Effectiveness of a mobile breastfeeding monitoring tool on breastfeeding exclusivity and self-efficacy: a per-protocol analysis of a randomized trial

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Abstract

Background: Globally, the pursuit of exclusive breastfeeding remains a formidable challenge. The surge in popularity of mHealth interventions has swiftly emerged as a promising avenue for promoting breastfeeding practices. Nevertheless, research investigating breastfeeding monitoring interventions via mHealth remains scarce.

Objective: This study aimed to use an application (app) called "Breastfeeding Aiding Tool" to monitor breastfeeding and provide feedback as a remote intervention to improve breastfeeding exclusivity and maternal breastfeeding self-efficacy.

Methods: This study embarked on a randomized controlled trial, leveraging an innovative app called "Breastfeeding Aiding Tool" as the intervention to monitor breastfeeding practice recorded by users and provide feedback automatedly facilitating remote education and consultation by health workers that enhanced breastfeeding exclusivity and maternal breastfeeding self-efficacy. Lactating mothers and their healthy primiparous infants aged 35-49 days were enrolled from clinics, and the on-line follow-up period was 2 months. Breastfeeding practices, maternal breastfeeding confidence assessed by the Breastfeeding Self-Efficacy Scale-Short Form and maternal depression status assessed by the Center for Epidemiological Survey Depression Scale were collected based on self-report through SoJump.

Results: 109 mother-infant dyads (55 in the intervention group and 54 in the control group) completed the 2-month follow-ups and 28 mothers actively engaged with the app tool. In the per-protocol analysis sample, the rate of exclusive breastfeeding of the using-tool group stood at 57.1%, compared to 48.2% in the comparison (Odds Ratio (OR)=1.44 (95% CI: 0.60,3.41); adjusted OR(aOR)=1.68 (95% CI: 0.60,4.70); p>0.05); the rate of full breastfeeding (comprising predominant and exclusive breastfeeding) was significantly higher in the mothers using the app tool than in the non-users (92.9% vs. 72.8%; OR=4.85 (95%CI: 1.06,22.15); aOR=6.96 (95%CI: 1.28,37.90); p<0.05). Furthermore, maternal breastfeeding self-efficacy in the app-use group improved by 1.36 (95%CI: -3.79,1.50), while it declined slightly by 0.16 (95%CI: -3.16,2.84) (p>0.05) in the non-users. The depression scores among the mothers using the app decreased by 2.29 (95%CI: -5.19,0.62), whereas those in the non-using group increased by 1.07(95%CI: -0.58,2.73) (p<0.05).

Conclusions: Our findings underscore the significant potential of the "Breastfeeding Aiding Tool" app as an aiding tool for breastfeeding guiding in sustaining breastfeeding practices, reducing formula usage, and enhancing maternal breastfeeding emotions. To further validate the effectiveness of improving breastfeeding exclusivity and self-efficacy, studies should endeavor to enroll a larger cohort of mothers utilizing the app. Clinical Trial: The intervention study was registered in the Chinese Clinical Trial Registry (ChiCTR2200065220).

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Conclusions Our findings underscore the significant potential of the "Breastfeeding Aiding Tool" app as an aiding tool for breastfeeding guiding in sustaining breastfeeding practices, reducing formula usage, and enhancing maternal breastfeeding emotions. To further validate the effectiveness of improving breastfeeding exclusivity and self-efficacy, studies should endeavor to enroll a larger cohort of mothers utilizing the app.

Keywords mHealth, exclusive breastfeeding, predominant breastfeeding, breastfeeding self-efficacy, per-protocol analysis

Introduction

Breastmilk is the optimal food for infants in the first few months. Despite the extensive evidence supporting the health and cognitive benefits of breastfeeding for babies, the vast majority of children globally are not breastfed in line with the recommendations [1,2]. World Health Organization (WHO) recommends 6 months of exclusive breastfeeding (EBF). Globally 44% of infants are EBF for 6 months, and only 29.2% in China [3,4]. One of the goals of the China Children's Development Plan (2021-2030) is to achieve an EBF rate of over 50% for infants aged 0-6 months [5]. Therefore, more effective measures need to be taken to tackle the barriers to practicing EBF.

Breastfeeding is affected by a wide range of historical, socioeconomic, cultural, and individual factors, and non-attainment of EBF is also a multifactorial issue [6,7,8]. Researchers have advocated for comprehensive breastfeeding consultation and education initiatives to tackle the barriers to

improve breastfeeding knowledge and enhance breastfeeding self-efficacy, so as to promote exclusive breastfeeding [9,10,11,12]. One approach with promise for addressing these issues is mobile health (mHealth). In recent years, mHealth has dramatically increased in popularity, fueled by its unparalleled flexibility in terms of time and space utilization, enhanced accessibility, and reduced costs. Health workers and researchers have hailed it as an efficacious technological intervention for online educational and support to foster breastfeeding practices, underscoring its potential to revolutionize healthcare delivery and support mothers worldwide[13,14,15,16].

However, these online interventions have focused predominantly on online education. To enhance their effectiveness, a multifaced approach has been suggested to integrate educational materials with interactivity and personalize the intervention content [17][18]. Ahmed et al, for example, conducted interventions that combined interactive web-based breastfeeding monitoring with standard breastfeeding education, and concluded that it could improve breastfeeding exclusivity, intensity and duration and promote maternal breastfeeding self-efficacy[19][20].

To the best of our knowledge, except for the study mentioned above, there have been almost no studies on breastfeeding monitoring interventions, and no trial in China has evaluated the effectiveness of a smartphone app that monitors breastfeeding and provides feedback. This study aimed to use an application (app) called "Breastfeeding Aiding Tool" to monitor breastfeeding and provide feedback as a remote intervention to improve breastfeeding exclusivity and maternal breastfeeding self-efficacy.

Methods

Study setting

A randomized controlled trial (RCT) with one intervention group (app + WeChat group) and one control group (WeChat group only) was conducted from September 2022 to January 2024. Recruiting was started from 2022 during the COVID19 pandemic. Intervention and follow-up were carried out based on smart phones. The intervention study was registered in the Chinese Clinical Trial Registry (ChiCTR2200065220).

Recruitment

Participants were recruited from healthcare clinics of two maternal and child healthcare hospitals in urban area of Beijing and screened by child health providers in the research team. The inclusion criteria were: 1) infants aged 35-49 days with gestation age≥37weeks, birth weight≥2500g and Apgar score≥9; 2) infants without serious health problems, including congenital and infectious diseases (such as tetralogy of Fallot, HIV infection et al); 3) infants without sucking and swallowing

problems; 4) naïve mothers of first infants;5) mothers who breastfed their infants in the lactogenesis stage and intended to fully or exclusively breastfeed before complementary feeding. Excluded criteria: 1) multiparous; 2) infants and mothers with serious diseases hampering breastfeeding. Mothers were asked to read through and sign consent forms, and researchers provided an explanation if participants could not understand any part of the consent form. Once they were consented, researchers administered a baseline survey that included demographic details, maternal and child health status, feeding information, self-reported depression and breastfeeding self-efficacy measurements.

Randomization

Cluster randomization was adopted. The numbers "1"(intervention group) and "2" (control group) were randomly assigned to the recruiting days using the "RAND" function in Excel. Two to three mothers were expected to be recruited on each recruiting day. The process continued until the designated number of eligible participants was recruited and consented.

Two WeChat groups (intervention group and control group) were established, and a Quick Response (QR) code was generated for each of the groups. Eligible mothers assigned to each group were requested to use their WeChat to scan the QR code enabling them to join their group.

Blinding was not performed due to the nature of the intervention participants could not be blinded [21].

Description of the intervention and control group

Three healthcare workers who were part of the research team joined in both intervention and control WeChat groups. For both groups, the health care workers conducted the following: (1) following-up the mothers and sending the digital questionnaire package; (2) sending breastfeeding knowledge once a week; (3) providing remote breastfeeding consulting services to mothers, including breastfeeding advice during COVID19 pandemic.

Intervention group: In addition to the above content, the intervention group was invited to participate in the utilization of an app that conducted surveillance on their breastfeeding practices, and offered feedback on nutritional value, and timing of breast feeding. The app was developed based on our previous study which explored the factors affecting breastmilk intake of one feed [22], and it is Android-compatible. A health-promotion software developer, two childcare experts, two medical informaticists, and end-users were volved in creating the app. The monitoring section was designed to collect 24h breastfeeding time and frequency. There were two ways for mothers to record breastfeeding time: (1) the app recorded automatically depending on when the mother clicked the start and end buttons; (2) mothers timed themselves and input breastfeeding time manually. Mothers

were shown a sucking picture before they started to record breastfeeding time to ensure recording effective breastfeeding time. The feedback section provided information on breastmilk, nutrients intake and the pattern of breastfeeding over time. Nutrients were calculated according to breastmilk composition of Chinese mothers [23]. Recommendations for daily breastfeeding frequency, daily breastmilk and nutrients intake were displayed as references for mothers to judge their breastfeeding status [24][25]. The app was downloaded and installed on the mothers' phones. Mothers were encouraged to use the app and sent a teaching video about how to use the app in the intervention WeChat group. The intervention was scheduled for a two-month period. The recommended use time for the tools was14 days: 5 days for the first week; 2 days for each of the second and third weeks; 1 day for each of the maintaining weeks.

Control group: Mothers who had access to the WeChat group only were also followed up for two months.

The main difference between the two groups was the surveillance and rapid feedback offered to the app group. The study hypotheses were: (1) Mothers who used the app tool to monitor breastfeeding practice, including breastfeeding frequency and breast milk intake, and to obtain feedback that compared monitoring data with recommendations, were more likely than those who used only WeChat to maintain breastfeeding practices; (2) The more frequently mothers utilized remote guidance on the WeChat platform, with their self-awareness of breastfeeding increased through assessments and feedback the more likely they were to maintain breastfeeding practices.

Data collection

A total sample size of 95 mother-infant pairs was estimated based on an 80% statistical power at a two-tailed α of 0.05, and the breastfeeding rates of intervention and control groups were estimated as 50% and 30% respectively. Therefore, the original study was planned with 48 women in each group. The randomization process resulted in intervention and control group of comparable size. Randomization was performed with a about 1:1 ratio between the intervention and control group. The follow-up was conducted at 1-month and 2-month timepoints. During each pre- and postintervention appointment, all mothers completed the follow-up digital questionnaire pack consisting of maternal breastfeeding self-efficacy, depression and feeding practice. Only feeding practices were collected at the 1-month follow-up. All the data were collected via the online survey platform SoJump (Changsha Ranxing Information and Technology Co.), which is widely used in China [26][27]. Data obtained through the use of the app tool for breastfeeding surveillance consisted of the output from the tool platform.

Measures: (1) sociodemographic questionnaire: includes infants' age and sex, mothers' age,

education and occupation; (2) feeding practice: assessed for the past 1 month, and includes average breastfeeding frequency per day, average formula feeding frequency per day and complementary information; (3) breastfeeding Self-Efficacy Scale-Short Form (BSES-SF): developed by Dennis for assessing maternal breastfeeding self-efficacy and used globally among numerous maternal populations; consists of 14 self-reported items; all items are scored ranging from 1(not at all confident) to 5(always confident); the higher the score, the better the self-efficacy of breastfeeding; the alpha coefficient of the Chinese version was 0.927[28][29] ; (4) Center for Epidemiological Survey, Depression Scale (CES-D): consists of 20 self-reported items and has been used extensively to screen for postnatal depression; items are scored 0, 1, 2 or 3 depending on the frequency of symptoms (rarely, some time, occasionally or all of time); depression can be adequately measured and screened for by a single-factor structure underlying the CES-D scores in China[30][Error: Reference source not found].

Outcome indicators

(1) Primary outcome

Breastfeeding exclusivity: referring to the WHO definition, pattern of breastfeeding (exclusive, predominant, partial) was defined as: a. Exclusive breastfeeding (EBF): the infants received only Breast milk; b. Predominant breastfeeding (PBF): infants received breast milk as the predominant source of nourishment, with water or water-based drinks, fruit juice, and water based calcium supplement in this study; c. partial breastfeeding (MF): referred to mixed feeding of breast milk and other food or food-based fluids, such as formula milk or weaning foods[27][Error: Reference source not found]. For the main primary outcome, we combined EBF and PFB into a single variable, as full breastfeeding (FBF).

Maternal breastfeeding self-efficacy: the scores of BSES-SF.

(2) Secondary outcomes

Breastfeeding frequency: the frequency of breastfeeding per day.

Maternal depression status: the scores of CES-D. Considering that postpartum depression (PPD) affects approximately 23.5% of the population in China[33], and as a maternal psychological aspect, it has been negatively related to exclusive breastfeeding and breastfeeding self-efficacy as reported in some studies[34][35].

Statistical Analysis

The data were analyzed by the SPSS statistical software (Version 20.0 for Windows). Descriptive statistics was calculated for all variables of interest. Numerical variables are presented as the means (M) and standard deviations (SD) for distribution, and categorical variables are presented as the

proportions. Two statistical approaches were used: (1) intention-to-treat (ITT, intervention vs control); (2) per-protocol (PP, using tool vs not using tool). In PP analyses, protocol adherence derived from the app tool data. Tool using was considered positive when there were use records of mothers, no matter the number of records. T-tests and chi-square tests were used to investigate the differences between two groups of ITT and PP. Bivariate logistic regression was used to acquire Odds Ratio (OR) and adjusted Odds Ratio (aOR). ORs and aORs were presented along with their associated 95% confidence intervals. aORs were adjusted by maternal education level, maternal job status, maternal age, diseases during pregnancy, maternal body mass index (BMI), delivery way, breastfeeding initial time, infant birth weight, gestational age, infant sex, child illnesses, breast problems. The changes between baseline and post-intervention in each group were differentiated to show the effectiveness of the intervention more clearly. The criterion for significance was set at $\alpha = 0.05$.

Ethics approval and consent to participate

The Ethics Committee of Capital Institute of Pediatrics approval number: SHERLL2022033) approved the study according to the International Organizations of Medical Sciences on “Human biomedical research international guidelines” and ethical principles from “the Declaration of Helsinki”. The purpose and content of the study were explained to the participants and the informed consent was signed by them before the study.

Large Language Models (LLMs) used declamation

ERNIE Bot (Baidu Inc.) was used for language checking.

Results

Recruitment and dropout analysis

Recruitment was from September 2022 to October 2023, and the intervention period continued until January 2024. Figure 1 explains the recruitment and drop out based on mobile Consolidated Standards of Reporting Trials (CONSORT) e-health criteria [Error: Reference source not found]. Finally, 109 mothers completed both before and after surveys, and the attrition rates were 21% (29/138) in total, 24% (17/72) in the intervention group and 18% (12/66) in the control group. No adverse events were reported.

Characteristics of participants

Table 1 presents the baseline characteristics of the participants with a mean age of 31.36$\pm$3.38 years. 96.2% had college or above education level. In the intervention groups 51% (28/55) mothers had records of using the app tool, of which 14 mothers had records of 1-13 days, and14 mothers had

records of more than14 days. Baseline characteristics were balanced between conditions for ITT and PP samples, except for maternal age in the ITT sample (p=0.04), mothers using tool with marginally greater maternal education in the PP sample (p=0.05), breast problems (nipple pain, mastitis) in the PP sample (p=0.02). there was no significant difference in sufficiency of breastmilk between the two groups of mothers in the ITT and PP samples. No mother smoked and no infant had neonatal asphyxia.

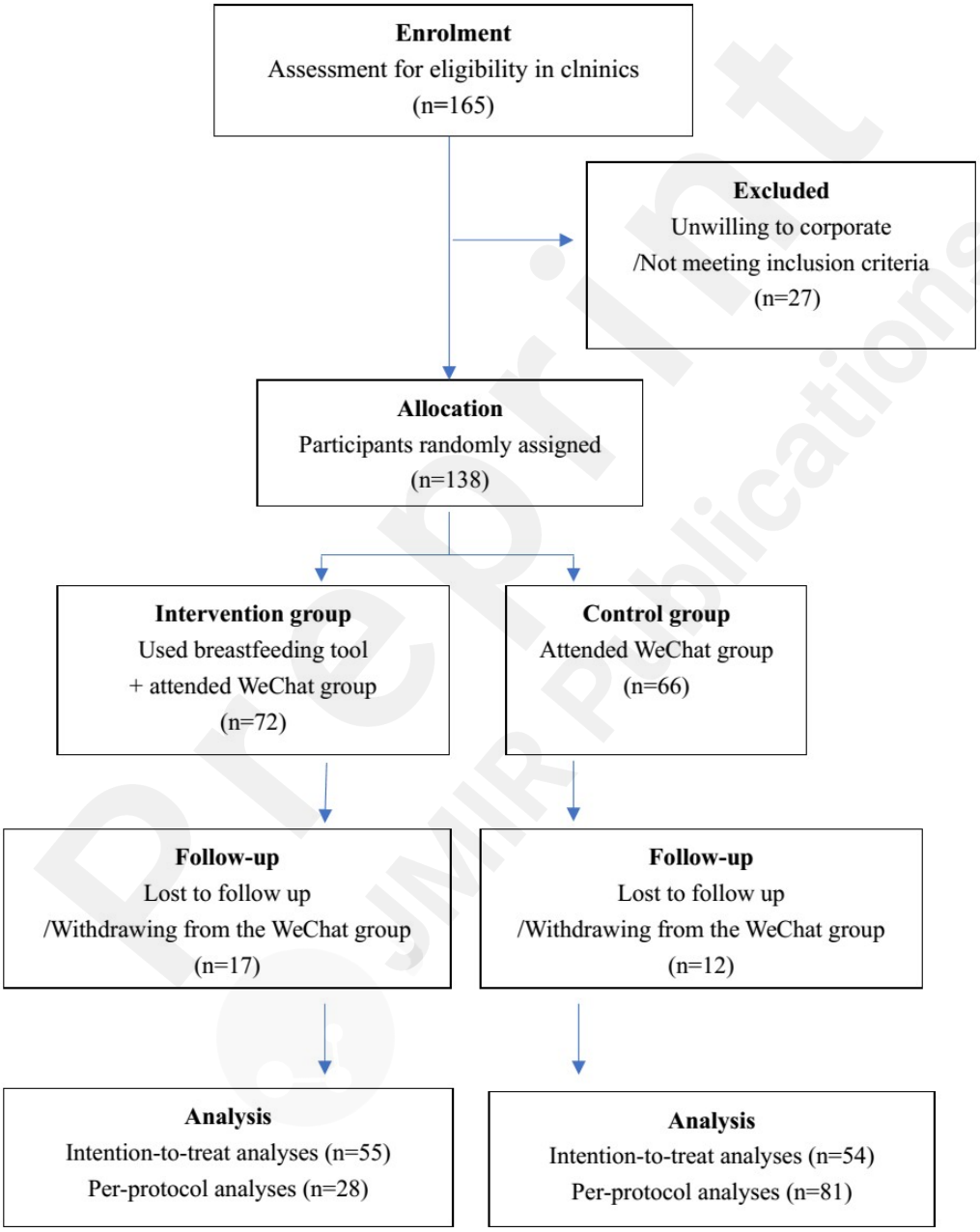

Figure 1 CONSORT diagram

Table 1 Baseline characteristics of participants

		Intention-to-treat			Per-protocol		
	All (n=109)	**Intervention(n=55)**	**Control (n=54)**	**p value**	**Using tool (n=28)**	**Not using tool (n=81)**	**p value**
Maternal age(years), Mean (SD)	31.36(3.38)	32.04 (3.32)	30.68(3.33)	**0.04**	32.32(2.92)	31.03(3.48)	0.08
Maternal education level, n (%)							
High school or below	4(3.7)	3(5.6)	1(1.9)	0.37	0(0.0)	4(5.1)	**0.05**
College	61(57.5)	28(51.9)	33(63.5)		12(42.9)	49(62.8)	
Master or above	41(38.7)	23(42.6)	18(34.6)		16(57.1)	25(32.1)	
C-section, n (%)	27(24.8)	13(23.6)	14(25.9)	0.08	4(14.3)	23(28.4)	0.14
Boy, n (%)	52(47.7)	24(43.6)	28(51.9)	0.39	11(39.3)	41(50.6)	0.30
Gestational age at birth (weeks), Mean (SD)	39.58(1.20)	39.49(1.03)	39.67(1.35)	0.45	39.64(1.10)	39.56(1.24)	0.73
Birthweight (g), Mean (SD)	3331.38(340.93)	3305.64(334.78)	3357.59(348.23)	0.43	3342.86(320.76)	3327.41(349.47)	0.84
Maternal BMI (kg/m^2), Mean (SD)	23.37(2.93)	22.98(2.43)	23.77(3.34)	0.16	23.01(2.48)	23.50(3.08)	0.43
Diabetes during pregnancy, n (%)	29(26.6)	16(29.1)	13(24.1)	0.55	9(32.1)	20(24.7)	0.44
Hypertension during pregnancy, n (%)	6(5.5)	3(5.6)	3(5.5)	0.98	0(0.0)	6(7.4)	0.33
Anemia during pregnancy, n (%)	28(25.7)	17(30.9)	11(20.4)	0.21	8(24.7)	20(28.6)	0.68
Maternal job status, n (%)							
Housewife/full maternity leave	4(3.7)	14(7.3)	0(0.0)	0.11	2(7.1)	2(2.5)	0.16
maternity leave and working	79(72.5)	37(67.3)	42(77.8)		18(64.3)	61(75.3)	
working	26(23.9)	14(25.5)	12(22.2)		8(28.6)	18(22.2)	
Alcohol, n (%)	1(0.9)	1(1.8)	0(0.0)	0.50	1(3.6)	0(0.0)	0.26
Breastfeeding initial time, n (%)							

Less than 1 h	42(38.5)	20(36.4)	22(40.7)	0.83	10(35.7)	32(39.5)	0.92
1 h-1 day	36(33.0)	18(32.7)	18(33.3)		10(35.7)	26(32.1)	
1 day later	31(28.4)	17(30.9)	14(25.9)		8(28.6)	23(28.4)	
Reported breast problems, n (%)	28(25.7)	18(32.7)	10(18.5)	0.09	12(42.9)	16(19.8)	**0.02**
Reported insufficient breast milk, n (%)	22(20.2)	9(16.4)	13(24.1)	0.32	6(21.4)	16(19.8)	0.85

Impact of the mobile app on breastfeeding practices

At baseline, the rates of EBF, PBF, FBF and MF were similar (p>0.05 in the ITT and PP samples, see Table 2). After the 2-month follow- up, the EBF rate the using-tool group stood at 57.1%, compared to 48.2% in the not-using-tool group (OR=1.44 (95%CI: 0.60,3.41); aOR=1.68 (95%CI: 0.60,4.70);p>0.05) in the PP sample; the FBF rate was significantly higher in the group of mothers using the app tool than those not using the tool (92.9% vs. 72.8%, p=0.03; OR=4.85 (95%CI: 1.06,22.15), p<0.05; aOR=6.96 (95%CI: 1.28,37.90), p<0.05) in the PP sample; the aOR (3.35(95%CI: 1.09,10.32)) of the intervention and control group was significant in the ITT sample. After the 2-month follow- up, the significant results of MF rate were similar to the FBF rate. After the 1-month follow- up, the PBF rate was significantly higher in the group of mothers using the app tool than the group not using the tool (35.7% vs. 16.0%, p=0.03; OR=2.91 (95%CI: 1.10,7.70), p<0.05; aOR=6.06 (95%CI: 1.34, 27.47), p<0.05) in the PP sample. There were no significant differences in the EBF rate between the two groups in the ITT and PP samples and in the FBF rate between the two groups in the ITT sample after the 1-month and 2-month follow-up.

As shown in Table 3, there were no significant differences on the post-intervention–pre-intervention Changes of breastfeeding frequency between the two groups in the ITT and PP samples.

Table 2 breastfeeding practices at different timepoint

	ITT					PP				
	Intervention	**Control**	**p value**	**Odds Ratio(95%CI)**	**Adjusted Odds Ratio(95%CI)**	**Using tool**	**Not using tool**	**p value**	**Odds Ratio(95%CI)**	**Adjusted Odds Ratio(95%CI)**
Baseline										
EBF rate, n (%)	25(45.5)	27(50.0)	0.64	0.83(0.39,1.77)	0.93(0.38,2.29)	12(42.9)	40(49.4)	0.55	0.77(0.32,1.83)	0.59(0.19,1.76)
PBF rate, n (%)	16(29.1)	13(24.1)	0.55	1.29(0.55,3.04)	1.59(0.60,4.23)	10(35.7)	19(23.0)	0.21	1.81(0.72,4.59)	3.14(0.99,10.00)
FBF rate, n (%)	41(74.5)	40(74.1)	0.96	1.02 (0.43,2.42)	1.57(0.56,4.42)	22(78.6)	59(72.8)	0.55	1.37(0.49,3.82)	1.81(0.53,6.12)
MF rate, n (%)	14(25.5)	14(25.9)	0.96	0.98(0.41,2.30)	0.64(0.23,1.79)	6(21.4)	22(27.2)	0.55	0.73(0.26,2.04)	0.55(0.16,1.87)
1-month follow-up										
EBF rate, n (%)	30(54.5)	33(61.1)	0.49	0.76(0.36,1.64)	1.11(0.44,2.80)	14(50.0)	49(60.5)	0.33	0.65(0.28,1.55)	0.80(0.27,2.33)
PBF rate, n (%)	15(27.3)	8(14.8)	0.11	2.16(0.83,5.62)	3.50(0.94,13.07)	10(35.7)	13(16.0)	**0.03**	2.91(1.10,7.70) **	6.06(1.34, 27.47) **
FBF rate, n (%)	45(81.8)	41(75.9)	0.45	1.43(0.56,3.60)	3.34(0.99,11.29)	24(85.7)	62(76.5)	0.30	1.84(0.57,5.96)	3.32(0.80,15.06)
MF rate, n (%)	10(18.2)	13(24.1)	0.45	0.70(0.28,1.77)	0.30(0.09,1.01)	4(14.3)	19(23.5)	0.30	0.55(0.17,1.76)	0.30(0.07,1.25)
2-month follow-up										
EBF rate, n (%)	29(52.7)	26(48.1	0.63	1.20(0.57,2.55)	1.67(0.69,4.02)	16(57.1)	39(48.1)	0.41	1.44(0.60,3.41)	1.68(0.60,4.70)

		)								
PBF rate, n (%)	17(30.9)	13(24.1)	0.42	1.41(0.60,3.29)	1.50(0.54,4.16)	10(35.7)	20(24.7)	0.26	1.69(0.67,4.27)	1.90(0.59, 6.13)
FBF rate, n (%)	46(83.6)	39(73.2)	0.15	1.97(0.78,4.98)	3.35(1.09,10.32) *	26(92.9)	59(72.8)	**0.03**	4.85(1.06,22.15) *	6.96(1.28,37.90) *
MF rate, n (%)	9(16.4)	15(27.8)	0.15	0.51(0.20,1.29)	0.30(0.10,0.92) *	2(7.1)	22(27.2)	**0.03**	0.21(0.04,0.94) *	0.14(0.03,0.78) *

*p<0.05

Abbreviations: ITT, intention-to-treat; PP, per-protocol; EBF, exclusive breastfeeding; FBF, full breastfeeding; MF, mix feeding.

Table 3 Breastfeeding self-efficacy and frequency at different timepoint (Mean(95%CI))

	ITT			PP		
	Intervention	**Control**	**p value**	**Using tool**	**Not using tool**	**p value**
Baseline						
BSES-SF score	51.78 (48.35,55.21)	51.59 (47.24,55.94)	0.94	50.93(46.59,55.26)	51.95(48.57,55.34)	0.75
CESD score	27.47 (25.09,29.85)	25.83 (23.97,27.70)	0.28	29.89 (25.74,34.04)	25.54 (24.13,26.95)	**0.05**
24h Breastfeeding frequency	9.19(8.72,9.66)	8.80(8.15,9.45)	0.33	9.09(8.30,9.88)	8.96(8.50,9.43)	0.78
2-month follow-up						
BSES-SF score	51.91(48.00,55.82)	51.93(47.29,56.56)	1.00	52.29 (47.12,57.45)	51.79 (48.14,55.44)	0.89
CESD score	27.25 (25.00,29.51)	26.48 (23.90,29.07)	0.65	27.61 (24.06,31.15)	26.62 (24.66,28.57)	0.61
24h Breastfeeding frequency	7.52(7.18,7.85)	7.15(6.54,7.75)	0.29	7.62(7.07,8.18)	7.24(6.81,7.66)	0.32
Post-intervention–pre-intervention Changes						
BSES-SF score	0.13(-3.69,3.94)	0.33(-3.18,3.85)	0.94	1.36(-3.79,1.50)	-0.16(-3.16,2.84)	0.61
CESD score	-0.22(-2.25,1.82)	0.65(-1.46,2.76)	0.55	-2.29(-5.19,0.62)	1.07(-0.58,2.73)	**0.046**
24h Breastfeeding frequency	-1.67	-1.65(-2.41, -0.89)	0.96	-1.46(-2.18, -0.75)	-1.73(-2.27, -1.19)	0.60

	1.20)

As shown in Figure 2, after intervention, the EBF proportion of the group using the tool was 57.1% and only 48.2% in the group that did not use the tool (p>0.05); PBF accounted for 35.7% in the group using the tool, and 24.7% in the non-tool group (p>0.05); the MF proportion was 7.1% in the group using the tool but 27.2% in the group not using the tool (p=0.03).

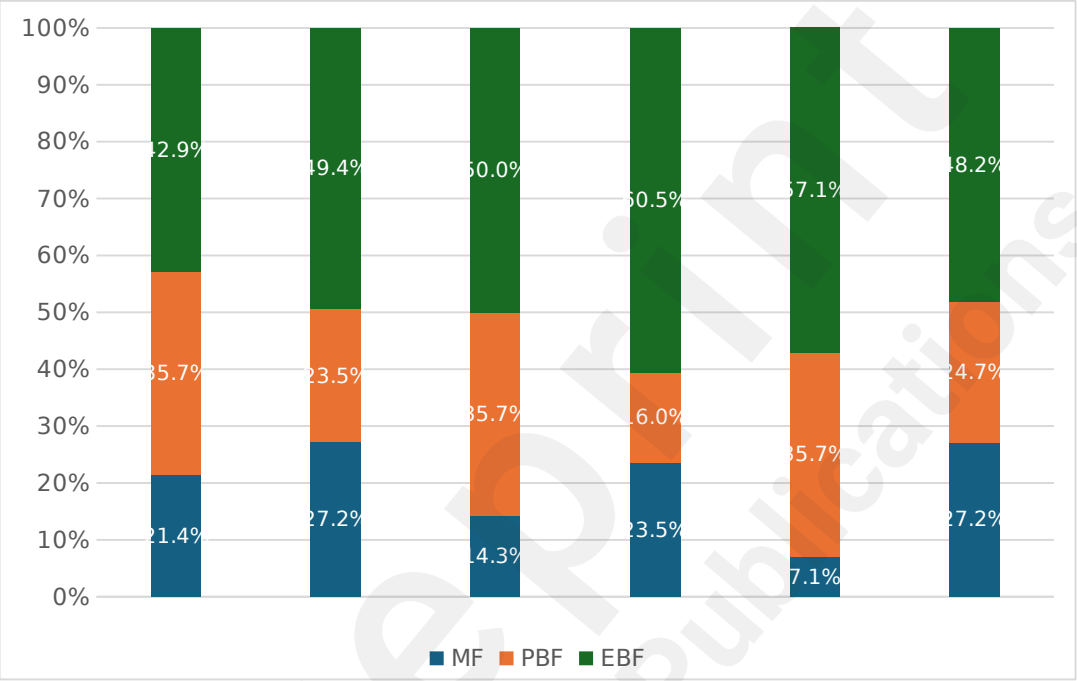

Figure 2 proportions of EBF, PBF and MF between groups using and not using the tool

Impact of the mobile app on maternal breastfeeding self-efficacy

As shown in Table 3, the mothers' breastfeeding self-efficacy scores were similar between the groups in the ITT and PP samples at baseline and 2-month follow-up (p>0.05). The mothers' self-efficacy in the group using the tool was enhanced by about 1.36 (95%CI: -3.79,1.50), and that of the group not using the tool decreased by about 0.16 (95%CI: -3.16,2.84), but there was no significant difference (p=0.61). The mothers' depression scores were similar between the groups in the ITT sample at baseline and 2-month follow-up (p=0.28). The score was marginally significantly higher in the group using the tool (29.89 (95%CI: 25.74,34.04) vs. 25.54 (95%CI: 24.13,26.95), p=0.05) at baseline. The mothers' depression score in the group of using the tool decreased by 2.29 (95%CI: -5.19,0.62), and that of the group not using the tool increased by 1.07(95%CI: -0.58,2.73) (p=0.046).

Discussion

This study represents the first randomized controlled trial investigating an app-based intervention, comprising two core elements: remote monitoring of breastfeeding practices and personalized feedback tailored to primiparous mothers in urban China. The objective was to evaluate its impact on breastfeeding exclusivity and maternal self-efficacy pertaining to breastfeeding as compared to the control condition, an education program on WeChat only. Notably, the ITT analysis failed to reveal a statistically significant intervention effect, primarily attributed to the fact that approximately half of the mothers did not utilize the app-based program. The PP results demonstrated significant improvement of breastfeeding and a decrease in the use of formula for the mothers who actively utilized the app tool compared to those who did not at 2 months. Although the present study did not show significance in the effectiveness of the app tool on exclusive breastfeeding, it did show the app's ability to maintain breastfeeding practice and reduce formula intake. Previous studies using interventions such as a breastfeeding diary to monitor lactation, also showed that monitoring was an effective way to improve breastfeeding [37]. Dinour et al reported that compared with nonusers, mothers who used apps to track breastfeeding were more likely to have ever breastfed and exclusively breastfed their infants [38]. Nevertheless, some mHealth intervention studies have also encountered difficulties in improving breastfeeding exclusivity or promoting longer exclusive breastfeeding periods[21][27].

There were several potential reasons for our study's failure to have a significant effect on exclusive breastfeeding. Firstly, in the definition of EBF, infants should not be provided water; mothers in our study gave water to babies mainly for nutrients supplementation, especially for calcium. Calcium supplementation for infant bone mineral density is suggested by pediatricians in China [39], and in the developed areas, this may have become a more critical problem for EBF promotion, than formula use. Ahmed et al's study proved the effectiveness of the intervention of the online interactive breastfeeding monitoring system on exclusive breastfeeding, with a

low rate of predominant breastfeeding in the whole sample [19]. The study revealed that the provision of water to locally breastfeeding infants was an uncommon practice, potentially stemming from a disparity in maternal anxiety concerning their infants' nutritional wellbeing between China and other countries. This divergence could also be attributed to a differing comprehension of the concept of "exclusive breastfeeding," which emphasizes the sole reliance on breastmilk for nourishment and no water from interruption during the initial months of life [40].

Based on the above information, mothers should be guided to use nutrients supplementation correctly to avoid non-essential nutrients supplements and extra water for their children to meet the stringent requirement of exclusive breastfeeding. Secondly, low maternal engagement in using the app tool led to a small sample size, which hindered the study's ability to achieve statistical significance. However, it is noteworthy that the group that actively used the tool had a higher EBF rate compared to those who did not use it.

According to the results, mothers' self-efficacy in the group using the tool was enhanced by about 1.36, and that of the group not using the tool decreased by about 0.16. The mothers' depression score in the group using the tool decreased by about 2.29, and that of the group not using the tool increased by 1.07, resulting a significant difference. Despite some statistical discrepancies, the results suggest that using the app tool may have a positive impact on breastfeeding mothers' emotional well-being. This is supported by Qian whose review showed that mHealth interventions could improve maternal well-being and reduce anxiety [15]. Ahmed and Dienelt also proved that a breastfeeding monitoring app or infant feeding apps with a feeding tracker component significantly gave mothers a perception of greater control, confidence and efficacy about infant feeding[21][41].

In this study, the mothers had a higher educational level, with 96.2% holding college degree or above, and they demonstrated a high-level ability to use the internet to improve their breastfeeding skills. But half of those offered the opportunity to use a new monitoring app did not choose to use it. The most possible explanation for the

non-use is that it may not have been sufficiently multifunctional to appeal to them. Or it might be that these non-acceptors used paper-based breastfeeding records or used other breastfeeding promotion apps [27], or they ignored it or didn't have time to record breastfeeding. Consequently, it is necessary to delve deeper into the underlying factors that hinder the acceptance of the current application, aiming to address these barriers and enhance its appeal and accessibility.

In addition, the data show that at baseline mothers who used the app tool had significantly more breast problems and a higher depression score than mothers who did not use it. This suggests that mothers with more breast problems and postpartum depression symptoms might have wanted to seek additional help and were more willing to accept and utilize the intervention. Previous studies have shown that mothers with postpartum depression may have a higher risk of non-exclusive breastfeeding without additional support and consultation[34][42]. However, in our study, mothers with higher depression scores who used the app were more willing to maintain breastfeeding.

Our study shows that despite its limitations in uptake of the app, this or other apps that include monitoring and feedback, did have an effect on breastfeeding patterns, improving the frequency of breastfeeding, and breastfeeding self-efficacy. With better understanding of mothers' reasons for choosing not to use the application, we should be able to improve its accessibility and acceptability for new mothers. We believe that an improved app, if used consistently can be a useful addition to existing social media and online interventions to improve breastfeeding exclusivity and self-efficacy in new mothers.

Conclusions

This study marks the first comparative trial examining the efficacy of remote monitoring interventions and feedback mechanisms specifically tailored for primiparous mothers an aiding tool for breastfeeding guiding in urban China. Leveraging a dedicated mobile application as a supportive tool, our findings indicate a noteworthy trend among participants: a substantial upholding of breastfeeding rates

coupled with a reduction in formula supplementation, subsequently enhancing maternal emotion with the breastfeeding experience. To consolidate these promising results, we urge the necessity for further exploration of reasons for non-acceptance of the existing application, followed by a more extensive trial that incorporates a larger cohort of mothers embracing the use of this app.

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Authors' contributions

Ni Jia and Yaohua Dai conceived and designed research; Ni Jia analyzed data and drafted the article. Jean J. Schensul and Meixian Zhang interpreted data and revised the article critically for important intellectual content. Lianfang Kong and Qi Yan designed research and did the field work. Ni Jia and Yao-shua Dai had primary responsibility for final content. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

Abbreviations

WHO: World Health Organization

EBF: exclusive breastfeeding

mHealth: mobile health

app: application

RCT: randomized controlled trial

QR: Quick Response

BSES-SF: breastfeeding Self-Efficacy Scale-Short Form

CES-D: Center for Epidemiological Survey, Depression Scale

PBF: Predominant breastfeeding

MF: partial breastfeeding

FBF: full breastfeeding

PPD: postpartum depression

M: means

SD: standard deviations

ITT: intention-to-treat

PP: per-protocol

OR: Odds Ratio

aOR: adjusted Odds Ratio

BMI: body mass index

CONSORT: Consolidated Standards of Reporting Trials

Multimedia Appendix 1

CONSORT-EHEALTH checklists

Screenshots of the "Breastfeeding Aiding Tool" app.

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Supplementary Files

Multimedia Appendixes

Untitled.
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