Individualized intervention to improve rates of exclusive breastfeeding
A randomised controlled trial
Pan Huang, MDa,b, Jianrong Yao, MDa,c, Xinghui Liu, PhDa,c, Biru Luo, PhDa,c,*

Abstract
Background: Despite breastfeeding is significant benefits for maternal and infant, the discontinuation of breastfeeding is high. Some of studies showed that the effect of intervention in improving the rate of exclusively breastfeeding is unclear. The aim of this study is to investigate the effectiveness of individualized intervention compared with routine care in improving rates of exclusive breastfeeding.

Methods: Women were divided into two groups. We provided individual antenatal breastfeeding education and postnatal lactation support to intervention group. Control group received routine care. Significance was set at P < .05.

Results: We recruited 352 women of whom 176 were randomized to intervention group, 176 to control group. In total, 293 (83.2%) completed 4 months of follow-up. At discharge from hospital, 43.2% of women randomized to intervention group were exclusively breastfeeding compared with 30.0% of women in control group (relative risk 1.78; 95% confidence interval [CI] 1.12–2.82). At 4 months, 70.9% of women in the intervention group were exclusively breastfeeding compared with 46.2% of the women in the control group (2.84; 1.76–4.60). At discharge from hospital, 95.1% of women in the intervention group were breastfeeding on demand compared with 68.1% of women receiving routine care (9.00; 4.09–19.74). At 4 months, 94.6% of women in intervention group were breastfeeding on demand compared with 75.9% of women in the control group (5.57; 2.48–12.49).

Conclusion: The regular ongoing individualized antenatal education and postnatal support can effective increase the rates of exclusive breastfeeding from delivery to postpartum 4 months and change the breastfeeding behavior.

Abbreviations: CTFPHC = the Canadian Task Force on Preventive Health Care, USPSTF = the United States Preventive Services Task Force.

Keywords: Individualized intervention, exclusive breastfeeding

1. Introduction
There are many advantages for breastfeeding. Some studies had indicated that breastfeeding can regulate gastrointestinal function and improve immune function, and prevent acute illnesses. [1–4] Compared with formula-fed, breast-fed infants may have lower rates of diarrhea, [5] respiratory tract illness, [6] acute otitis media, [6] and urinary tract infection. [7] The long-term benefits of breastfeeding for infants included that reduced the risk of hospitalization, [8] and promoted neurodevelopment. [1] During lactation and long-term, women can acquire a lot of benefits from breastfeeding including acceleration uterine involution [9] and reduction postpartum stress. [10] Meanwhile, several studies shown that breastfeeding can reduce the risk of breast cancer, endometrial cancer, and ovarian cancer. [11,12] The benefits of exclusive breastfeeding for family and society include economic savings and reduction the infant mortality rate. [13–15] Therefore, the World Health Organization recommend breastfeeding as the optimal feeding for all infants and exclusive breastfeeding for the first 6 months of life. [16–19] However, the rate of exclusive breastfeeding within 4 months after delivery in the world is still low. High-income countries, breastfeeding duration is shorter compared with low-income and middle-income countries which the rate of exclusively breastfeeding was only 37% in 6 months after delivery. [20] A community-based, cross-sectional survey conducted 2354 infants in 26 poor, rural counties in 12 central and western provinces. Overall, 98.3% children had been breastfed. However, only 28.7% were exclusively breastfed for 6 months. [21] In the United States in 2015, of the nearly 83.2% of infants who had ever been breastfed, less than 50% of infants younger than 3 months had been exclusively breastfed, and only 25% of infants younger than 6 months were exclusively breastfed. [22]

Early discontinuation of breastfeeding is associated with difficulties in breastfeeding. Women lack confidence in their ability to breastfeed because they considered that their infants
had difficulty in breastfeeding or were not satisfied.\textsuperscript{[23,24]} Moreover, other factors related with early termination of breastfeeding include that women return to work and maternal depression.\textsuperscript{[25]}

Initiation and duration breastfeeding depend on professionals that provide breastfeeding education, and a conducive birthing environment promoting breastfeeding. The Canadian Task Force on Preventive Health Care (CTPHC)\textsuperscript{[26]} and the United States Preventive Services Task Force (USPSTF)\textsuperscript{[18]} recommend that the combination of prenatal and postpartum lactation support can effectively promote the initiation and duration of breastfeeding more than either interventions.

However, Bonnuck et al\textsuperscript{[27]} study showed that a prenatal and postnatal breastfeeding education group infants received more human milk than controls, but exclusively breastfeeding rates remained low and had no statistical difference between groups at any point. A randomized trial in London also doubted the effectiveness of prenatal breastfeeding education and postpartum lactation support.\textsuperscript{[28]} A randomized trial in Brazil found that the hospital-training and postnatal home visits intervention achieved a high rate (70\%) of exclusive breastfeeding in the hospitals, but the rates fell rapidly at home.\textsuperscript{[30]} There those studies showed that the effect of professional lactation support effect in improving the rate of exclusively breastfeeding is unclear.\textsuperscript{[27–30]}

The aim of this study is to investigate the effectiveness of an antenatal breastfeeding education and a postnatal lactation support both compared with routine care in improving rates of exclusive breast feeding.

2. Methods

2.1. Study population

Three research assistant, who acquired international certified lactation consultant qualification, recruited women from the obstetric admission office. Inclusion criteria for subjects are including: age over 18, >34 gestation weeks, and had no complications that contraindicate breastfeeding. Women with high risk and multiple pregnancies were excluded. Subjects who agreed to participate signed informed consent.

2.2. Assignment

Women were divided into intervention group and control group, in accordance with the random number table. The sample was stratified by practice and admission time using sets of envelopes for pregnant woman. The participants of different group were separated to different wards in order to avoid contamination. The participants and analyzer were blinded to intervention. Counselors played no part in assessing feeding outcome.

2.3. Intervention

Group 1 was the control group. Women received routine antenatal, and postnatal obstetric care, in accordance with the requirements of Baby-Friendly Hospital. At our hospital, they received 1 session of antenatal breastfeeding education in which they were shown a 30 minute educational video, which introduced the benefits of breastfeeding, barriers to breastfeeding, proper feeding posture, etc. After delivery, they received postnatal visits by a lactation consultant who instruct mothers to breastfeed and solve any breastfeeding problems. They were also given printed guides on breast feeding at discharge from hospital.

Group 2 was intervention group. The researchers provided individual antenatal breastfeeding education and postnatal lactation support. They were visited by a researcher at hospital admission. At the time of admission, the researcher used the breastfeeding attrition prediction scale and the breastfeeding knowledge scale to understand and analysis the problems of breastfeeding knowledge of subjects. Afterwards, on the basis of the results, the researcher provides individualized intervention by face to face. After delivery, researchers provided professional breastfeeding guidance for mothers. At discharge, researchers used breast-feeding assessment scale and breastfeeding knowledge scale to analyze maternal breastfeeding problems and give intervention. Researchers monthly asked for details of breastfeeding situation, and gave guidance by telephone follow-up after maternal hospital discharge to postpartum 4 months. They also received the same routine antenatal and postnatal obstetric care.

The study was approved by the Ethics Committee of West China Second University Hospital, Sichuan University. Informed consent was obtained from all participants.

2.4. Outcome measures

The primary outcomes were the rate of exclusive breastfeeding. The measuring time points are including discharge from the hospital, 42 days and 4 months after delivery. Exclusive breastfeeding was defined that infant was given only breast milk, medicines, and vitamins may be given but no formula or water. Secondary outcomes were the breastfeeding behavior including on-demand lactation, maternal cracked nipple, maternal and baby satisfaction of breastfeeding, breastfeeding knowledge.

2.5. Statistical analysis

To calculate sample size, we used the formula

\[
N = \frac{2 \left( u \cdot \sqrt{2 \times \bar{p} (1 - \bar{p}) + u \cdot \rho \cdot (1 - p_T) + p_C(1 - p_C)} \right)^2}{\delta^2}
\]

n1 = n2, \quad N = n1 + n2, \quad \bar{p} = (p_T + p_C)/2

The exclusive breast feeding at 4 months after delivery is 59%.\textsuperscript{[32]} We estimated that the rate of behavior change is 15\% and the missed rate is 20\% with 80\% power, we needed to randomize 352 women equally into the 2 groups.

The trial data were entered into Epidata, specialized software facilitates interactive entry and data correction and maintains consistent and accurate trial data. We used SPSS version 21 (SPSS Inc., Chicago, IL) for statistical analyses. We used chi-square test or rank sum test to analyze the statistical differences of qualitative data and used analysis of variance to analyze quantitative data for the 3 point times. Significance was set at \( P < .05 \).

3. Results

Overall, 352 women (176 control, 176 intervention) were recruited. In total, 293 (83.2\%) completed 4 months of follow-up, with a similar number lost in the 2 study groups. The Fig. 1
shows the flow of participants through the trial. Table 1 shows the characteristics of participants at baseline. The 2 study groups were also similar in the variables related to maternal and infant, including the mode of delivery and the mean birth weight (Table 2).

### 3.1. Outcomes

Table 3 shows the relative risk (95% confidence interval) in biomedical outcomes at the various time points for each group. The rates of exclusive breastfeeding from discharge from hospital to 4 months after delivery was higher in the intervention group than in the control group. At discharge from hospital, 43.2% (70/162) of women randomized to intervention group were exclusively breastfeeding compared with 30.0% (47/157) of women who received routine care (relative risk 1.78; 95% confidence interval [CI] 1.12–2.82). At 4 months, 70.9% (105/148) of women in the intervention group were exclusively breastfeeding compared with 46.2% (67/145) of the women in the control group (2.84; 1.76–4.60). This significant improvement was still present at discharge from hospital and 4 months after delivery. However, there was no significant difference among the 2 groups at 42 days after delivery (Table 3).

We also assessed the secondary outcome. Women randomized to intervention group were more likely to breastfeed on demand compared with the control group from discharge to 4 months after delivery, when 95.1% (154/162) of women in the intervention group were breastfeeding on demand compared with 68.1% (107/157) of women receiving routine care (9.00; 4.09–19.74). At 4 months, 94.6% (140/148) of women

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**Figure 1.** Flow of participants through each stage of randomized trial.
randomized to receiving individualized intervention were breastfeeding on demand compared with 75.9% (110/145) of women in the control group (5.57; 2.48–12.49) (Table 4). The incidence of cracked nipple was lower in women who received individual intervention than in women in the control group (0.49; 0.29–0.81) at 42 days after delivery and (0.50; 0.29–0.85) at 4 months after delivery (Table 5).

The maternal satisfaction of breastfeeding was higher in women who received individualized intervention than in women in the control group ($F=0.98$, $P=.32$) (Table 6). Meanwhile, we compared the degree of breastfeeding knowledge to master of 2 groups and found significant difference in improvements in the breastfeeding knowledge at discharge ($P<.00$) (Table 7).

### Table 1
Baseline characteristics of participant.

| Variable                        | Intervention group (N=176) | Control group (N=176) | $\chi^2/t$ | $P$ |
|---------------------------------|---------------------------|-----------------------|------------|-----|
| **Education**                   |                           |                       |            |     |
| High school or less             | 20 (11.4)                 | 20 (11.4)             |            | .3  |
| Some college                    | 35 (19.9)                 | 48 (27.3)             | 3.32       | .3  |
| College graduate                | 121 (68.7)                | 108 (61.3)            |            |     |
| **Income (RMB)**                |                           |                       |            |     |
| <3000                           | 14 (8.0)                  | 12 (6.8)              |            |     |
| 3001–5000                       | 28 (15.9)                 | 27 (15.3)             |            |     |
| 5001–10,000                     | 116 (65.9)                | 123 (69.9)            | 0.88       | .8  |
| >10,000                         | 16 (10.2)                 | 14 (8.0)              |            |     |
| **Smoke**                       |                           |                       |            |     |
| Yes                             | 2 (1.1)                   | 3 (1.7)               |            |     |
| No                              | 174 (98.9)                | 173 (98.3)            |            |     |
| **Parity:**                     |                           |                       |            |     |
| Primiparous                     | 114 (64.8)                | 110 (62.0)            |            |     |
| Multiparous                     | 62 (35.2)                 | 66 (38.0)             | 0.20       | .7  |
| **Had previously breast fed:**  |                           |                       |            |     |
| Yes                             | 53 (30.1)                 | 55 (31.3)             |            |     |
| No                              | 123 (69.9)                | 121 (68.7)            | 0.05       | .8  |
| **Mean (SD) age, y**            |                           |                       |            |     |
| 31.7 (5.6)                      | 32.2 (4.3)                | 1.06                  | .28        |     |
| **BMI, kg/m²**                  |                           |                       |            |     |
| 26.2 (2.7)                      | 26.3 (2.6)                | 0.07                  | .96        |     |
| **Gestational weeks, wk**       |                           |                       |            |     |
| 39.2 (1.1)                      | 39.1 (2.8)                | 0.75                  | .42        |     |
| **Hemoglobin, g/L**             |                           |                       |            |     |
| 126.2 (11.1)                    | 125.4 (10.3)              | 1.09                  | .23        |     |
| **Total protein, g/L**          |                           |                       |            |     |
| 69.2 (4.8)                      | 70.3 (4.5)                | 0.72                  | .41        |     |
| **Albumin, g/L**                |                           |                       |            |     |
| 36.8 (2.2)                      | 36.9 (2.2)                | 1.35                  | .13        |     |
| **Prenatal breastfeeding intention, mo** | 8.5 (3.8) | 8.0 (2.9) | 0.50 | .62 |
| **The time receiving health education** | 0.9 (0.4) | 0.9 (0.5) | 1.32 | .25 |

*Fisher exact test.

### Table 2
Perinatal factors of women by group allocation.

|                          | Intervention group (N=162) | Control group (N=157) | $\chi^2/t$ | $P$ |
|--------------------------|---------------------------|-----------------------|------------|-----|
| **Mode of delivery:**    |                           |                       |            |     |
| Normal vaginal           | 36 (22.2)                 | 32 (20.4)             | 0.2        | .36 |
| Caesarean section        | 126 (77.8)                | 125 (79.6)            |            |     |
| **Infant sex**           |                           |                       |            |     |
| Boy                      | 82 (50.6)                 | 81 (51.6)             |            |     |
| Girl                     | 80 (49.4)                 | 76 (48.4)             | 0.03       | .47 |
| **Maternal sleep time**  |                           |                       |            |     |
| <6 h                     | 66 (40.7)                 | 84 (53.6)             | 5.3        | .02 |
| 6–8 h                    | 94 (58.0)                 | 72 (45.8)             |            |     |
| >8 h                     | 2 (1.3)                   | 1 (0.6)               |            |     |
| **Maternal appetite**    |                           |                       |            |     |
| Poor                     | 66 (40.7)                 | 76 (48.4)             | 4.7        | .09 |
| General                  | 88 (54.3)                 | 79 (50.3)             |            |     |
| Good                     | 8 (5.0)                   | 2 (1.3)               |            |     |
| **Nipple state**         |                           |                       |            |     |
| Prominent                | 140 (86.4)                | 130 (82.8)            | 0.87       | .65 |
| Flat                     | 17 (10.5)                 | 20 (12.7)             |            |     |
| Sunken                   | 5 (3.1)                   | 7 (4.5)               |            |     |
| **Mean (SD) birth weight, g** | 3188.5±415 | 3258.4±496 | -1.16 | .25 |
| **Mean (SD) birth length, g** | 49.0±4.6 | 49.5±2.2 | -1.09 | .28 |
4. Discussion

Individualized antenatal breastfeeding education and postnatal support can significantly improve the rates of exclusive breastfeeding from birth to 4 months after delivery versus routine care. Our results were also consistent with several researches. Su et al.\cite{31} study showed that antenatal breastfeeding education or postnatal lactation support, as single interventions, can significantly improve rates of exclusive breastfeeding up to 6 months after delivery. Systematic reviews have shown that antenatal educational and postnatal support programs improved the rates of exclusive breastfeeding; and individual counseling was most effective when used in conjunction with antenatal and postnatal educational and support.\cite{32,33} Some reasons can explain this outcome. Firstly, we provided professional support for breastfeeding mothers. Gerd et al.\cite{34} study had showed that many mothers reported breastfeeding problems that are associated with an early cessation; and the time of preventable support is crucial. Researchers have advocated that the support should be practical, covering specific areas, rather than a superficial query about whether there are any breastfeeding problems.\cite{32,33} Meanwhile the family member for example the baby’s father who are engaged and educated in the breastfeeding process is also associated with increased rates of breastfeeding.\cite{35} Secondly, we timely given targeted and individualized guidance for mothers to breastfeed after delivery, ensued a conducive environment for initiation of breastfeeding, provided personal counsel (e.g., maternal diet), and supported for the breastfeeding after discharge. Thirdly, in order to avoid incorrect feeding, we give ongoing individualized support to mother by telephone in the postpartum follow-up. As discussed in some studies,

| Table 3 | Number (percentage) of women exclusively breast feeding. |
|------------------|------------------|------------------|------------------|
|                  | Intervention group | Control group | Relative risk (95% CI) intervention group vs control group |
| At discharge from hospital | 70/162 (43.2) | 47/157 (30.0) | 1.78 (1.12–2.82) (P = .01) |
| Postpartum 42 d | 114/153 (74.5) | 108/150 (72.0) | 1.14 (0.68–1.89) (P = .62) |
| Postpartum 4 mo | 105/148 (70.9) | 67/145 (46.2) | 2.84 (1.76–4.60) (P = .00) |

| Table 4 | Number (percentage) of breastfeeding on demand. |
|------------------|------------------|------------------|------------------|
|                  | Intervention group | Control group | Relative risk (95% CI) intervention group vs control group |
| At discharge from hospital | 154/162 (95.1) | 107/157 (68.1) | 9.00 (4.09–19.74) (P = .00) |
| Postpartum 42 d | 141/153 (92.2) | 138/150 (92.0) | 1.02 (0.44–2.35) (P = .95) |
| Postpartum 4 mo | 140/148 (94.6) | 110/145 (75.9) | 5.57 (2.48–12.49) (P = .00) |

| Table 5 | Number (percentage) of the incidence of cracked nipple. |
|------------------|------------------|------------------|------------------|
|                  | Intervention group | Control group | Relative risk (95% CI) intervention group vs control group |
| At discharge from hospital | 17/162 (10.5) | 14/157 (8.9) | 1.20 (0.57–2.52) (P = .70) |
| Postpartum 42 d | 33/153 (21.6) | 54/150 (36.0) | 0.49 (0.29–0.81) (P = .01) |
| Postpartum 4 mo | 31/148 (21.0) | 50/145 (34.5) | 0.50 (0.29–0.85) (P = .01) |

| Table 6 | Comparison of breastfeeding satisfaction of 2 groups. |
|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|
|                  | Intervention group | Control group | Time effect | Interaction effect | Inter-group effect |
| At discharge from hospital | Maternal satisfaction | 54.4 ± 3.4 | 53.9 ± 3.4 | 0.05 | 0.98 | 0.98 | 36.4 .00 |
| | Infant satisfaction | 24.6 ± 3.5 | 26.7 ± 3.4 | 0.05 | 0.98 | 0.98 | 36.4 .00 |
| | Maternal lifestyle | 24.8 ± 2.4 | 19.5 ± 1.7 | 27.2 | 0.00 | 32.7 | 0.00 |
| Postpartum 42 d | Maternal satisfaction | 53.6 ± 6.5 | 53.9 ± 6.5 | 0.05 | 0.98 | 0.98 | 36.4 .00 |
| | Infant satisfaction | 26.9 ± 3.8 | 26.7 ± 3.4 | 0.05 | 0.98 | 0.98 | 36.4 .00 |
| | Maternal lifestyle | 19.8 ± 2.3 | 19.5 ± 1.7 | 27.2 | 0.00 | 32.7 | 0.00 |
| Postpartum 4 mo | Maternal satisfaction | 53.9 ± 5.0 | 50.0 ± 9.4 | 0.05 | 0.98 | 0.98 | 36.4 .00 |
| | Infant satisfaction | 26.9 ± 3.4 | 25.0 ± 5.0 | 0.05 | 0.98 | 0.98 | 36.4 .00 |
| | Maternal lifestyle | 19.2 ± 1.9 | 19.8 ± 2.9 | 27.2 | 0.00 | 32.7 | 0.00 |

| Table 7 | Score of breastfeeding knowledge. |
|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|
|                  | Intervention group | Control group | t | P |
| At admission of hospital | 90 ± 5.3 | 90 ± 6.9 | 0.5 | .6 |
| At discharge from hospital | 120 ± 2.4 | 93 ± 2.3 | 2.3 | .00 |

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counselors provided ongoing postpartum support for patients by telephone can effective increases the proportion of women continuing breastfeeding several months postpartum.\[36,37\] Ideally, this support is integrated into both antenatal and postnatal care,\[30\] and does not rely upon the motivation of new mothers to contact someone for help.\[36–38\]

Compared with the control group, women randomized to intervention group were significantly more likely to breastfeeding on demand and the incidence of cracked nipple was lower from discharge to 4 months after delivery. Meanwhile, the results of this study show that the number were adding formula, using bottle in the intervention group was less than the control group, the difference was significant. The results were supported by a systematic review which illustrated professionals support can effectively reduce adding formula and improve breastfeeding on demand.\[39\]

Compared with control group, the intervention group increased maternal satisfaction and baby satisfaction. Gao et al\[40\] research showed that satisfaction was closely related to form of feeding and the score of satisfaction in people of exclusive breastfeeding are higher than other way of feeding. In this study, the rate of exclusively breastfeeding in the intervention group was higher than that of control group, therefore the satisfaction of the mothers and infants was effectively increased. Previous studies have suggested that the satisfaction of breastfeeding was associated with any breastfeeding problems, appetite, and sleep time of maternal. So it is important for medical staff that solve breastfeeding problems in a timely by monthly phone calls or face-to-face support, thereby increasing maternal and infant satisfaction.\[41\] Su et al\[31\] study showed that compared with women who received routine care, women in the postnatal support group face to face visited by a lactation consultant were more likely to breastfeed exclusively at 3 months (1.87, 1.03–3.41). In our study, at 4 months, 70.9% of women in the intervention group were exclusively breastfeeding compared with 46.2% of the women in the control group (2.84; 1.76–4.60). The intervention group were offered regular ongoing visits by phone calls. Therefore, compared with face to face visits, the regular ongoing visits by phone calls can effectively reduce economic costs for improvement of breastfeeding practice.

5. Limitations

Although combined antenatal education and postnatal support ideal, this may be limited by economic or time resources, we just followed 4 months. The World Health Organization recommends that infants should be exclusively breastfed until 6 months of age with breastfeeding continuing as an important part of the infant’s diet till at least 2 years of age. Therefore, future research should compare the rate of 6-month exclusively breastfeeding and the rate of 2 years breastfeeding of such strategies. Our study was not compared the differences in the breastfeeding practice among the different family support. All forms of extra support, analyzed together, can increase the length of time that women continued to breastfeed without introducing any other types of liquids or foods. Support by both lay supporters and professionals had a positive impact on breastfeeding outcomes.\[32\] In our study, we used the breastfeeding attrition prediction scale to understand the attitudes of breastfeeding of important family members. Meanwhile, we provided breastfeeding guidance to family members in hospitals. However, we did not compare the differences between the 2 groups.

6. Conclusion

The regular ongoing individualized antenatal education and postnatal support can effective increase the rates of exclusive breastfeeding from delivery to postpartum 4 months and change the breastfeeding behavior. In addition, the personalized behavior intervention can enhance maternal and infant satisfaction. Therefore, all women should be offered professional antenatal and postnatal support to breastfeed their babies. Strategies that rely mainly on face to face intervention used the breastfeeding attrition prediction scale and the breastfeeding knowledge scale are more likely to find problems of lactating mother. The medical staff can solve partly breastfeeding problems by monthly phone calls. Therefore, the breastfeeding women should be offered regular ongoing visits by phone calls. Compared with face to face visits, the regular ongoing visits by phone calls can effectively reduce economic costs for improvement of breastfeeding practice.

Author contributions

Conceptualization: Biru Luo.
Data curation: Pan Huang.
Formal analysis: Pan Huang.
Methodology: Biru Luo, Xinghui Liu.
Software: Jianrong Yao.
Validation: Jianrong Yao.
Writing – original draft: Biru Luo, Pan Huang.
Writing – review & editing: Biru Luo, Pan Huang, Xinghui Liu.

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