# Professional breastfeeding support for first-time mothers: a multi-centre cluster randomised controlled trial

Idy Chui Yuk **Fu**[1], RN, MPHC, Daniel Yee Tak **Fong**[1], PhD, Michelle Heys[2], BMBS, MPH, MD, MRCPCH, Irene Lai Yin Lee[3], RN RM MHA MPHC, Alice Sham[4], RN RM MSc MBA, & Marie **Tarrant**[1], RN MPH PhD

**Affiliations:**

[1]School of Nursing, The University of Hong Kong, 21 Sassoon Rd., Pokfulam, Hong Kong

[2]Institute of Child Health, University College London, 30 Guilford Street, London, UK

[3]Queen Mary Hospital, 102 Pokfulam Rd., Pokfulam, Hong Kong

[4]Kwong Wah Hospital, 25 Waterloo Rd., Kowloon, Hong Kong

**Short title:** Professional breastfeeding support

**Address Correspondence to:** Marie Tarrant**,** School of Nursing, The University of Hong Kong, 4/F, William M. W. Mong Block, 21 Sassoon Road, Hong Kong, tarrantm@hku.hk, tel: +852 2819 2643, fax: +852 2872 6079.

## Abstract

**Objective:** To evaluate the effect of two postnatal professional support interventions on the duration of any and exclusive breastfeeding.

**Design:** Multi-centre, three-arm, cluster randomised controlled trial.

**Population:** 722 primiparous breastfeeding mothers with uncomplicated, full-term pregnancies.

**Methods:** The three study interventions were (1) standard postnatal maternity care, (2) standard care plus three 30 to 45-minute in-hospital professional breastfeeding support sessions, or (2) standard care plus weekly 20 to 30-minute post-discharge breastfeeding telephone support for four weeks. The interventions were delivered by four trained research nurses, who were either highly experienced registered midwives or certified lactation consultants.

**Main outcome measure:** Prevalence of any and exclusive breastfeeding at one, two, and three months postpartum.

**Results:** Rates of any and exclusive breastfeeding were higher among participants in the two intervention groups at all follow-up points when compared with those who received standard care. Participants receiving the telephone support were significantly more likely to continue any breastfeeding at 1 month (76.2% vs. 67.3%; OR=1.63, 95% CI 1.10-2.41) and 2 months (58.6% vs. 48.9%; OR=1.48, 95% CI 1.04-2.10), and to be exclusively breastfeeding at 1 month (28.4% vs. 16.9%; OR=1.89, 95% CI 1.24-2.90). Participants in the in-hospital support group were also more likely to be breastfeeding at all time points but the effect was not statistically significant.

**Conclusions:** Professional breastfeeding telephone support provided early in the postnatal period and continued for the first month postpartum improves breastfeeding duration among first-time mothers. It is also possible that it was the on-going nature of the support that

increased the effectiveness of the intervention, rather than the delivery of the support by telephone specifically.

**Keywords:** Breastfeeding, intervention, professional support, randomised controlled trial

**Clinical Trial Registration** This trial is registered with the Hong Kong Clinical Trials Registry at www.hkclinicaltrials.com (HKCTR-957).

## Introduction

Exclusive breastfeeding is the ideal nutrition for infants in the first six months of life with continued breastfeeding recommended for up to two years of age and beyond.[1] Extensive research has shown that the benefits of breastfeeding are dose-dependent and infants experience better health outcomes with a longer duration of exclusive breastfeeding.[1, 2] Although breastfeeding initiation rates are high in most developed countries, the proportion of infants exclusively breastfed drops substantially in the first three months.[3, 4] In Hong Kong, current breastfeeding patterns are similar to other developed countries, with >80% of women initiating breastfeeding[5] but only 20% continuing to breastfeed exclusively for three months.[6]

Premature breastfeeding cessation is a complex issue that is influenced by biophysical factors (pain, nipple injury and insufficient milk), psychosocial factors (maternal motivation and confidence, breastfeeding knowledge, family support, and breastfeeding intentions), hospital practices (delayed initiation of breastfeeding, early formula supplementation, and delivery interventions), and sociodemographic factors (household income, maternal education level, and return to work).[7, 8] Women who discontinue breastfeeding prematurely are often reluctant to seek help from others when problems arise as they perceive breastfeeding as a task they should be able to easily master.[9] Furthermore, in Chinese and other hierarchical cultures, when new mothers encounter breastfeeding problems they are often pressured by significant others, such as their mother-in-law, to begin formula supplementation.[10]

Breastfeeding cessation rates are highest during the first month, thus the early postpartum is the most critical period for healthcare professionals to identify lactation difficulties and assist women to establish breastfeeding and avoid early cessation.[11, 12] Breastfeeding is a natural process that requires teaching and learning,[13, 14] and it is important that health care professionals provide new mothers with informational and instrumental support in the early postpartum period. While some postnatal professional support interventions reported in the literature have resulted in significant improvements in

breastfeeding rates at three months or beyond,[15-19] others had little or no effect.[20-25] Recent systematic reviews have highlighted several limitations in the current evidence, such as small sample size, variations in the components and intensity of the interventions, and differing recruitment criteria.[26-28] Hence, further trials with structured professional breastfeeding support and larger sample sizes should provide further evidence on the effectiveness of postnatal interventions. The aim of this study was to examine the effectiveness of two early postnatal support interventions provided to first-time mothers by trained healthcare professionals on breastfeeding outcomes.

## Methods

### Design, Setting and Participants

We conducted a multi-centre, prospective, cluster randomized controlled trial to assess the efficacy of two professional breastfeeding support interventions. Mother-infant pairs were recruited from the postnatal units of three geographically distributed public hospitals providing obstetrical services. Hong Kong has a total of eight public and nine private hospitals providing comprehensive obstetric services. Two of the study hospitals have over 300 deliveries per month and one hospital has over 500 deliveries per month. At the time of participant recruitment, a large proportion of obstetric patients in most private hospitals and some public hospitals were birth tourists from Mainland China.[29] Thus, the study hospitals were selected to provide geographic variation while also maximizing recruitment of Hong Kong mothers. Hong Kong public hospitals provide modern, up-to-date obstetric services and postnatal obstetric units are staffed primarily with midwives, some of whom may also be board certified lactation consultants.

Eligible participants were Hong Kong Chinese primiparas, at least 18 years of age, intending to breastfeed, and without any major obstetric complications (i.e., severe postpartum hemorrhage) or serious medical problems (i.e., psychiatric illness). Additional

eligibility criteria for the infant included: gestational age ≥37 weeks; birth weight ≥2500 grams, 5-minute Apgar score ≥8, and no physical anomalies that would contraindicate or complicate breastfeeding. Mothers who were planning to live in Mainland China after delivery were excluded.

**Interventions**

The study interventions were (1) standard hospital postnatal care, (2) in-hospital support that included three 30-minute professional breastfeeding support sessions in the first 48 hours postpartum, or (3) telephone follow-up support weekly for up to 4 weeks postpartum or until breastfeeding had been completely stopped, whichever came first. Standard postnatal care consisted of routine perinatal care according to the type of delivery, group postnatal lactation education provided by a midwife or lactation consultant, one-on-one assistance with breastfeeding if problems arose and time permitted, and post-discharge follow-up either at the outpatient clinic of the delivery hospital or the nearest Maternal and Child Health Centre. Information on available peer-support groups is also provided on hospital discharge.

In-hospital support consisted of three, one-to-one sessions, with two delivered to participants in the first 24 hours postpartum and one in the second 24 hours prior to discharge. Participants were given information on the benefits of exclusive breastfeeding, the physiology of lactation, and common early breastfeeding problems. In addition, participants were given guidance and instruction on breastfeeding techniques, such as positioning the infant, latching and attachment, assessing feeding behaviors, and manual breastmilk expression. During each session, participants were observed positioning, attaching and feeding the newborn with appropriate feedback provided and hands-on guidance only when necessary.[30] Each session lasted for 30 to 45 minutes and participants were encouraged to raise questions and concerns.

Participants in the telephone support intervention were contacted within 72 hours of hospital discharge and then weekly up to four weeks postpartum or until they had stopped

breastfeeding. Early support sessions focused on general breastfeeding knowledge, assessing infant feeding patterns, the physical and emotional health of mother, and guidance on managing problems such as poor latching, poor weight gain, insufficient milk production, and breast complications. In later support sessions, additional advice was given on breastfeeding discreetly in public places, preparation for returning to work, and expressing and storing breast milk. Exclusive breastfeeding was promoted and encouraged at each telephone support session and participants were told where to seek further professional support or medical consultation, if necessary. Sessions lasted for 20 to 30 minutes.

Separate log sheets were kept on all participants in the two intervention groups and the study research nurses recorded details of all support sessions. The log sheets recorded the date and time the intervention was delivered, the duration of the session, the topics covered, and any problems reported by the mother to the research nurse. The interventions were delivered by four trained research nurses, who were either highly experienced registered midwives or certified lactation consultants. All research nurses had more than 20 years of experience working in the postnatal setting delivering breastfeeding support to new mothers, had completed a comprehensive lactation support program, and had personal breastfeeding experience. Prior to implementing the study protocol, the research nurses were provided with an additional eight hours of training on the study protocols and to ensure that breastfeeding support practices were consistent and evidence-based. In addition, a trial coordinator regularly monitored the study sites and reviewed the log sheets to ensure proper implementation of the interventions. Identified issues were then discussed and resolved at regular research team meetings.

**Randomization and Concealment**

Because of the crowded conditions on maternity wards of public hospitals in Hong Kong, there would be a high chance of contamination of the different intervention groups if

participants within each hospital site were individually randomized to the three treatment groups. Therefore, cluster randomization was used with hospitals being the unit of randomization. Each week, we randomly assigned each study hospital to one of the three treatment groups. The allocation sequence was generated using an online program (www.randomization.com) by a person not involved in the subject recruitment or data collection and were placed in sequential numbered opaque sealed envelopes. All participants at each study site were allocated to the intervention to which the hospital was randomly assigned for that week. Participants were recruited from Monday to Friday and there was no recruitment on Saturday and Sunday. The normal length of stay for a vaginal delivery was 48 hours and for caesarean section was 72 hours. Saturday and Sunday would then allow adequate washout before the start of the next round of randomization in the following week. The research nurses and study sites were only informed of the weekly treatment allocation 48 hours prior to commencing that week's recruitment and informed written consent was obtained from all participants before the intervention was started.

**Data Collection**

The research nurses used the daily ward logbooks to screen eligible participants. All participants completed a standardized questionnaire that included information on age, education, employment, family income, antenatal education, and planned duration of breastfeeding. The research nurse also collected relevant obstetric and neonatal data (i.e., birth weight, gestational age, delivery method) from the participant. Follow-up infant feeding data, which included the amount and type of all milk (breastmilk and infant formula) and other liquid feeds provided to the infant in the preceding 24-hours,[31] were collected by telephone at 1, 2, 3, and 6 months or until they stopped breastfeeding. A research nurse not involved with delivering the intervention recruited the participants to both the standard care and telephone support groups. However, because of study logistics it was not possible to have one nurse

recruit the participants for the in-hospital support group and another nurse deliver the intervention. Thus, for this group, the nurse who recruited the participants also delivered the intervention. All eligible participants on the wards were invited to participate in the study and no coercion was used to encourage recruitment. The importance of voluntary participation was reinforced to the research nurses during the study training session and the trial coordinator regularly monitored participant recruitment for all three groups to ensure that participation was completely voluntary. The same research nurse provided all support sessions to participants, thus ensuring consistency of care. A study research assistant, who was blinded to the participants' treatment allocation, conducted the telephone follow-up.

**Outcome Measures**

The primary outcomes were the prevalence of any and exclusive breastfeeding at one, two, and three months. Exclusive breastfeeding was defined as giving only breastmilk without food or other liquids, with the exception of vitamins or medications.[31] We therefore classified infant feeding status into three categories: exclusive breastfeeding, any breastfeeding and exclusive formula feeding. Secondary outcomes were the overall duration of any and exclusive breastfeeding. We measured the duration of any and exclusive breastfeeding as the age of the infant in weeks when the participant completely stopped breastfeeding and first introduced infant formula, respectively.

**Sample Size Calculation**

Previous studies of similar professional support interventions have shown differences between control and intervention groups ranging from 17% to 85%.[17, 19, 32, 33] Therefore, the sample size calculation was based on 80% power to detect a 15% difference among the three groups in the proportion of participants exclusively breastfeeding at 3 months postpartum. A Bonferroni adjustment was done and the level of significance was set at 0.025 (0.05/2). We

took 0.25 as the coefficient of variation of true proportions (k) which is often the maximum to account for the variation between clusters.[34] Estimating an average cluster size of six, a total of 33 clusters were required, yielding a sample size of 198 participants per treatment group or a total of 594 participants.

**Data Analysis**

We examined the homogeneity in baseline characteristics between treatment groups using ANOVA for continuous variables and Chi-square for categorical variables. We used mixed-effects logistic regression models to compare intervention efficacy on breastfeeding rates between groups at the study follow-up points and to account for the intra-cluster correlation between participants. We adjusted for multiplicity by using the Holm procedure, which is less conservative than the Bonferroni adjustment.[35] Participants who were lost to follow-up were considered to have stopped breastfeeding at the point of last follow-up. Study site was also entered as a covariate into the logistic regression models for adjustment before assessing the treatment efficacy. To compare the overall duration of any and exclusive breastfeeding among participants in the three treatment groups, we constructed Kaplan-Meier survival curves to estimate the cumulative survival distribution.[36] In addition, a Frailty model[37] with adjustment for the study site and to control for clustering effects, was used to compare the duration of different types of breastfeeding. Finally, we also conducted several sensitivity analyses. First, we further adjusted both the mixed-effects logistic regression models and Frailty models for baseline covariates that showed some variation across the three treatment groups. Second, instead of assuming that participants who were lost to follow-up had stopped breastfeeding, we excluded them from the subsequent analysis after the point of last follow-up and reanalysed both the minimally and fully adjusted mixed effects logistic regression models. All statistical tests were two-tailed and a p-value of less than 0.05 was considered significant. Data analyses were performed using Stata Version 13.1 (Stata Corp, College Station, Tx).[38]

Before data collection, we obtained ethical approval for the study from the Institutional Review Board of the University of Hong Kong/Hospital Authority Hong Kong West Cluster and from all of the participating institutions. All participants, irrespective of their treatment group, were provided with the same study information, which included information on the purpose of the study, possible treatments they could receive, the potential risks and benefits of participation, the measures taken to protect the confidentiality of their data, and the assurance that participation or non-participation would not affect the care that they received during their hospital stay. All participants provided informed written consent before their participation.

## Results

We recruited 724 mother-infant pairs, and randomized 264 to the standard care group, 191 to the in-hospital support group, and 269 to the telephone support group (Figure 1). After recruitment, two participants were excluded because they did not meet the eligibility criteria, leaving a total of 722 participants. Eleven (1.5%) participants had no follow-up after study recruitment in the hospital, 11 (1.5%) participants had partial follow-up, and 700 (97%) participants had complete follow-up. All loss to follow-up was because we were unable to contact the participants. Participants were recruited between November 2010 and September 2011 and all follow-up was completed by May 2012.

Of the 191 participants allocated to the in-hospital support group, 137 (71.7%) received all three sessions, 52 (27.2%) received two sessions, and 2 (1.0%) received only one session before hospital discharge. Of the 268 participants in the telephone support group, 199 (74.3%) receive all support sessions for which they were eligible; 27 (10.1%), 24 (9.0%), 13 (4.9%) and 5 (1.9%) missed 1, 2, 3 and 4 sessions respectively. Because some participants stopped breastfeeding during the four-week intervention, not all were eligible to receive four telephone support sessions.

Baseline characteristics and maternal and birth data were similar across the three groups (Table 1), although there were some minor variations in maternal education, family income, intention to exclusively breastfeed, and antenatal breastfeeding class attendance. The proportion of participants continuing any and exclusive breastfeeding were consistently higher in the two intervention groups at all follow-up points when compared with those receiving standard care (Figure 2). In comparison to the standard-care group, participants in the telephone support group were significantly more likely to continue any breastfeeding at both one month (76.2% vs. 67.3%; Odds Ratio [OR]=1.63, 95% CI 1.10 to 2.41) and two months (58.6% vs. 48.9%; OR=1.48, 95% CI 1.04 to 2.10) and significantly more likely to be exclusively breastfeeding at 1 month (OR=1.89; 95% CI 1.24 to 2.90) (Table 2). Participants in the telephone support group were also more likely to be breastfeeding at three months, but the effect was not statistically significant (OR=1.39; 95% CI 0.98 to 1.98). Adjustment for multiplicity using the Holm procedure did not affect the outcomes and all statistically significant values remained significant. We also compared the effectiveness of the telephone support and the in-hospital support on breastfeeding outcomes and although the telephone support was more beneficial than the in-hospital support, there were no statistically significant differences between the two groups.

Figure 3 shows the overall duration of any breastfeeding by treatment group over the six-month follow-up period. Results of the Frailty models (Table 3) show that when compared with the standard care group, participants who received the telephone support had a significantly lower overall risk of stopping breastfeeding (hazard ratio [HR]=0.79; 95% CI 0.64 to 0.98) but there was no significant difference between the in-hospital support group and the standard care group. The overall duration of exclusive breastfeeding by treatment groups is shown in Figure 4. Approximately one-half of participants, irrespective of their treatment group, did not exclusively breastfeed at all after birth. Although the risk of stopping exclusive breastfeeding was lower in both the in-hospital support and telephone support

groups, the effects were not statistically significant. Sensitivity analyses show that further adjustment for the baseline characteristics of maternal education, family income, intention to exclusively breastfeed, and antenatal breastfeeding class attendance did not have any substantial impact on the primary study outcomes (see supplementary Table 2a) and resulted in a statistically significant effect of the telephone support on the duration of exclusive breastfeeding (see supplementary Table 3a). Removing participants who were lost to follow-up from subsequent analyses had little impact on the primary study outcomes (See supplementary Tables 2b & 2c).

## Discussion

### Main Findings

Early professional breastfeeding support, especially weekly telephone support, significantly increased the rates of any and exclusive breastfeeding in the early postnatal period and significantly increased the overall duration of breastfeeding across the first 6 months. When compared with the standard care group, participants receiving professional telephone support were 60% more likely to be giving any breastmilk and almost twice as likely to be exclusively breastfeeding at one month postpartum. Across the first six months, participants receiving professional telephone support were about 20% less likely to stop breastfeeding when compared with the standard care group.

### Strengths and Limitations

This study is one of the larger randomized trials of professional breastfeeding support,[26, 39] with high treatment fidelity and follow-up rates. We limited our sample to first-time mothers so that previous positive and negative breastfeeding experiences would not affect the study outcomes. We used a multi-centre approach, recruiting participants from three large publicly funded tertiary care hospitals in Hong Kong. The cluster randomization reduced the chance of

contamination of the treatment groups and regular telephone follow-up of the participants minimized recall bias related to breastfeeding outcomes. The study outcomes show a consistent pattern of improved breastfeeding outcomes across all time points, thus supporting the study conclusions.

The cluster randomization however, did result in an imbalance in the number of participants in the three treatment groups, especially the in-hospital support group. The number of eligible participants varied among the three study sites over the 33 weeks of recruitment leading to unequal numbers of participants in the study groups. Furthermore, measurement of study outcomes relied on maternal report of infant feeding status at each follow-up interval. However, this was unlikely to bias our results as we used the 24-hour recall method recommended by WHO[31] and maternal recall of breastfeeding duration has been found to be accurate up to 20 years after breastfeeding.[40] Finally, blinding of either participants or those delivering the intervention is not possible in this type of study design. Measures were taken however, to reveal the treatment allocation only before the next week of data collection and the research assistant ascertaining the outcome data was blinded to the participants' group allocation.

**Interpretation of Findings**

Previous studies have found that in-person, postnatal professional support is more effective than other types of remote support.[16, 19, 41] However, we did not observe such an effect. We designed our in-hospital intervention to facilitate the establishment of breastfeeding in the first 24 hours after birth as observational studies have shown that early initiation of breastfeeding and avoidance of infant formula supplementation in the hospital are associated with longer breastfeeding duration.[42] The lower effectiveness of the in-hospital support may be attributable to several factors. First, the immediate postnatal period is often overwhelming for first-time mothers. Participants may have experienced residual pain or fatigue during the

support sessions, causing them to be less receptive to the intervention. Also, many breastfeeding problems do not present until after hospital discharge. The milk supply is usually not well established until day 3 to 4, after which problems such as perceived insufficient milk supply, breast engorgement and nipple trauma present more frequently. These problems are well-known predictors for early formula supplementation and breastfeeding cessation, especially if they are not adequately addressed.[9, 43, 44] In addition, the continuous support provided by the regular telephone contact may have been especially helpful to new mothers at a time when they were less likely to have other types of support. In Chinese cultures, many new mothers face substantial family and sociocultural pressure to stop breastfeeding after hospital discharge[10] and these topics were included in the telephone support intervention. This continuous professional support can increase maternal confidence and satisfaction in caring for their infant.[45] Thus, it is possible that it was the on-going nature of the telephone support, rather than telephone support itself, that enabled participants to breastfeed for longer. It is possible that if direct, in-person support could be provided over the first month postpartum that it would be equally effective. However, as regular in-person support is logistically and economically more difficult to provide, telephone support is substantially more feasible to provide during this time period, especially in resource limited settings.

Another factor possibly contributing to the effectiveness of the interventions was the continuity of care from having the same nurse deliver all of the intervention sessions, thus ensuring that participants received advice and support that was consistent and evidence-based. Studies have shown that conflicting advice from health-care professionals happens frequently and contributes to early formula supplementation and breastfeeding cessation.[46, 47] Furthermore, much of the breastfeeding support available to new mothers is client initiated and mothers themselves must seek support. This is especially true in Hong Kong where postnatal home visits by nurses or midwives are not routine and there are no health visitors or

community-based midwives to support new mothers. In the early post-natal period, they may be too tired and overwhelmed to actively seek support themselves and it may be easier to switch to infant formula. Furthermore, the home environment may have been more conducive for women to receive information and support[48] as participants were able to negotiate the timing of the support that best fit their family routine.

Another finding of this study were the overall low rates of exclusive breastfeeding, with only about one-half of all participants exclusively breastfeeding for any duration. Even in the two study treatment arms, where rates of exclusive breastfeeding were higher than the standard care group, only one-third of all participants who were still breastfeeding, were doing so exclusively. This is lower than in previous studies, where approximately 50% of breastfeeding mothers were exclusively breastfeeding.[6] Although rates of breastfeeding initiation in this population are increasing,[5] the proportion of mothers exclusively breastfeeding is decreasing. Formula supplementation of breastfeeding infants continues to be pervasive in most developed countries[49, 50] and has been shown to have a negative impact on breastfeeding duration.[42, 51] Since the benefits of breastfeeding are dose-dependent,[2] it is important to further explore why so few new mothers exclusively breastfeed.

The obstetric settings used for this study were large tertiary care hospitals, settings similar to obstetric services offered in many developed countries. The interventions carried out by the study research nurses were not outside of the expertise of midwives or lactation consultants working in most hospital postnatal obstetric units or those working in community-based health clinics. As such the results are generalizable to similar settings in other countries.

## Conclusions

Findings from this study provide some of the strongest evidence yet of the effectiveness of professional telephone support to improve breastfeeding outcomes in first-time mothers. The benefit of the telephone support in extending the duration of breastfeeding was sustained

396 across the first six months postpartum. Rates of exclusive breastfeeding, however, were only
397 improved in the early postnatal period. Therefore, while it is important that professional
398 support is initiated soon after birth and is continued for a minimum of one month postpartum,
399 it is likely that further or different support is needed to sustain the improvements in exclusive
400 breastfeeding. Further research is needed to explore and identify the reasons for the
401 persistently low rates of exclusive breastfeeding and to test further interventions to improve
402 exclusive breastfeeding rates.
403
404 **Figure Caption List**
405 Figure 1. Flow diagram for randomized controlled trial of professional breastfeeding support
406 Figure 2. Proportion of participants continuing any or exclusive breastfeeding at follow-up
407 Figure 3. Overall duration of any breastfeeding by treatment group
408 Figure 4. Overall duration of exclusive breastfeeding by treatment group
409

**Disclosures of Interest:** The authors have no conflicts of interest to disclose.

**Contribution to authorship:** IF contributed to the study design, coordinated and supervised data collection, conducted data analysis, wrote the first draft of the manuscript, and approved the final manuscript as submitted. DF contributed to the study design, assisted with data analysis, critically reviewed and revised the manuscript, and approved the final manuscript as submitted. MH contributed to the study design, critically reviewed and revised the manuscript, and approved the final manuscript as submitted. IL facilitated participant recruitment, critically reviewed and revised the manuscript, and approved the final manuscript as submitted. AS facilitated participant recruitment, critically reviewed and revised the manuscript, and approved the final manuscript as submitted. MT conceptualized the study, obtained funding, oversaw the implementation of the study, assisted with data analysis, critically reviewed and revised the manuscript, and approved the final manuscript as submitted.

**Ethics approval:** Ethical approval was obtained from the (1) Institutional Review Board of the University of Hong Kong/Hospital Authority Hong Kong West Cluster (HKU/HA HKW IRB) Cluster Research Ethics Committee (Ref. #UW-09-307), August 2009, (2) Ethics Committee of the Hong Kong East Cluster (Ref.#HKEC-2010-028), May 2010 and (3) Clinical Research Ethics Committee, Kowloon West Cluster (Ref.#KW/EX/10-034), June 2010.

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559

560

**Enrollment**

Assessed for eligibility (n=1945)

Excluded (n=1221)
- Did not meet inclusion criteria (n=1045)
- Declined to participate (n=176)

Randomized participants (n=724)

**Allocation**

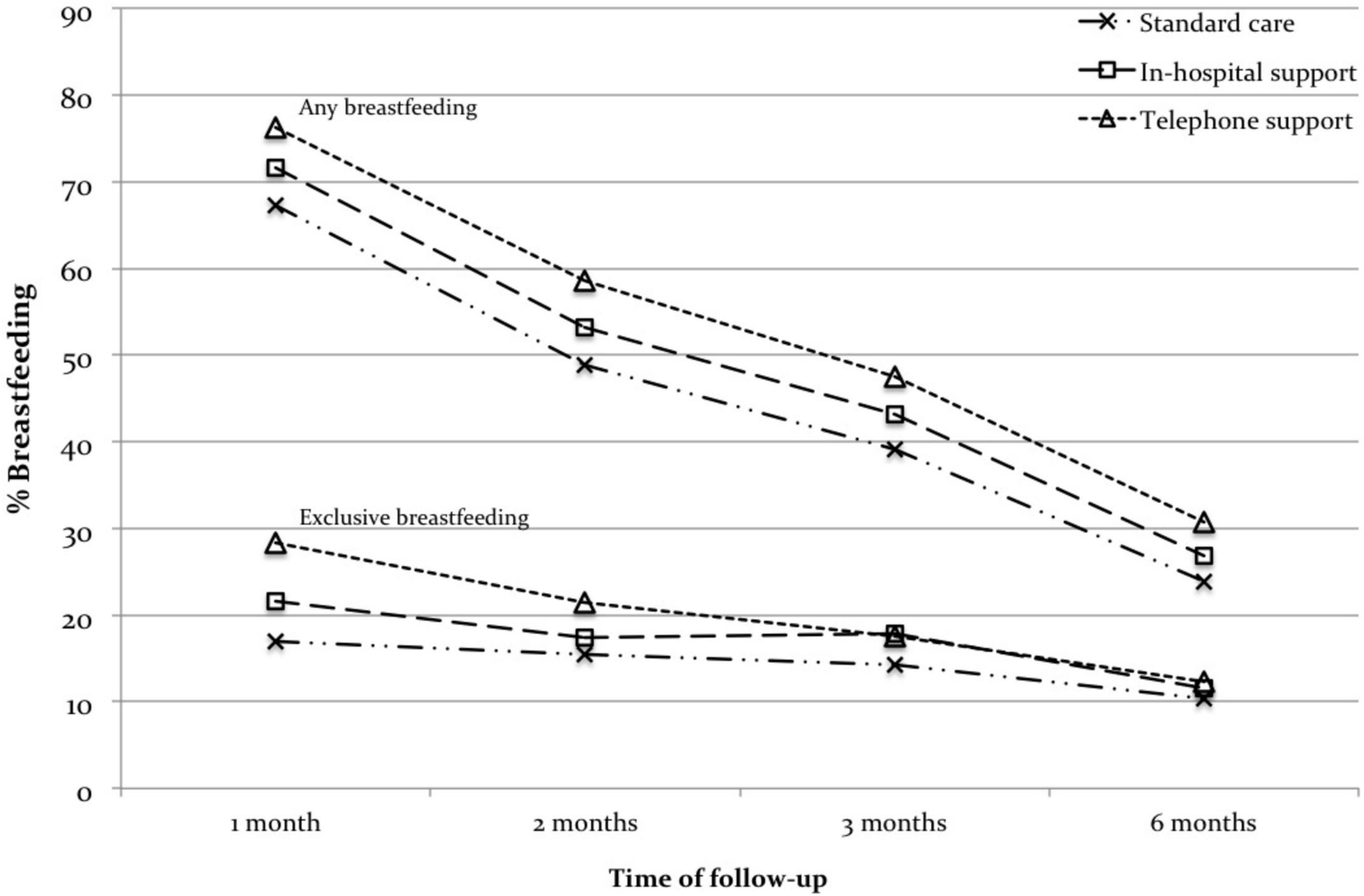
| Usual care (n=264) | In-hospital support (n=191) | Telephone support (n=269) |
|---|---|---|
| Excluded (n=1)<br>▪ Infant admitted to special care unit | | Excluded (n=1)<br>▪ Mother was multiparous |

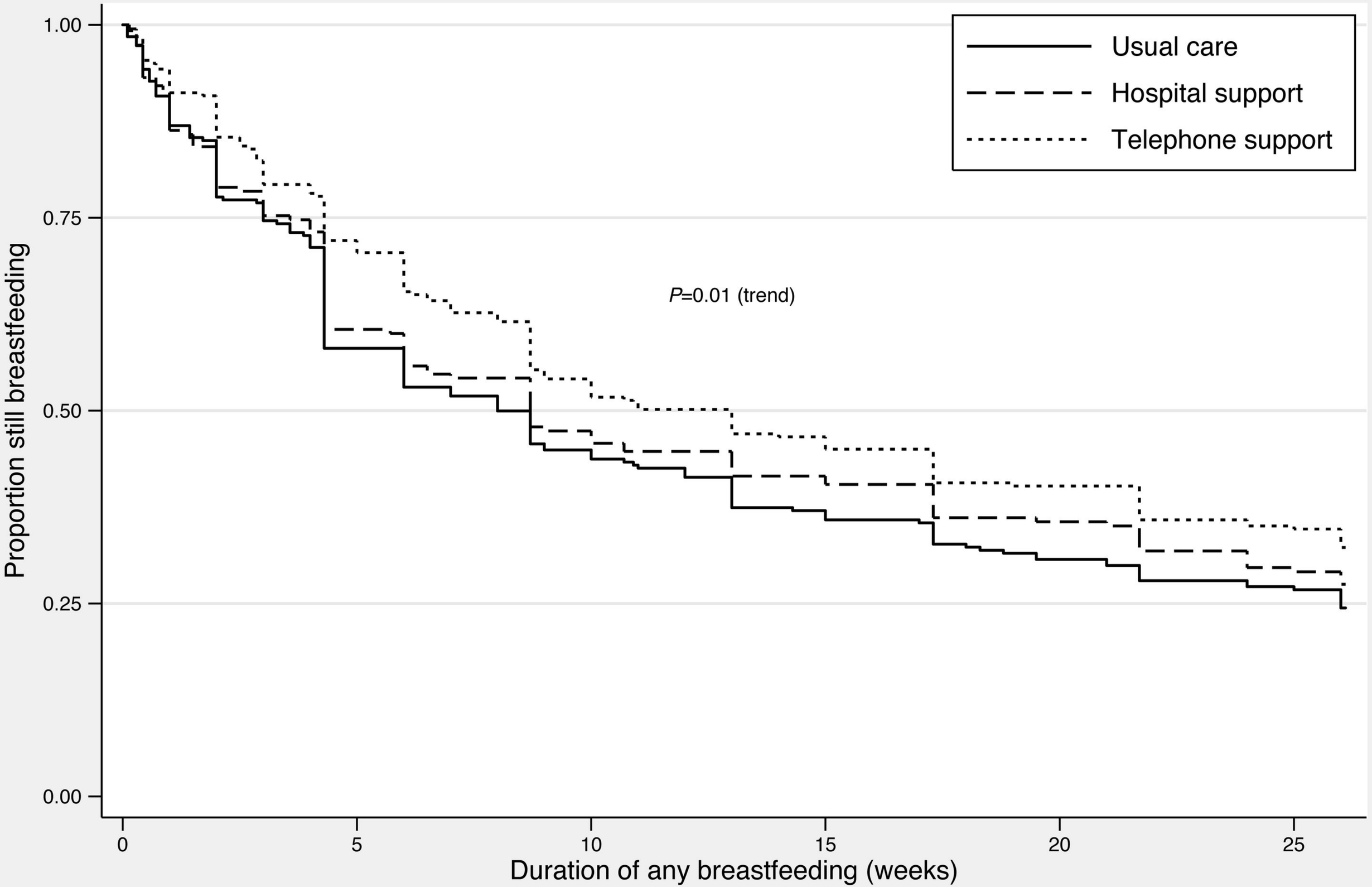
**Follow-up**

| No follow-up (n=3) | No follow-up (n=1) | No follow-up (n=7) |
|---|---|---|

**Analysis**

| Analyzed (n=260)<br>▪ Full follow-up (n=257)<br>▪ Lost to follow-up at 2 mon (n=1)<br>▪ Lost to follow-up at 3 mon (n=2) | Analyzed (n=190)<br>▪ Full follow-up (n=188)<br>▪ Lost to follow-up at 3 mon (n=1)<br>▪ Lost to follow-up at 6 mon (n=1) | Analyzed (n=261)<br>▪ Full follow-up (n=255)<br>▪ Lost to follow-up at 2 mon (n=3)<br>▪ Lost to follow-up at 3 mon (n=2)<br>▪ Lost to follow-up at 6 mon (n=1) |
|---|---|---|


90
80
70
60
50
40
30
20
10
0
% Breastfeeding
Any breastfeeding
Exclusive breastfeeding
Standard care
In-hospital support
Telephone support
1 month
2 months
3 months
6 months
Time of follow-up


1.00
0.75
0.50
0.25
0.00
Proportion still breastfeeding
Usual care
Hospital support
Telephone support
P=0.01 (trend)
0
5
10
15
20
25
Duration of any breastfeeding (weeks)

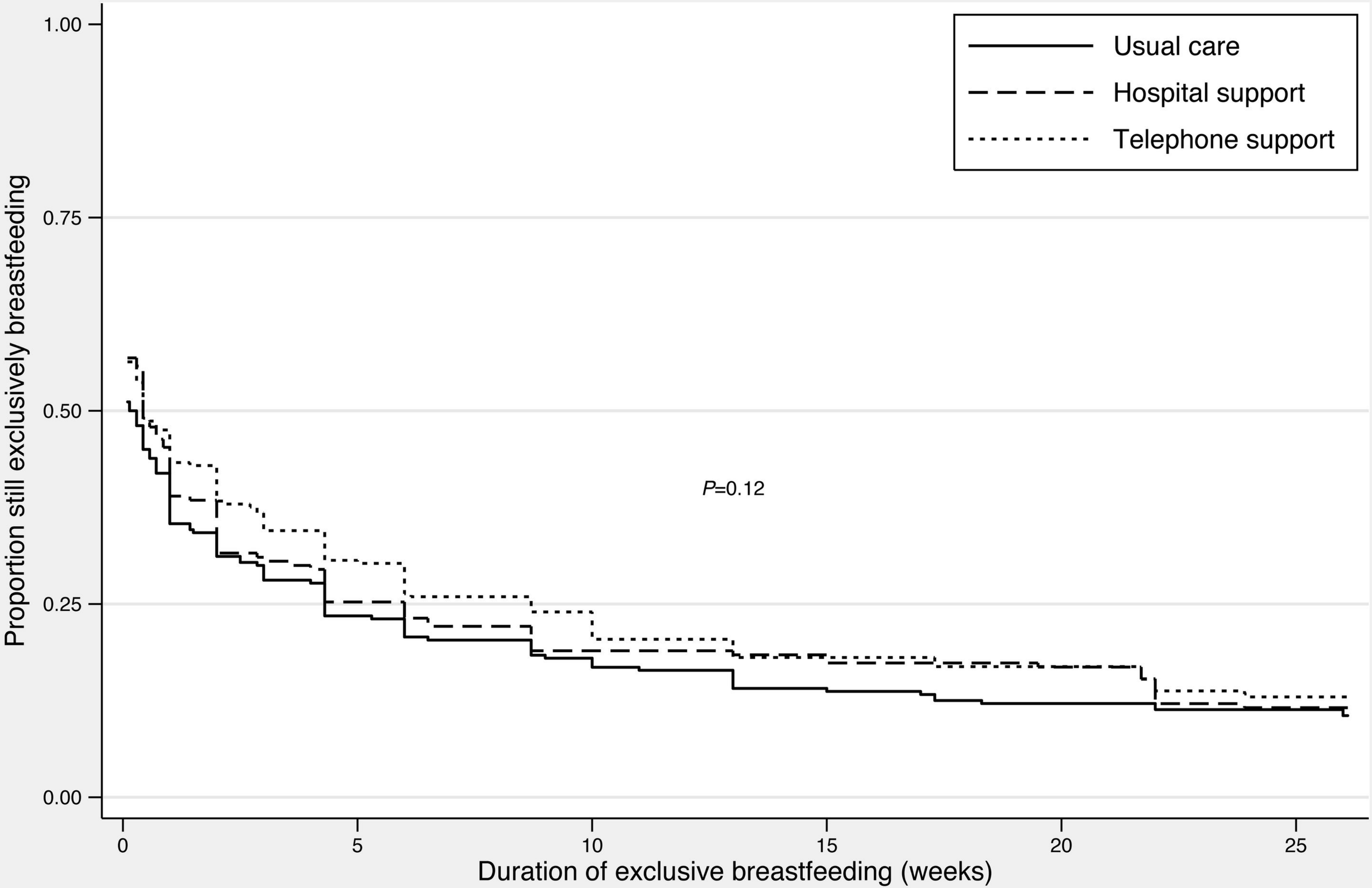

Usual care
Hospital support
Telephone support
P=0.12
Proportion still exclusively breastfeeding
1.00
0.75
0.50
0.25
0.00
0
5
10
15
20
25
Duration of exclusive breastfeeding (weeks)

**Table 1.** Baseline characteristics of participants by intervention group

| | Standard care group (n=263) | In-hospital group (n=191) | Telephone group (n=268) | Total (n=722) |
|---|---|---|---|---|
| Maternal age Mean (SD) | 30.2 (4.5) | 31.0 (4.6) | 30.3 (4.3) | 30.5 (4.5) |
| Maternal education | | | | |
| 0 – 9 years | 17 (6.5) | 13 (6.8) | 16 (6.0) | 46 (6.4) |
| 10 – 13 years | 122 (46.4) | 83 (43.7) | 115 (42.9) | 320 (44.4) |
| Post-secondary | 39 (14.8) | 24 (12.6) | 39 (14.6) | 102 (14.1) |
| University degree or above | 85 (32.3) | 70 (36.8) | 98 (36.6) | 253 (35.1) |
| Monthly family income[a] | | | | |
| <HK$14,999 | 39 (14.9) | 21 (11.1) | 43 (16.2) | 103 (14.4) |
| HK$15,000-29,999 | 121 (46.2) | 73 (38.6) | 116 (43.6) | 310 (43.2) |
| >HK$30,000 | 102 (38.9) | 95 (50.3) | 107 (40.2) | 304 (42.4) |
| Mother planning to exclusively breastfeed | | | | |
| No | 110 (41.8) | 89 (46.8) | 105 (39.5) | 304 (42.3) |
| Yes | 153 (58.2) | 101 (53.2) | 161 (60.5) | 415 (57.7) |
| Mother attended antenatal breastfeeding classes | | | | |
| No | 160 (60.8) | 121 (63.7) | 157 (58.6) | 438 (60.7) |
| Yes | 103 (39.2) | 69 (36.3) | 111 (41.4) | 283 (39.3) |
| Mother returning to work | | | | |
| No | 58 (22.1) | 38 (19.9) | 59 (22.0) | 155 (21.5) |
| Yes | 205 (77.9) | 153 (80.1) | 209 (78.0) | 567 (78.5) |
| Type of delivery | | | | |
| Spontaneous vaginal | 217 (82.5) | 148 (77.5) | 212 (79.1) | 577 (79.9) |
| Instrumental vaginal | 15 (5.7) | 15 (7.9) | 22 (8.2) | 52 (7.2) |
| Planned caesarean section | 9 (3.4) | 10 (5.2) | 10 (3.7) | 29 (4.0) |
| Emergency caesarean section | 22 (8.4) | 18 (9.4) | 24 (9.0) | 64 (8.9) |
| Study site | | | | |
| Hospital A | 53 (20.2) | 43 (22.5) | 81 (30.2) | 177 (24.5) |
| Hospital B | 140 (53.2) | 85 (44.5) | 116 (43.3) | 341 (47.2) |
| Hospital C | 70 (26.6) | 63 (33.0) | 71 (26.5) | 204 (28.3) |

Note: Figures are numbers (percentages) unless otherwise specified
SD=Standard Deviation
[a]1 USD = 7.78 HKD

**Table 2.** Association between study interventions and breastfeeding status at follow-up

| | **Odds Ratio[a] (95% Confidence Interval) for any breastfeeding** | | | **Odds Ratio[a] (95% Confidence Interval) for exclusive breastfeeding** | | |
|---|---|---|---|---|---|---|
| | In-hospital vs. standard care | Telephone vs. standard care | Telephone vs. in-hospital | In-hospital vs. standard care | Telephone vs. standard care | Telephone vs. in-hospital |
| At 1-month | 1.27 (0.84, 1.92), P=0.25 | 1.63 (1.10, 2.41), P=0.01 | 1.28 (0.84, 1.97), P=0.26 | 1.32 (0.82, 2.13), P=0.25 | 1.89 (1.24, 2.90), P=0.003 | 1.43 (0.92, 2.22), P=0.11 |
| At 2-months | 1.19 (0.82, 1.73), P=0.37 | 1.48 (1.04, 2.10), P=0.03 | 1.24 (0.85, 1.81), P=0.26 | 1.13 (0.68, 1.87), P=0.65 | 1.43 (0.91, 2.26), P=0.12 | 1.27 (0.79, 2.06), P=0.32 |
| At 3-months | 1.16 (0.79, 1.70), P=0.44 | 1.37 (0.96, 1.95), P=0.08 | 1.18 (0.81, 1.72), P=0.40 | 1.26 (0.76, 2.11), P=0.37 | 1.20 (0.74, 1.94), P=0.45 | 0.95 (0.58, 1.56), P=0.84 |
| At 6-months | 1.13 (0.73, 1.74), P=0.58 | 1.33 (0.90, 1.98), P=0.15 | 1.18 (0.78, 1.79), P=0.44 | 1.13 (0.62, 2.06), P=0.69 | 1.21 (0.70, 2.09), P=0.49 | 1.07 (0.60, 1.90), P=0.82 |

[a]Adjusted for cluster and hospital

**Table 3.** Risk of weaning from any and exclusive breastfeeding during the entire follow-up period

| | **Hazard Ratio[a] (95% Confidence Interval)** | | |
|---|---|---|---|
| | In-hospital vs. standard care | Telephone vs. standard care | Telephone vs. in-hospital |
| Any breastfeeding | 0.93 (0.74, 1.15) P=0.49 | 0.79 (0.64, 0.98) P=0.03 | 0.86 (0.68, 1.07) P=0.18 |
| Exclusive breastfeeding | 0.92 (0.75, 1.14) P=0.46 | 0.83 (0.69, 1.01) P=0.06 | 0.90 (0.73, 1.10) P=0.31 |

[a]Adjusted for cluster and hospital

**Table 2a.** Association between study interventions and breastfeeding status at follow-up adjusted for baseline variables

| | **Odds Ratio[a] (95% Confidence Interval) for any breastfeeding** | | | **Odds Ratio[a] (95% Confidence Interval) for exclusive breastfeeding** | | |
|---|---|---|---|---|---|---|
| | In-hospital vs. standard care | Telephone vs. standard care | Telephone vs. in-hospital | In-hospital vs. standard care | Telephone vs. standard care | Telephone vs. in-hospital |
| At 1-month | 1.30 (0.85, 2.00), P=0.23 | 1.65 (1.10, 2.47), P=0.02 | 1.27 (0.81, 1.98), P=0.30 | 1.42 (0.86, 2.34), P=0.17 | 1.86 (1.20, 2.90), P=0.006 | 1.31 (0.82, 2.10), P=0.25 |
| At 2-months | 1.24 (0.83, 1.84), P=0.29 | 1.49 (1.03, 2.15), P=0.03 | 1.20 (0.81, 1.79), P=0.37 | 1.20 (0.70, 2.05), P=0.51 | 1.36 (0.84, 2.19), P=0.21 | 1.13 (0.68, 1.89), P=0.63 |
| At 3-months | 1.22 (0.81, 1.83), P=0.34 | 1.38 (0.95, 2.00), P=0.09 | 1.13 (0.76, 1.69), P=0.54 | 1.48 (0.86, 2.54), P=0.16 | 1.16 (0.70, 1.91), P=0.57 | 0.78 (0.46, 1.32), P=0.36 |
| At 6-months | 1.23 (0.78, 1.95), P=0.37 | 1.36 (0.90, 2.05), P=0.15 | 1.10 (0.71, 1.71), P=0.68 | 1.35 (0.72, 2.56), P=0.35 | 1.17 (0.66, 2.08), P=0.59 | 0.87 (0.47, 1.60), P=0.64 |

[a]Adjusted for cluster, hospital, maternal education, family income, intention to exclusively breastfeed, and antenatal breastfeeding class attendance

**Table 2b.** Association between study interventions and breastfeeding status at follow-up (complete case analysis)

| | **Odds Ratio[a] (95% Confidence Interval) for any breastfeeding** | | | **Odds Ratio[a] (95% Confidence Interval) for exclusive breastfeeding** | | |
|---|---|---|---|---|---|---|
| | In-hospital vs. standard care | Telephone vs. standard care | Telephone vs. in-hospital | In-hospital vs. standard care | Telephone vs. standard care | Telephone vs. in-hospital |
| At 1-month | 1.27 (0.84, 1.92), P=0.26 | 1.63 (1.10, 2.41), P=0.01 | 1.28 (0.84, 1.97), P=0.25 | 1.32 (0.82, 2.13), P=0.25 | 1.89 (1.24, 2.90), P=0.003 | 1.43 (0.92, 2.22), P=0.11 |
| At 2-months | 1.18 (0.81, 1.72), P=0.39 | 1.51 (1.06, 2.14), P=0.02 | 1.28 (0.87, 1.87), P=0.21 | 1.12 (0.67, 1.86), P=0.66 | 1.45 (0.92, 2.28), P=0.11 | 1.30 (0.80, 2.09), P=0.30 |
| At 3-months | 1.15 (0.78, 1.69), P=0.34 | 1.39 (0.98, 1.98), P=0.07 | 1.21 (0.83, 1.77), P=0.32 | 1.25 (0.75, 2.09), P=0.39 | 1.21 (0.75, 1.95), P=0.43 | 0.97 (0.59, 1.58), P=0.89 |
| At 6-months | 1.12 (0.73, 1.74), P=0.59 | 1.36 (0.91, 2.01), P=0.13 | 1.20 (0.79, 1.83), P=0.39 | 1.12 (0.62, 2.05), P=0.70 | 1.25 (0.72, 2.15), P=0.43 | 1.11 (0.62, 1.98), P=0.73 |

[a]Adjusted for cluster and hospital



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**Table 2c.** Association between study interventions and breastfeeding status at follow-up adjusted for baseline variables (complete case analysis)

| | **Odds Ratio[a] (95% Confidence Interval) for any breastfeeding** | | | **Odds Ratio[a] (95% Confidence Interval) for exclusive breastfeeding** | | |
|---|---|---|---|---|---|---|
| | In-hospital vs. standard care | Telephone vs. standard care | Telephone vs. in-hospital | In-hospital vs. standard care | Telephone vs. standard care | Telephone vs. in-hospital |
| At 1-month | 1.30 (0.85, 2.00), P=0.23 | 1.65 (1.10, 2.47), P=0.02 | 1.27 (0.81, 1.98), P=0.30 | 1.42 (0.86, 2.34), P=0.17 | 1.86 (1.20, 2.90), P=0.006 | 1.31 (0.82, 2.10), P=0.25 |
| At 2-months | 1.22 (0.82, 1.82), P=0.32 | 1.51 (1.04, 2.19), P=0.03 | 1.23 (0.83, 1.84), P=0.30 | 1.18 (0.69, 2.03), P=0.54 | 1.36 (0.84, 2.19), P=0.21 | 1.15 (0.69, 1.92), P=0.59 |
| At 3-months | 1.21 (0.81, 1.82), P=0.36 | 1.40 (0.96, 2.03), P=0.08 | 1.15 (0.77, 1.73), P=0.48 | 1.47 (0.85, 2.53), P=0.17 | 1.16 (0.70, 1.91), P=0.57 | 0.79 (0.47, 1.33), P=0.37 |
| At 6-months | 1.23 (0.78, 1.95), P=0.37 | 1.37 (0.90, 2.07), P=0.14 | 1.11 (0.71, 1.73), P=0.65 | 1.34 (0.71, 2.55), P=0.36 | 1.21 (0.68, 2.15), P=0.52 | 0.90 (0.49, 1.66), P=0.73 |

[a]Adjusted for cluster, hospital, maternal education, family income, intention to exclusively breastfeed, and antenatal breastfeeding class attendance



3

**Table 3a.** Risk of weaning from any and exclusive breastfeeding during the entire follow-up period adjusted for baseline variables

| | **Hazard Ratio[a] (95% Confidence Interval)** | | |
|---|---|---|---|
| | In-hospital vs. standard care | Telephone vs. standard care | Telephone vs. in-hospital |
| Any breastfeeding | 0.86 (0.69, 1.07) P=0.18 | 0.76 (0.62, 0.94) P=0.01 | 0.89 (0.71, 1.11) P=0.31 |
| Exclusive breastfeeding | 0.82 (0.66, 1.02) P=0.07 | 0.79 (0.65, 0.96) P=0.02 | 0.97 (0.78, 1.20) P=0.76 |

[a]Adjusted for cluster, hospital, maternal education, family income, intention to exclusively breastfeed, and antenatal breastfeeding class attendance



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