

# Effects of breastfeeding education based on the self-efficacy theory on women with gestational diabetes mellitus

## A CONSORT-compliant randomized controlled trial

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### Abstract

**Background:** Women with gestational diabetes mellitus (GDM) face big challenges of breastfeeding. In order to improve breastfeeding self-efficacy and breastfeeding rate of them, we formulated perinatal individualized interventions based on self-efficacy theory and conducted a randomized controlled trial to verify the effectiveness.

**Methods:** We conducted a randomized controlled trial. The perinatal individualized interventions based on the self-efficacy theory including 4 phases were led by the International Board Certified Lactation Consultant (IBCLC). Women allocated to the control group received usual care for lactation support during the antenatal and postnatal period. Data collection occurred at admission, discharge, 6 weeks postpartum, 4 months postpartum, and 6 months postpartum.

**Results:** We enrolled 226 women with GDM, 113 in the intervention group and 113 in the control group. The scores of breastfeeding self-efficacy in the intervention group were significantly higher than those in the control group at discharge, at 6 weeks, 4 months, and 6 months postpartum ( $P < .05$ ). We found higher rates of exclusive and any breastfeeding in the intervention group at discharge (Exclusive: 25.2% vs 13.5%,  $P < .05$ ; Any: 94.4% vs 89.4%,  $P > .05$ ), at 6 weeks postpartum (Exclusive: 75.5% vs 62.5%,  $P < .05$ ; Any: 100.0% vs 96.2%,  $P > .05$ ), at 4 months postpartum (Exclusive: 68.9% vs 43.3%,  $P < .05$ ; Any: 94.3% vs 83.7%,  $P < .05$ ) and at 6 months postpartum (Exclusive: 55.8% vs 36.9%,  $P < .05$ ; Any: 88.5% vs 64.1%,  $P < .05$ ).

**Conclusion:** Perinatal individualized breastfeeding education based on the self-efficacy theory had positive effects on breastfeeding self-efficacy and breastfeeding rate of women with GDM.

**Abbreviations:** CONSORT = CONSolidated Standards Of Reporting Trials, GDM = gestational diabetes mellitus.

**Keywords:** breastfeeding, gestational diabetes mellitus, individualized intervention, perinatal period, self-efficacy theory

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The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

HY and AL have contributed equally to this study.

The authors have no conflicts of interest to disclose.

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## 1. Introduction

Gestational diabetes mellitus (GDM) is defined as any degree of glucose intolerance with onset or first recognition during pregnancy.<sup>[1]</sup> A system review reported the global prevalence estimates of GDM had a wide range from 1.8% to 25.1%.<sup>[2]</sup> Moreover, with the wide application of the new diagnostic criteria by World Health Organization (WHO) which lowered the critical value of diagnostic criteria for GDM in 2013,<sup>[3]</sup> the incidence of GDM were expected to be higher. Under the new diagnostic criteria, the incidence of GDM is range from 9.3% to 19.9% in China.<sup>[4,5]</sup>

A large number of studies have reported that GDM has adverse effects on the maternal and neonatal outcomes. It was well-known that breastfeeding was an effective way to improve the near-term and long-term prognosis of mothers and children.<sup>[6]</sup> For women with GDM, breastfeeding is known to have a protective effect against type 2 diabetes.<sup>[7]</sup> For children, breastfeeding may reduce the risk of developing obesity, hypertension, cardiovascular disease, and diabetes later in life.<sup>[8,9]</sup> Therefore, women with GDM should insist on breastfeeding. However, several studies have shown that women with GDM are less willing to breastfeed than women with normal blood glucose, and breastfeeding rates are falling faster.<sup>[10–12]</sup>

Some reasons may contribute to this result. On the one hand, high blood glucose level has an impact on fetal neurodevelopment, which leads to the decline of infant sucking ability. On the other hand, infants of insulin-treated mothers with GDM have worse sucking ability than infants of women with GDM treated with diet. Moreover, the older age and obesity in women with GDM might lead to delayed lactation initiation, which increases the probability of neonatal formula use.<sup>[13]</sup> Furthermore, women with GDM are prone to a variety of adverse pregnancy outcomes, such as premature delivery, premature rupture of membranes, macrosomia, cesarean section, and neonatal hypoglycemia, which have adverse effects on the initiation and persistence of breastfeeding.<sup>[14,15]</sup> Therefore, women with GDM face more challenge of breastfeeding and it is necessary to take interventions to improve breastfeeding practices of them.

Previous studies have found that interventions based on self-efficacy theory were feasible and effective in behavioral change.<sup>[16–18]</sup> Self-efficacy is the belief in one's capabilities to perform a task, giving motivation and ability to someone to achieve success. It is usually influenced through performance accomplishments; vicarious experience; verbal persuasion; and physiological and affective states.<sup>[19,20]</sup> A systematic review suggested that interventions based on self-efficacy theory might help women to delay early breastfeeding cessation.<sup>[21]</sup> However, there are fewer studies have evaluated whether individualized interventions based on self-efficacy theory were effective in improving breastfeeding outcomes for women with GDM, who face more challenge of breastfeeding. Therefore, this study formulated perinatal individualized interventions based on self-efficacy theory on women with GDM and examined the effectiveness of the interventions.

## 2. Materials and methods

### 2.1. Trial design

We conducted a randomized controlled trial. Pregnant women inducted over a 2-month enrollment period from a hospital in west China. The pregnant women who met the inclusion criteria were selected as the study subjects. After they signed the informed consent, they were assigned to either the control group or the intervention group by using a random number table method. The allocation ratio is 1:1.

### 2.2. Participants

Women were recruited from West China Second Hospital of Sichuan University, which is a women and children's medical center in West China serving >5 provinces. Women were eligible if they: were diagnosed with GDM with  $\geq 1$  75-g Oral Glucose Tolerance Test (OGTT) values exceeding established thresholds (fasting 5.1 mmol/L, 1 hour 10.0 mmol/L, 2 hours 8.5 mmol/L); were older than 36 weeks' gestation; between the ages of 18 and 45; have ability to read and write in Chinese. Women were excluded if they cannot breastfeed because of medical indications or have an A1C  $\geq 6.5$  mg/dL indicating type 2 diabetes mellitus.

### 2.3. Intervention

The intervention includes 4 phases. Phase I is a baseline investigation. We used designed questionnaires to investigate the women's breastfeeding knowledge level and breastfeeding intention when they were admitted to the hospital. Phase II,

researchers (HY, BL, JH) made an individualized intervention program based on the results of Phase I and implemented it before delivery. Firstly, researcher (HY) corrected the women's wrong knowledge and addressed the importance of breastfeeding for metabolic control and progression of GDM to prediabetes and type 2 diabetes mellitus and infant health. Secondly, taught them breastfeeding skills hand by hand. Thirdly, gave a designed GDM breastfeeding handbook to them. The handbook includes the advantages of breastfeeding, the differences between breast milk and formula milk, the breastfeeding position and matters needing attention, and postnatal diet. At last, we invited the participants to join our Wechat Group for breastfeeding mothers. Wechat is the most popular social software in China, and almost everyone is using it. We encouraged mothers to share succeed breastfeeding experiences. Phase III, researcher helped mothers to breastfeed hand by hand within 24-hour postpartum and check their breastfeeding skills level before they discharged. Phase IV is a telephone breastfeeding counseling and telephone follow-up period. Mothers called the breastfeeding counseling number when they met breastfeeding problems. The researcher gave them advices about breastfeeding. In total, we conducted at least 6 counseling contacts, which occurred at the following time points: before birth (antenatal period); immediately and during after birth (perinatal period up to the first 1–3 days after birth); at 6 weeks after birth (neonatal period); in the first 3 months (early infancy); at 6 months (at the start of complementary feeding), with additional contacts as needed.

All the interventions were led by the study's International Board Certified Lactation Consultant (IBCLC) (JX).

Women allocated to the control group received usual care for lactation support during the antenatal and postnatal period.

Data collection occurred at admission, discharge, 6 weeks postpartum, 4 months postpartum, and 6 months postpartum.

### 2.4. Measurement

We used self-designed questionnaire to assess the duration of breastfeeding. Exclusive breastfeeding was defined as no formula fed during 2 interview time points. Breastfeeding knowledge level was assessed at admission and discharge, using the Breastfeeding Knowledge Questionnaire. This questionnaire was designed by ZM, and revised by ZY and WHW. This is a Chinese 5-point Likert scale, including 25 items. Cronbach  $\alpha$  coefficient was 0.820. Responses range from "Very much agree" to "Very much disagree." Breastfeeding knowledge scores range from 25 to 125, with higher scores indicating the higher breastfeeding knowledge level.<sup>[22,23]</sup>

Breastfeeding Self-Efficacy Scale-Short Form (BSES-SF), which is a 5-point Likert scale that assesses strength of self-efficacy of breastfeeding. This scale includes 14 items. The Cronbach  $\alpha$  coefficient of the Chinese version of BSES-SF is 0.927, the test-retest reliability is 0.811, and the average construct validity index is 0.972, which shows that BSES-SF has good reliability and validity.<sup>[24]</sup> Responses range from "extremely agree" to "extremely disagree." Breastfeeding self-efficacy scores range from 14 to 70, with higher scores indicating higher breastfeeding self-efficacy.<sup>[25,26]</sup>

### 2.5. Sample size

The number of patients in the intervention group was the same as that in the control group. According to the reference literature,

the rate of exclusive breastfeeding at 4 to 6 months in pregnant women with diabetes mellitus was 11.34%. The estimated rate of behavioral change is 15%. According to the sample content formula for 2 rate comparisons, we calculated the sample content of each group as 103 cases, a total of 206 cases. We estimated that there was a loss of follow-up rate of 10% to 20%, and each group needed to increase 10 to 21 cases. According to the degree of cooperation of the trial test subjects, the total sample size was finally determined to be 226 cases, and the sample size of the intervention group and the control group was 113 cases.

## 2.6. Randomization

The participants were divided into control group and intervention group by random number table method. A computer-generated table of random numbers with odd and even matching was used to start counting at any location. The obtained numbers were assigned to the continuously included patients, even numbers were assigned to the intervention group, and odd numbers were assigned to the control group. The generated random distribution sequence was placed in sequentially coded, sealed, and light-tight envelopes. After determining the eligibility of the participant, the researcher (YW) opened the envelope in order and assigned the participant to the intervention group or control group.

## 2.7. Blinding

Participants and medical staff were blinded to participants' allocation. Moreover, researcher (AL) who collected all outcome data was blinded to study group assignment.

## 2.8. Statistical methods

The qualitative data were described by composition ratio and rate, and the data were statistically inferred by chi-square test, rank sum test, and Fisher exact probability method. The quantitative data were statistically described by means of mean, standard deviation, median, quartile, and the data were statistically inferred by *t* test and rank sum test ( $\alpha=0.05$ ). SPSS 21.0 (SPSS Inc, Chicago, IL) was used for statistical analysis.

Our study was approved by the Ethics Committee of West China Second University Hospital, Sichuan University.

## 3. Results

### 3.1. Participant recruitment and retention

We enrolled 226 women with GDM, 113 in the intervention group and 113 in the control group. In the first stage, 107 effective questionnaires were collected from the intervention group upon admission, with an effective rate of 94.7%, and 105 effective questionnaires were collected from the control group, with an effective rate of 92.9%. The number of retaining participants and drop-out reason in each phase were showed in CONSORT flow diagram (Fig. 1).

### 3.2. Baseline characteristics of participants

No differences in demographic characteristics were observed between women in the intervention group and control group. Moreover, we did not find statistically significant differences in women's breastfeeding experience, their breastfeeding intention,

their delivery way, and their infants' health condition. We also did not find the differences in OGTT values between women in 2 groups (Table 1).

### 3.3. Breastfeeding knowledge level at admission and discharge

The results showed that there was no significant difference in the score of breastfeeding knowledge between the 2 groups at admission ( $P>.05$ ). At discharge, the results showed the score of breastfeeding knowledge in the intervention group was higher than that in the control group ( $P<.05$ ). The difference of breastfeeding knowledge scores at admission and discharge in the intervention group was higher than that in the control group, and the difference between the intervention group and the control group was statistically significant ( $P<.05$ ). (Table 2).

### 3.4. Comparison of breastfeeding self-efficacy

The scores of breastfeeding self-efficacy in the intervention group were significantly higher than those in the control group at discharge, 6 weeks postpartum, 4 months postpartum, and 6 months postpartum ( $P<.05$ ). After discharge, the score of breastfeeding self-efficacy of women with GDM in the intervention group increased at first and then decreased slightly, showing an upward trend as a whole. The score of breastfeeding self-efficacy in the control group increased at first and then decreased, showing a downward trend as a whole (Fig. 2).

### 3.5. Comparison of exclusive and any breastfeeding rates

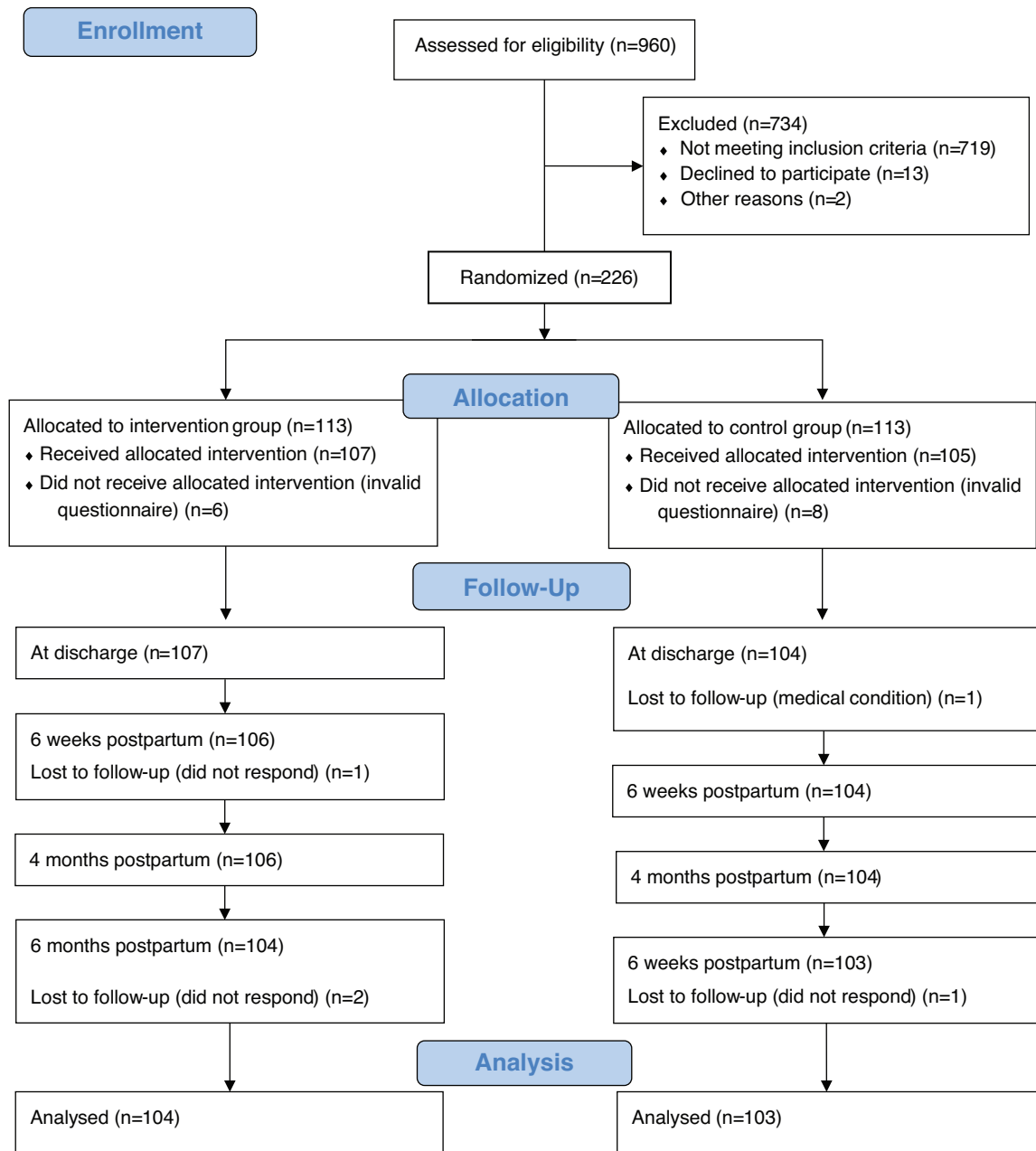
We analyzed rates of exclusive and any breastfeeding among 2 groups during postnatal follow-up. At discharge, we found higher rates of exclusive and any breastfeeding in the intervention group (Exclusive: 25.2% vs 13.5%; Any: 94.4% vs 89.4%), but there was no significant difference in the rate of any breastfeeding ( $P>.05$ ). At 6 weeks postpartum, we found higher rates of exclusive and any breastfeeding in the intervention group (Exclusive: 75.5% vs 62.5%; Any: 100.0% vs 96.2%), but there was also no significant difference in the rate of any breastfeeding ( $P>.05$ ). At 4 months postpartum and 6 months postpartum, we found the higher rates of exclusive and any breastfeeding in the intervention group (Exclusive: 68.9% vs 43.3%; 55.8% vs 36.9%; Any: 94.3% vs 83.7%; 88.5% vs 64.1%), and all the differences between the intervention group and the control group were statistically significant ( $P<.05$ ) (Tables 3 and 4).

## 4. Discussion

Our study aims to explore the efficiency of perinatal individualized breastfeeding interventions based on self-efficacy theory for Chinese women with GDM. The results in this study showed the interventions are effective in improving the breastfeeding knowledge, breastfeeding self-efficacy, and breastfeeding rate of Chinese women with GDM.

### 4.1. Breastfeeding knowledge

At discharge, we found women in 2 groups both had higher breastfeeding knowledge scores. Moreover, the breastfeeding



**Figure 1.** CONSORT flow diagram of participant recruitment and retention.

knowledge scores of intervention group is higher than that of control group. This result indicated that antenatal and postnatal individualized health education could improve the breastfeeding knowledge level of women with GDM. Our study was consistent with earlier studies. Shi et al<sup>[27]</sup> reviewed 15 intervention studies conducted in developing country, in which they found that effective health education interventions can improve the breastfeeding knowledge level and be conducive to developing better breastfeeding behaviors. Wallenborn et al<sup>[28]</sup> and Jain et al<sup>[29]</sup> reported that mother’s knowledge of breastfeeding recommendations impacts breastfeeding practices. Healthcare providers should educate mothers about breastfeeding. Therefore, individualized breastfeeding education for women with

GDM are needed. Wrong notions or the knowledge fade zone of each woman with GDM should be highlighted by healthcare providers. Future breastfeeding counselling should be targeted rather than scripted.

**4.2. Breastfeeding self-efficacy**

It was not surprised to find that individualized education can improve the breastfeeding self-efficacy from discharge to 6 months postpartum. This finding extended the results of previous studies, which indicated that earlier education interventions can help women get higher breastfeeding self-efficacy at 6-hour postpartum, hospital discharge, 2 weeks and 2 months postpar-

**Table 1**  
Baseline characteristics of women with gestational diabetes mellitus in intervention group and control group.

	Intervention group (N = 107)	Control group (N = 105)	P value
Nationality			
Han	102 (95.3)	101 (96.2)	
Minority	5 (4.7)	4 (3.8)	>.99
Education			
Primary school or less	1 (0.9)	2 (1.9)	
Middle school	5 (4.7)	6 (5.7)	
High school	8 (7.5)	7 (6.7)	.91
Some college	25 (23.4)	20 (19.0)	
College graduate or more	68 (63.6)	70 (66.7)	
Occupation			
Professional	17 (15.9)	19 (18.1)	
Administrative	28 (26.2)	34 (32.4)	
Clerk	29 (27.1)	26 (24.8)	.77
Farmer	1 (0.9)	1 (0.9)	
Freelance	18 (16.8)	11 (10.5)	
Unemployed	14 (13.1)	14 (13.3)	
Marital status			
Never married	0 (0)	0 (0)	
Married	105 (98.1)	105 (100)	.50
Divorced	2 (1.9)	0 (0)	
Per capita monthly household income			
<3000 RMB	9 (8.4)	6 (5.7)	
3001–5000 RMB	23 (21.5)	28 (26.7)	
5001–10,000 RMB	44 (41.1)	47 (44.7)	.56
>10,000 RMB	31 (29.0)	24 (22.9)	
Parity			
0	48 (44.9)	60 (57.1)	
≥1	59 (55.1)	45 (42.9)	.07
Breastfeeding experience			
Yes	54 (50.5)	45 (42.9)	
No	53 (49.5)	60 (57.1)	.27
Insulin used			
Yes	10 (9.3)	5 (4.8)	
No	97 (90.7)	100 (95.2)	.28
Breastfeeding intention			
Yes	107 (100)	104 (99.0)	
No	0 (0)	1 (1.0)	.50
Delivery way			
Natural delivery	28 (26.2)	27 (25.7)	
Cesarean section	79 (73.8)	78 (74.3)	.95
Twins			
Yes	10 (9.3)	10 (9.5)	
No	97 (90.7)	95 (90.5)	.97
Infant has complication			
Yes	8 (7.5)	8 (7.6)	
No	99 (92.5)	97 (92.4)	.97
	Median (quartile)	Median (quartile)	P value
Age at baseline	33.0 (30.0, 37.0)	34.0 (31.0, 37.0)	.29
BMI at baseline, kg/m <sup>2</sup>	26.1 (24.2, 28.6)	25.8 (23.4, 28.3)	.96
75-g oral glucose tolerance test values, mmol/L			
Fasting	4.8 (4.5, 5.2)	4.9 (4.5, 5.3)	.43
1 h	10.3 (9.1, 10.9)	10.3 (9.2, 10.9)	.92
2 h	8.7 (7.8, 9.5)	8.9 (8.2, 10.0)	.15
Infant birth weight, g	3.3 (2.9, 3.6)	3.1 (2.8, 3.5)	.15

tum.<sup>[30,31]</sup> Wu et al<sup>[32]</sup>. also confirmed the effectiveness of individualized intervention based on the self-efficacy theory in enhancing mothers' breastfeeding self-efficacy and breastfeeding rates.<sup>[33,34]</sup> In self-efficacy theory, breastfeeding self-efficacy is

**Table 2**  
Scores of breastfeeding knowledge of women with gestational diabetes mellitus at admission and discharge.

	Intervention group (N = 107)	Control group (N = 104)	Z	P value
Admission	106.0 (95.0, 112.0)	104.0 (97.3, 111.0)	-0.35	.73
Discharge	112.0 (103.0, 118.0)	108.0 (102.0, 114.0)	-2.53	.01
Difference	6.0 (4.0, 10.0)	4.0 (2.0, 6.0)	-4.10	<.01

influenced through performance accomplishments; vicarious experience; verbal persuasion; and physiological and affective states.<sup>[19]</sup> In intervention group of this study, researcher taught them breastfeeding skills hand by hand to increase their performance accomplishments. Perinatal individualized breastfeeding education is the way to implement verbal persuasion. Wechat Group is a successful experiment sharing platform, which could increase their vicarious experience. Moreover, the breastfeeding telephone counseling and online counseling might also be contributable. In addition, we found the breastfeeding self-efficacy was an uptrend in the intervention group and a downtrend in the control group after hospital discharge in this study. So we inferred that perinatal individualized breastfeeding education based on self-efficacy theory could prevent the decrease of the breastfeeding self-efficacy of women with GDM. Moreover, breast-feeding self-efficacy has been showed to correlated with breastfeeding outcomes.<sup>[21,35,36]</sup> Therefore, future breastfeeding education should consider using self-efficacy theory as theoretical framework to improve the effectiveness of breastfeeding education.

#### 4.3. Breastfeeding outcomes

Based on the WHO guidelines,<sup>[37]</sup> this study conducted perinatal individualized breastfeeding health education and breastfeeding skills training for the women in the intervention group. In the results, we found that women with GDM in intervention group started breastfeeding earlier and had higher breastfeeding frequency. The exclusive breastfeeding rate and any breastfeeding rate are also higher in intervention group. This is consistent with earlier intervention study by Stuebe et al,<sup>[38]</sup> who found the targeted breastfeeding support for women with GDM was feasible and efficacious. We inferred that the combination of antenatal health education and postnatal breastfeeding skills training is an effective way to improve breastfeeding behaviors of women with GDM. Previous studies reached the same conclusion. Fisun and Birol<sup>[39]</sup> confirmed the antenatal small group sessions combined with postnatal individual problem-oriented support could increase the exclusive breastfeeding rates. Schreck et al<sup>[40]</sup> regarded both antenatal education and ongoing postnatal support are needed to improve breastfeeding continuation. Pan et al<sup>[41]</sup> also emphasized the personalization and continuity of the breastfeeding interventions. Therefore, we inferred that continuous dynamic perinatal individualized breastfeeding counseling can promote the breastfeeding duration and intensity for women with GDM. We suggest that future study should consider providing continuous dynamic perinatal individualized breastfeeding counseling and postnatal breastfeeding skills training for women with GDM.

In our study, we have 2 limitations. Firstly, we only included 1 hospital as our study site, which is the one of the best hospitals of

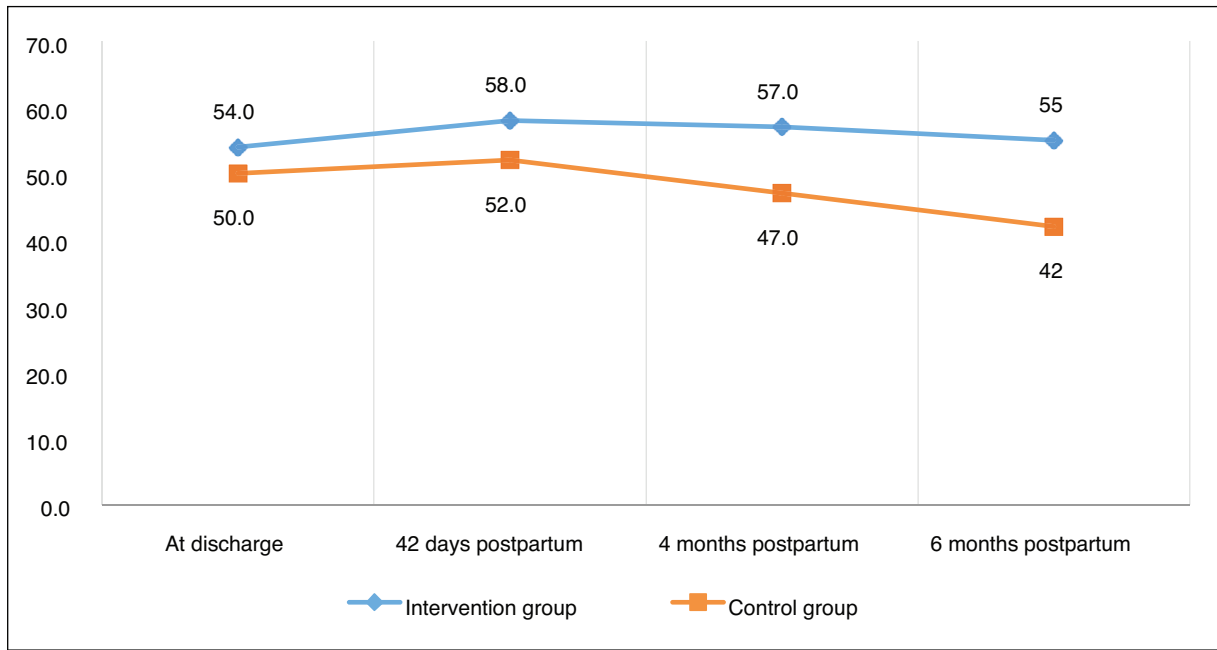


Figure 2. The trend of breastfeeding self-efficacy of women with gestational diabetes mellitus in 2 groups.

west China. Our participants almost are well educated and have high household income. So, this may reduce the representativeness of the sample in this study. Secondly, our follow-up time is 6 months, at this time, most mothers return to work. Their breastfeeding rhythm might change and they might face more breastfeeding challenges. At this time, infants start being complementary fed. So, our intervention might not be efficient enough to improve the breastfeeding outcomes of women with GDM after 6 months postpartum. Therefore, we suggest the future study could conduct complex multi-component interventions to protect, support, and promote breastfeeding among women returning to work.

### 5. Conclusion

We conducted perinatal individualized intervention based on self-efficacy theory among Chinese women with GDM, and we found the intervention are effective in improving breastfeeding knowledge, breastfeeding self-efficacy, and breastfeeding rate of them. We suggest that future study should consider providing continuous perinatal individualized breastfeeding education for women with GDM. In addition, future study could try to apply this breastfeeding education framework to women with other complications or health women.

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### Author contributions

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**Writing – original draft:** Huaxuan You.  
**Writing – review & editing:** Biru Luo.

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**Table 3**  
**Exclusive breastfeeding rate of women with gestational diabetes mellitus in 2 groups.**

Time point	Intervention group	Control group	$\chi^2$	P value
At discharge	27/107 (25.2)	14/104 (13.5)	4.67	.03
42 days postpartum	80/106 (75.5)	65/104 (62.5)	4.13	.04
4 months postpartum	73/106 (68.9)	45/104 (43.3)	13.97	<.01
6 months postpartum	58/104 (55.8)	38/103 (36.9)	7.41	<.01

**Table 4**  
**Any breastfeeding rate of women with gestational diabetes mellitus in 2 groups.**

Time point	Intervention group	Control group	$\chi^2$	P value
At discharge	101/107 (94.4)	93/104 (89.4)	1.76	.19
42 days postpartum	106/106 (100.0)	100/104 (96.2)	2.35	.13
4 months postpartum	100/106 (94.3)	87/104 (83.7)	6.15	.01
6 months postpartum	92/104 (88.5)	66/103 (64.1)	17.03	<.01

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