPDS).[31] The EPDS is a 10-item screening tool designed to assess postnatal depressive symptoms experienced by mothers in the previous week. Participants rate each item on a scale from 0 to 3. The total score can range from 0 to 30, with higher scores indicating more severe depressive symptoms. A score of 13 is used as a cut-off point indicating the likelihood of a depressive disorder. The Chinese version of the EPDS has been validated and shown to have high sensitivity in the detection of postnatal depression.[32] The EPDS will be administered at 1 month and 2 months post partum, and the scores will be compared between the two groups at each time interval.

Proposed data analysis

The baseline characteristics of the two study groups will be compared using t-tests for continuous variables and χ^2 tests for categorical variables. Intention-to-treat analysis will be conducted for all recruited subjects.

To study the primary outcome, which is whether home-based peer support programme increases the duration of exclusively breastfeed, χ^2 test will be used to compare the proportion of exclusive breastfeeding at 1, 2, 4 and 6 months post partum between the two groups. To control for confounding factors, generalised linear mixed models with logit link will be used to compare breastfeeding rates between the two groups at different study follow-up time points.

For the secondary outcome analyses, independent two-sample t-tests will be used to compare breastfeeding self-efficacy scores between the two study groups at baseline, 2 months and 4 months post partum, as well as the EPDS scores at baseline, 1 month and 2 months post partum. To control for confounding factors, generalised linear mixed models with identity link will be used to compare the scores between the groups.

A 95% CI and a 5% level of significance will be used in all statistical tests unless otherwise specified. The analysis will be conducted using STATA V.16.[33]

Interim analyses will be conducted annually, and the study investigators will have access to the results. A summary of the interim results will be submitted to the funding agency and ethics review boards.

Ethics and dissemination

Ethics approval for this study has been obtained from the Institutional Review Board of the University of Hong Kong and Hospital Authority Hong Kong West Cluster (UW-20-564). Written informed consent will be obtained from all participants.

As the current study involves only a peer support intervention, no additional risk to participants is expected. The principal investigator and other study investigators will closely monitor the intervention process and outcomes, and will make the final decision to terminate the trial if necessary.

A summary of the study protocol and results will be updated on the relevant clinical trial registries. Trial results will be submitted for publication in peer-reviewed journal(s) within 12 months of study completion. Key outcomes will be publicly available on the clinical trial registry within 12 months of study completion. In accordance with the Consolidated Standards of Reporting Trials statement, main findings of the study will be available publicly within 24 months of study completion.

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