Study title:
A feasibility randomised controlled study of an innovative postnatal home-based breastfeeding peer counselling programme (BFPC1)

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Study Protocol (Version 1, 8 August 2018)

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Background

Peer counselling and support has been shown to be effective in improving breastfeeding (BF) initiation, duration and exclusiveness.(1, 2) Peer counselling is being introduced into different country settings worldwide as an intervention to support women to achieve successful commencement and maintenance of breastfeeding, given the range of health benefits for the woman and her infant. Findings from one Cochrane review suggested that postnatal contacts in the home may reduce infant health service utilisation in the weeks following the birth, and that more home visits may encourage more women to exclusively breastfeed.(3)

Study significance

A feasibility randomized controlled trial (RCT) study is proposed in the current study as women who had given birth to their first babies recruited to a previous project specifically expressed the need for postnatal BF support from peer counsellors at home and there is evidence that this could be of benefit for women and their infants. Evidence of whether women in Hong Kong who had peer counsellors have better breastfeeding outcomes compared to women who had standard care, however, is not available.

This study is important for several reasons. Chinese women are expected to be housebound during the first month postnatally due to the tradition of 'doing the month', when problems with infant feeding and/or infants failing to thrive due to poor feeding could result in a decision to stop breastfeeding. The innovative home-based intervention we will undertake will address an important service gap in Hong Kong to promote and sustain exclusive breastfeeding, and could be an effective strategy which reflects local culture.

Study aim

The aim of this feasibility study is to inform a future definitive RCT to meet the support and other needs of breastfeeding mothers during the postnatal period to increase the exclusivity and duration of breastfeeding through the provision of home based peer counselling (PC) programme to support new breastfeeding mother.

Methods

Study design

This is an open-labelled feasibility randomized controlled trial. Twenty pregnant women admitted to postnatal ward of the designated study trial site will be recruited into the study. Trained peer counsellors will provide home based one-to-one breastfeeding intervention sessions to participants allocated to the intervention group. Baseline demographics and medical data will be collected at study entry. Follow-up assessments will be conducted at 1-month, 2-month, 4-month, and 6-month postpartum.

Recruitment, randomization, and data collections

1. Recruitment and baseline assessments

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 on postnatal ward. Baseline data will be collected from consented participants. Relevant medical data will be extracted from electronic patient record.

2. Randomization and allocation

Participants will be randomized into either the intervention or control group. This study include two study arms: (a) Intervention group receiving home-based PC programme and standard usual care (n=10) and (b) Control group receiving only standard usual care (n=10).

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.

3. Telephone follow-up

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

4. Qualitative interview

Views on the intervention and how it can be improved will be sought from participants through in-depth qualitative interviews on completion of the study. For the qualitative interview, what the mothers think about the peer counselling breastfeeding support and how it can be improved will be explored. For example, the timing, content, what worked well and what didn't and how they got on with the peer counsellor. Face to face semi-structured interviews with open-ended questions will be conducted at 6 month postpartum. Each interview will last approximately 45 minutes and will be audio-recorded with participants' written permission.

Measures

Primary outcome:

- Views on the Peer Counselling Breastfeeding Intervention
    - The views of participants in the intervention group on the peer counselling breastfeeding intervention will be collected through study completion and at the qualitative interview after 6 months. The data will inform if a future definitive RCT of a home-based peer-counselling programme is feasible.

Secondary outcomes:

- 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.(4) The rates and duration of exclusive breastfeeding will be collected at one, two, four, and six months postpartum.
- Breastfeeding Self-efficacy
    - Maternal breastfeeding self-efficacy will be measured using the Breastfeeding Self-Efficacy Scale Short-Form (BSES-SF) (Chinese and English version). (5, 6) [5,6] Data will be collected at baseline, two, and four months postpartum.
- Breastfeeding Attitude
    - Attitudes and beliefs toward breastfeeding will be measured using items modified

from the Iowa Infant Feeding Attitude Scale (IIFAS).(7) IIFAS have been translated into traditional Chinese and validated for use in this population.(8) Data will be collected at baseline, two, and four months postpartum.

Statistical Analysis Plan

The number recruited, withdraw from study, and loss to follow up will be reported. Descriptive statistics of demographic and baseline variables will be reported and compared across groups.

For qualitative interviews, the audio recordings will be transcribed verbatim into Chinese and crosschecked for accuracy. We will use a 2-step thematic analysis process. First, the research team will repeatedly review each transcribed interview and then develop an open-code list derived directly from the data to provide a greater opportunity for the participants' voices to drive the analysis. All relevant textual data will be coded. The second level of the analysis will group the codes thematically using a process of contextualizing codes into conceptually similar and overarching themes. We will use a manual data management strategy to map out broad categories of information.

In preparation for conducting data analysis in a full RCT, t-tests will be used for continuous variables and chi square test for categorical variables to compare the baseline characteristics between the two study groups. 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 unless otherwise specified. The analysis will be performed using the Stata version 14.0 statistical software.

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