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ORIGINAL PAPER

Effects of a Mindfulness-Based Intervention Delivered by Mobile Phone on Perinatal-Specific Stress and Neonatal Outcomes: A Randomized Controlled Trial

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Abstract

Objectives Whereas some women may perceive pregnancy as a welcome challenge and a source of satisfaction, self-development, and maturity, others may experience perinatal-specific stress (PSS). Emerging evidence has demonstrated the efficacy of mindfulness-based interventions (MBIs) for perinatal women. Given the debate about the effects of MBIs on PSS reduction, as well as the limitations of existing studies, such as practical concerns and small sample sizes, the current study aimed to contribute further evidence by utilizing a randomized controlled trial (RCT) to investigate the effects of mobile-delivered MBIs on women's PSS and neonatal outcomes, compared with outcomes from a mobile-delivered psychoeducation intervention.

Method One hundred and seventy-eight adult pregnant women were randomized into two groups—one to receive a mobile-delivered eight-session MBI ($n=93$) and the other to receive a web-based perinatal education program ($n=85$). Outcomes included perinatal distress, mindfulness, and neonatal outcomes.

Results Women in the MBI group showed a significantly greater reduction in their PSS levels from baseline to the follow-up-timepoint (T2) compared with the control group. The MBI group had a significant enhancement of mindfulness, and their newborns had higher Apgar scores compared with the control group. Mindfulness improvement levels after the intervention significantly mediated the intervention effect in reducing the participating women's PSS levels.

Conclusions With a reasonably high participation rate (approximately 75%), the MBI delivered by mobile phone can be a feasible, desirable, and efficacious intervention for reducing perinatal-specific stress throughout pregnancy and enhancing neonatal outcomes.

Keywords Mindfulness · Mindfulness-based intervention · Mobile-delivered intervention · Perinatal-specific stress · Neonatal outcome

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Entering motherhood marks a significant life transition for women, as it causes them to undergo numerous social, psychological, and physiological changes (Leng et al., 2023a, b; Ng et al., 2022). In addition, they are likely to face medical issues, financial difficulties, and worries about future parenting (Hulsbosch et al., 2023). Although some women perceive pregnancy as bringing welcome challenges and sources of satisfaction, self-development, and maturity, others may experience perinatal-specific stress (PSS) (Korja et al., 2024). PSS refers to fears and worries related to pregnancy and maternal responsibilities, including specific stressors such as the health of the fetus, and also the pregnant individual's physical and psychological changes during pregnancy, concerns about maternal responsibilities in the future, relationships with others, and worries about the

giving-birth process (Alderdice & Lynn, 2011). It is estimated that roughly 15 to 25% of pregnant women experience PSS (Dennis et al., 2017; Hulsbosch et al., 2023; Okagbue et al., 2019). Recent studies have estimated that, in China, the prevalence of depression in pregnancy is 16.3% (Nisar et al., 2020), and anxiety in pregnancy is 17.4% (Yang et al., 2023).

A large body of research has shown that PSS is associated with negative outcomes for both mothers and infants, including unexpected cesareans, premature deliveries, lower birth weights, smaller head circumferences, and poor Apgar scores (Azimah et al., 2023; Ibrahim & Lobel, 2020; Sun et al., 2021). Furthermore, these negative outcomes can have even more severe consequences, such as neonatal mortality (Class et al., 2013) and perinatal suicide (Dudeney et al., 2023). Thus, given the potential for serious adverse outcomes of PSS, it is necessary to assess and screen for PSS using a rigorous measurement and to facilitate effective interventions to reduce PSS.

Pregnant individuals and clinical social workers face challenges from PSS interventions, necessitating careful consideration of the potential advantages and risks for the physiological and psychological well-being of both the pregnant individual and the developing fetus. Possible interventions for stress reduction include psychotropic medication therapy and behavioral interventions (Zhang et al., 2023). Although psychotropic medications have a large body of reproductive safety data, potential adverse effects for pregnant women (e.g., persistent pulmonary hypertension of the newborn and cardiovascular malformations) have been reported (Brandon & Freeman, 2011). Hence, nonpharmacological behavioral therapy interventions are comparatively preferred options. Among varied psychosocial interventions, mindfulness-based interventions (MBIs) have been considered promising interventions for effectively reducing PSS (Ng et al., 2022; Yan et al., 2022).

Mindfulness refers to consciously and nonjudgmentally focusing one's attention on the present moment (Kabat-Zinn, 2023), and mindfulness practices can enhance people's awareness of their individual physical senses, thoughts, and emotions in the present moment (Braeken et al., 2017). By combining this awareness with the principles of mindfulness, such as acceptance, nonjudgment, trust, and letting go, MBIs can promote tolerance in individuals suffering from PSS (Hulsbosch et al., 2023; Kabat-Zinn, 2023).

A large body of empirical evidence, including findings from systematic reviews and meta-analyses, shows that MBIs can mitigate various types of stress in general populations (Cillessen et al., 2020; Roemer et al., 2021; Zhang et al., 2021) and specifically in pregnant women (Goetz et al., 2020; Hulsbosch et al., 2023; Leng et al., 2023a, b; Yang et al., 2023; Zhang et al., 2019, 2022). For example, the latest meta-analysis that included 25 randomized controlled trials with 2495 pregnant women participants revealed that MBIs demonstrated efficacy in reducing depressive and anxious symptoms during the perinatal period (e.g., Leng et al., 2023a, b). In addition, over the past few decades, numerous explorations have demonstrated the beneficial effects of MBIs on PSS and neonatal outcomes among pregnant women (Leng et al., 2023a, b; Li et al., 2024; Zhang et al., 2019).

However, a meta-analysis also found that several effects of MBIs were not superior to those in the control group among healthy pregnant participants (Yan et al., 2022). These conflicting results may be attributed to the limited sample size in existing studies, especially in RCT designs (Chan, 2014). Also, previous face-to-face MBIs were usually conducted for 6 to 8 weeks with a weekly 3-h session, which might have been time-consuming, difficult to access, and labor-intensive (Leng et al., 2023a, b; Yan et al., 2022). Therefore, the development of MBIs that are easily accessible, low-cost, located conveniently, and delivered via an online format is of great importance. Specifically, online-formatted MBIs serve as a viable alternative to traditional in-person interventions, demonstrating the capacity to extend the reach of a larger number of people requiring such approaches. Indeed, in recent years, research on online MBIs tailored for pregnant women has risen rapidly (Goetz et al., 2020; Hulsbosch et al., 2023; Leng et al., 2023a, b; Yang et al., 2023; Zhang et al., 2021), and a recent meta-analysis with 25 RCTs and 3239 participants reported significant outcomes in which digital psychotherapeutic interventions alleviated PSS among perinatal individuals, irrespective of whether they belonged to clinical or non-clinical populations (Lau et al., 2021).

Furthermore, a comprehensive meta-analysis of mediation studies has demonstrated robust evidence supporting the role of mindfulness improvement as a pivotal mechanism through which MBIs affect psychological functioning and well-being (Gu et al., 2015). However, despite the well-documented efficacy of MBIs in reducing PSS among perinatal individuals, there remains a dearth of research studies among perinatal individuals that have explored the specific mechanisms (e.g., mindfulness) that underlie the positive effects of MBIs.

Given the ongoing debates about the use of MBI to reduce PSS in perinatal populations, as well as the limitations of existing studies, such as small sample sizes and practical concerns, this study aimed to contribute further supportive evidence by employing a randomized controlled trial (RCT) to investigate the effects of a mobile-delivered MBI in reducing PSS and neonatal outcomes, compared with the effects from a mobile-delivered psychoeducation intervention. The primary outcome was PSS, and the secondary outcomes were neonatal outcomes and participants' mindfulness. We hypothesized that (H1) after receiving the

MBI delivered by mobile phone, women in the intervention group would experience statistically significantly larger reductions in their PSS than the women in the control group that received psychoeducation. Second, we hypothesized (H2) that the mobile-delivered MBI would be associated with improved mindfulness for the women and better neonatal outcomes in the intervention group than in the control group. Third, we hypothesized (H3) that improved mindfulness would mediate the relationship between the intervention and reduced PSS.

In order to draw a rigorous conclusion regarding the hypothesized unique component of the mobile-delivered MBI, we utilized an active control group — mobile-delivered perinatal education program — in the current RCT. An active control group provided a parallel and comparable condition to the intervention group (e.g., in terms of design, intervention context, and attention from the research team) (Aycock et al., 2018). In addition, considering the ethical perspective, it is worth noting that participants in the active control group might also benefit from the programs assigned regardless of the specific intervention they receive (Aycock et al., 2018).

Method

Study Design

This study employed an 8-week, two-armed, randomized controlled trial design, with four data collection time points: baseline (T0, before the intervention), post-intervention (T1, immediately after the completion of the 8-week intervention), the 37th week of gestation (T2), and a follow-up conducted 5 weeks postpartum (T3). Throughout the study, we strictly adhered to the CONSORT guidelines pertaining to nonpharmacological treatments. Prior to their participation, all participants provided written informed consent, signifying their understanding and agreement to be part of this research endeavor. This study is not preregistered.

Participants

The study participants were a cohort of pregnant women of Chinese ethnicity in Hong Kong communities. The recruitment occurred in three waves—through advertisement on relevant websites, maternal discussion forums, and postings on Facebook. The research associates facilitated an online application questionnaire to ascertain the eligibility of perinatal women applicants for the intervention programs. Subsequently, applicants fulfilling the preliminary inclusion criteria were contacted and invited to participate in a brief intake one-to-one video screening, which ranged from 15 to 20 min. To verify each applicant's eligibility and introduce the study in detail, the screening interviews were conducted by a social worker registered and experienced in providing mental health services. Before being randomly assigned, eligible participants were requested to complete a questionnaire as a baseline assessment via a Qualtrics link.

Inclusion Criteria

The inclusion criteria for the study required that eligible participants must (1) be 18 years of age or older; (2) be in the 6th to 28th week of gestation; (3) be able to read and hear Chinese; and (4) demonstrate adequate proficiency in using a mobile phone and have access to the Internet.

Exclusion Criteria

Conversely, the exclusion criteria precluded applicants who (1) were identified as having a high-risk pregnancy, including preterm labor risk, placental abnormalities, multiple gestations, or morbid obesity; (2) had a history of psychiatric disorders necessitating attention and care, such as bipolar disorder, psychosis, organic mental disorders, schizoaffective disorder, drug/alcohol use disorder, or pervasive developmental delay; or (3) had suicidal ideation and behaviors.

Participants' Enrollment and Intervention Procedure

In accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines for nonpharmacological interventions, we conducted a rigorous process of participant enrollment, screening, and intervention process. As shown in Fig. 1, initially, a total of 240 Chinese pregnant women were assessed for eligibility. Of these, 50 were excluded from the sample pool. Specifically, 42 participants were excluded due to gestational weeks not aligning with established criteria. Two individuals reported severe depressive symptoms and suicidal ideation during the one-to-one video screening interview and were subsequently referred to specialized psychiatric care. Six participants were excluded due to other reasons, for instance, experiencing a miscarriage between the program registration and the screening interview. This resulted in a final sample of 190 pregnant women who were enrolled in the intervention study.

Prior to the intervention's commencement, a power analysis was conducted. The results of this analysis suggested that a target sample size of 90 participants (i.e., 45 per arm in RCT) was required, based on a (two group*three timepoint) repeated-measure design to account for time*group interactions. The analysis is based on a standard of Cohen's *d* effect size of 0.40 for the intervention, with an expected power of 95% and a two-sided type I error of 0.016 (corrected for three outcomes) and a baseline correlation of 0.50.

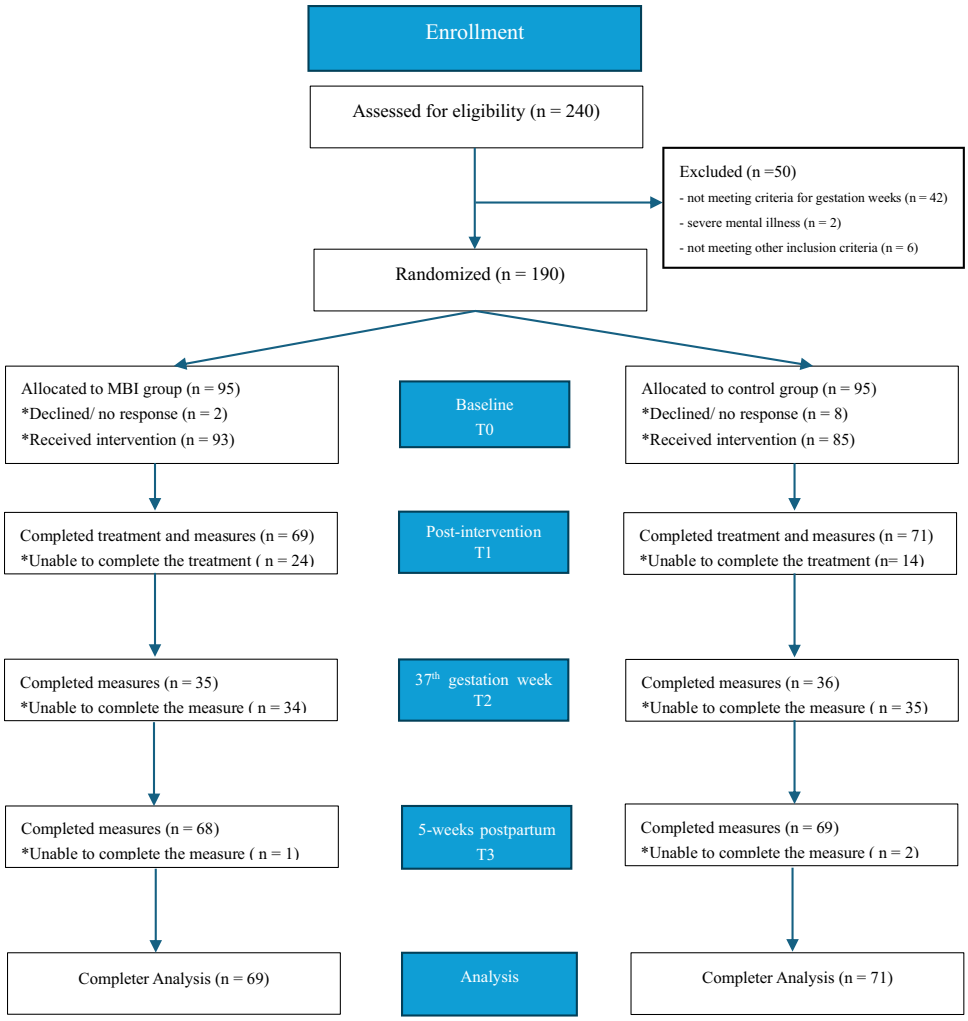

Fig. 1 Flow diagram of the participating women in the current study

The target sample size calculation also incorporated a consideration for a 20% attrition rate (GPower, version 3.1).

Sample Randomization and Blinding

Simple randomized sampling was conducted by the research associate via an online random grouping generator. A total of 190 pregnant women were enrolled in the study and randomly assigned to one of two groups: the MBI group, consisting of 95 participants; and the educational control group, also consisting of 95 participants. To ensure equitable distribution of participants' gestational weeks and their ages across the two groups, stratified randomization was employed (Suresh, 2011).

Due to several personal reasons (e.g., changed mind; overfull schedule), 10 participants (2 in the MBI group and 8 in the control group) declined to participate before the program commenced. Thus, in the final total, 178 pregnant women were enrolled in the intervention programs, with 93 participants in the MBI group and 85 in the control group. Participants were informed of their group allocation information 1 to 2 weeks prior to the program commencement.

The aim of the study was concealed from the participants to minimize potential biases. Furthermore, the statistical analysis was conducted in a blinded manner, ensuring that the group allocation information was not disclosed to the analysts.

The dataset utilized in the study excluded participant's personal identifiers to ensure confidentiality and anonymity. Prior to their participation, participants were informed that they would be randomly assigned to one of two groups, both of which were presented as being equally efficacious and beneficial. The assessments were conducted through self-report questionnaires and submitted via secure online Qualtrics links, facilitating ease of data collection and management. Furthermore, neonatal health outcomes were collected through an online self-report questionnaire after each participant's delivery.

Mobile-delivered MBI Program

Participants in the mobile-delivered MBI group received structured mindfulness training with one session per week over 8 weeks. Each participant was suggested to finish the eight MBI lessons in 8 weeks and practice mindfulness for approximately 30 min to 1 hr daily. The eight-session MBI was designed by integrating and modifying elements from Mindfulness-Based Cognitive Therapy (MBCT) (Dhillon et al., 2017). Our MBI program integrated the four-session advanced practice of the Four Immeasurables Meditation (FIM), which encompasses the development of loving-kindness (one's goodwill and kindness), self-compassion (engaging in compassionate thoughts and actions with oneself and others), appreciative joy (one's good fortunate and joy), and equanimity (wholesome attitude and profound state of balance) (Lv et al., 2020). FIM emphasizes self-awareness and the achievement of enlightenment dedicated to caring for others and the world (Chan, 2010). Several studies argued that cultivating the "Four Immeasurables" could effectively enhance pregnant women's self-efficacy for being a mother, develop a compassionate connection with themselves and others (e.g., incoming baby, partners, and significant others), generate positive emotions, decrease the risk of experiencing perinatal specific distress, and influence infant health status (Chan, 2010, 2014). Our MBI was conducted in a secular way (e.g., using easily understood terms instead of Buddhist concepts), aiming to make it more accessible to pregnant women from varied religious beliefs. During the interventions, different themes that were tailored to the needs and concerns of perinatal women were introduced to the participants as customized mindfulness practices, such as connecting with your body and baby and inner inspection of being a mother. Each participant received prompts and guidance for daily mindfulness practices sent by our research associates via email or a social media platform. Each session contained two compulsory components: (1) participants attended mobile-delivered self-learning didactic mindfulness training through video platforms and PowerPoint slides; (2) participants engaged in mindfulness practices for 30 to 60 min, which were supported by recorded audio guides. In addition, as extra homework, the participants were encouraged to reflect on each course's theme. For more information regarding the MBI protocol, please see the supplementary materials (S1).

As an optional component, participants were able to seek practical guidance and technical support from a registered social worker with experience in mindfulness practice through email when needed. Those communications mainly focused on participants' experiences or difficulties in their mindfulness practices.

Control Group: Mobile-delivered Perinatal Education Program

The participants in the control group received a mobile-delivered perinatal education program that adhered to an equivalent timeline as the MBI group, consisting of eight structured educational sessions focused on perinatal knowledge, such as "A guide to pregnancy changes, common discomforts, and health care" and "Dietary considerations during pregnancy." The knowledge contents did not include mindfulness elements or counseling support. The educational program was developed utilizing curricular materials sourced from the systematic perinatal education classes provided by a renowned local medical institution. A mental health practitioner was available for online support throughout the eight-session program period whenever participants in the control group had questions or concerns about their perinatal knowledge. For more information regarding the psycho-education intervention protocol, please see the supplementary materials (S1).

Outcome Measures

Perinatal-specific Stress

The Prenatal Distress Questionnaire (PDQ) measures individuals' subjective perceptions of their PSS (Alderdice & Lynn, 2011). The PDQ is a 12-item questionnaire that uses a 5-point Likert-type reporting scale ranging from 0 (*not at all*) to 4 (*extremely*), and it is structured to cover three dimensions of the individual's concerns related to pregnancy: concerns about the birth, about their emotions and interpersonal relationships, and about their physical condition. The scale does not establish a specific cutoff point, so in this study the overall scores obtained by the participants were used by summing the scores for each item. The higher score represents higher levels of PSS. The overall Cronbach alphas of the prenatal distress questionnaires for this study at each assessment timepoint were 0.86 (T0), 0.87 (T1), and 0.87(T2), respectively.

Mindfulness

The Five Facet Mindfulness Questionnaire–Short Form (FFMQ-SF) measures the individual's level of mindfulness using a 5-point Likert-type scale ranging from 1 (*never*) to 5 (*always*) for reporting the responses (Hou et al., 2014). The FFMQ-SF is a 20-item scale consisting of five dimensions of an individual's state mindfulness, with subscales for the following facets of mindfulness: observing one's inner events, describing one's experiences, acting with awareness, being nonjudgmental of one's inner experiences, and not reacting to one's inner experiences. The

higher score indicates higher levels of state mindfulness. The overall Cronbach alphas of FFMQ-SF for this study in each assessment timepoint were 0.88 (T0), 0.96 (T1), 0.93 (T2), and 0.92 (T3), respectively.

Neonatal Outcomes

We used the participants' babies' Apgar scores, birth weights, and infant maturity levels as the indicators of neonatal outcomes in this study. Infant maturities were reported in two categories: premature (less than 37 gestation weeks), or full-term/normal birth weeks (more than 37 gestation weeks). The babies' weights at birth were given in three categories: less than 2.5 kg; 2.5–4 kg; and more than 4 kg. A widely used method to evaluate a newborn's immediate physical status after birth is to use the Apgar score (Cnattingius et al., 2017; Iliodromiti et al., 2014), in which the better the neonate's physical condition is, the higher the baby's Apgar score is. An elevated Apgar score is linked to an increased likelihood of neonatal survival. The calculation of an Apgar score is based on five assessments: skin tone, respiration, heart rate, reflexes, and muscle tone. In this study, the participants were invited to report their infant's Apgar level—specifically, Apgar level 1 referred to an emergent situation, with the baby's Apgar raw score less than 4; level 2 referred to a mildly emergent situation, with the baby's Apgar score ranging from 4 to 6; and level 3 referred to a normal situation, in which the baby's Apgar score ranged from 7 to 10. When we analyzed the Apgar levels in our regression model, we recoded the three Apgar levels to number variables using the median of each Apgar level: "2," "5," and "8.5."

Covariates

An individual's daily mindfulness practice was used as a baseline control variable in this study because the participants' basic levels of daily mindfulness practice could affect the effectiveness of the MBI. We utilized the Daily Mindful Responding Scale (DMRS) to measure the participants' daily mindfulness practice (Lacaille et al., 2015). The four-item scale instructed participants to rate the frequency ranging from 1 (*rarely*) to 10 (*often*) at which they engaged in daily mindfulness. The Cronbach alpha in that research item was 0.87.

In addition, the data analysis controlled for several confounding factors, including each participant's pre-pregnancy body mass index (BMI), age, and baseline gestation weeks, given the robust evidence from prior research demonstrating significant associations between these covariates and the study's primary outcomes (Leng et al., 2023a, b).

Completion of the Intervention

Participants who finished 100% of the 8-week intervention program were considered perinatal women who had completed the intervention. Those who completed fewer than 8 weeks of sessions did not receive the postpartum assessment or the follow-up assessment.

Data Analyses

Baseline differences in the groups were calculated using the independent sample *t*-test for continuous variables and the χ^2 test for categorical variables. The between-group differences in outcomes were examined using repeated-measures MANCOVAs. Linear regression models for the continuous-outcome variables were utilized for analyzing the mediation model and the intervention's effects on neonatal outcomes. Several serial-trend analyses from T0 to T3 were conducted on the outcome variables to investigate the within-group intervention effect. The mediation analysis was conducted utilizing the bootstrapping method (with a 95% confidence interval, CI) to calculate the indirect effects. The analysis controlled for the participant's age, pre-pregnancy body mass index (BMI), gestation weeks at baseline, and daily mindfulness practice frequencies. The statistical tests were conducted utilizing SPSS version 27. The mediation test was conducted via the PROCESS package (Hayes, 2017).

Results

Participants' Characteristics

A total of 178 pregnant women who completed the baseline assessment were included in the baseline data analysis. Their mean age was 33.60 ($SD = 7.59$), and their mean gestational age was 20.35 weeks ($SD = 5.38$). The majority of participants were married or cohabiting ($n = 177$, 99.4%), most had a bachelor's degree or above ($n = 174$, 86.5%), most had a full-time job ($n = 145$, 81.5%), and a majority had a monthly income of 20,000 HKD or above ($n = 137$, 77%). There was no significant difference between the intervention group ($n = 93$) and the control group ($n = 85$) in the demographic and outcome variables, except for their BMIs and daily practice of mindfulness. More information about the participants' characteristics and baseline measurements can be found in Table 1.

Those who completed the intervention were invited to complete the post-intervention assessments. A total of 140 pregnant women who completed the intervention sessions were included in the final data analysis, with 69 in the intervention group and 71 in the control group. Independent sample *t*-tests were conducted for comparing the

Table 1 Baseline demographic characteristics and baseline assessments—intervention group and control group ($n = 178$)

Variables	Total participants ($n = 178$)				Intervention group ($n = 93$)				Control group ($n = 85$)				*p* value	Test-statistics[a]
	Mean	*(SD)*	*n*	(%)	*Mean*	*(SD)*	*n*	(%)	*Mean*	*(SD)*	*n*	(%)		
Perinatal-specific stress	33.60	7.59	178		33.22	6.68	93		34.01	8.50	85		0.486	7.07
Mindfulness	63.68	7.66	176		64.23	7.65	91		63.09	7.67	85		0.327	7.66
Daily mindfulness practice	23.65	6.42	176		24.35	6.02	91		22.89	6.77	85		0.063	6.39
Age (years)	33.55	3.79	178		33.69	4.00	93		33.41	3.56	85		0.621	3.80
Gestational weeks	20.35	5.38	178		20.49	5.46	93		20.21	5.33	85		0.732	5.40
Current BMI	23.34	3.72	177		23.88	4.06	92		22.77	3.25	85		**0.047***	**3.69**
Previous BMI	21.79	3.84	178		22.42	4.40	93		21.10	2.98	85		**0.021***	**3.80**
Marital status													0.297	0.08
Married/cohabitating			177	(99.4%)			93	(100.0%)			84	(98.8%)		
Single/divorced/windowed			1	(0.6%)			0	(0.0%)			1	(1.2%)		
No. of children													0.285	0.40
No children			125	(70.2%)			61	(65.6%)			64	(75.3%)		
1 child			32	(17.9%)			20	(21.5%)			12	(14.11%)		
2 children			20	(11.2%)			12	(12.9%)			7	(8.2%)		
3 or more children			1	(.5%)			0	(/)			1	(1.2%)		
Education													0.794	0.81
High school or below			11	(6.2%)			5	(5.4%)			6	(7.1%)		
Post-secondary			13	(7.3%)			7	(7.5%)			6	(7.1%)		
Bachelor's degree			94	(52.8%)			50	(53.8%)			44	(51.8%)		
Master's degree or above			60	(33.7%)			31	(33.4%)			29	(34. 1%)		
Employment													0.182	0.73
Full-time job			145	(81.5%)			74	(79.6%)			71	(83.5%)		
Part-time job			13	(7.3%)			6	(6.5%)			7	(8.2%)		
Housewife			13	(7.3%)			10	(10.8%)			3	(3.5%)		
Unemployed			5	(2.8%)			3	(3.2%)			2	(2.4%)		
Income													0.314	1.21
No income/not applicable			17	(9.6%)			13	(14.0%)			4	(4.7%)		
< $10,000 HKD			6	(3.4%)			1	(1.1%)			5	(5.9%)		
$10,000–$19,999 HKD			18	(10.1%)			9	(9.7%)			9	(10.6%)		
$20,000–$39,999 HKD			73	(41.0%)			37	(39.8%)			36	(42.4%)		
≥ $40,000 HKD			64	(36.0%)			33	(35.5%)			31	(36.5%)		

*$p < 0.05$; ** $p < 0.01$; *** $p < 0.001$

[a]Independent sample *t*-tests were conducted for the continuous variables, and the chi-squared test was used for the categorical variables

continuous variables, and chi-squared tests were conducted for the categorical variables when comparing completers and non-completers. Results revealed that there was no significant difference between the completer ($n = 69$) and non-completer ($n = 24$) in each of the demographic characteristic and assessment variable, except for their age and gestational weeks. In the control group comparison tests, there was no significant difference between the completer ($n = 71$) and non-completer ($n = 14$) in each of the demographic characteristic and assessment variable. More information about the comparisons of completers and non-completers can be found in Tables S1–S2 (Supplementary Information).

Intervention Effects

As shown in Table 2, the analysis revealed a statistically significant interaction effect between time and group across three assessment time points ($F(2,65) = 4.98$, $p < 0.01$, partial eta squared = 0.08) regarding the PSS change. Interaction effects analysis showed that the time*group effect across T0 to T1 was not significant ($F(1, 138) = 0.29$, $p = 0.59$, partial eta squared = 0.01). The time*group effect across T0 to T2 was significant ($F(1,65) = 4.067$, $p < 0.05$, partial eta squared = 0.06). Specifically, at the post-intervention assessment (T1), there was no significant difference in the reduction of PSS levels between women in the MBI group and those in the control group (t (138) = 0.47, $p = 0.641$, Cohen's $d = 0.08$, 95% CI = [− 0.25, 0.41]). In addition, during their 37th week of gestation (T2), results showed a significant reduction in PSS among women in the MBI group, which was significantly greater than that reduction among women in the control group (t (69) = 2.07, $p < 0.05$, Cohen's $d = 0.50$, 95% CI = [0.02, 0.96]).

In addition to PSS, we examined the effect of the intervention on mindfulness; the overall interaction effect between time and group across all four assessment time points was not significant ($F(3, 60) = 2.00$, $p = 0.116$, partial eta squared = 0.04). However, the time*group effect across T0 to T1 was significant ($F(1, 137) = 4.58$, $p < 0.05$, partial eta squared = 0.03), and the time*group effect across T0 to T2 was marginally significant ($F(1, 65) = 3.91$, $p = 0.052$, partial eta squared = 0.06). The time*group effect across T0 to T3 was not significant ($F(1, 133) = 2.99$, $p = 0.086$, partial eta squared = 0.02). Specifically, at the immediate post-intervention assessment (T1), women in the MBI group showed a significant increase in mindfulness level compared to the control group (t (138) = − 2.02., $p < 0.05$, Cohen's $d = -0.35$, 95% CI = [− 0.69, − 0.01]). In addition, the effect of the MBI on the women's mindfulness enhancement was marginally sustained in the 37th gestation week (t (69) = − 1.86, $p = 0.055$, Cohen's $d = -0.42$, 95% CI = [− 0.90, 0.02]), thus suggesting that the MBI program had potential sustained effects. However, in the 5th week postpartum, we found no significant between-group effect size difference in the participants' mindfulness (t (69) = − 0.90, $p = 0.185$, Cohen's $d = -0.15$, 95% CI = [− 0.49, 0.18]).

As is shown in Table 3, the hierarchical linear regression analysis showed a significant group difference in the neonates' Apgar scores. Infants of mothers in the MBI group had significantly higher Apgar scores compared to infants of mothers in the control group ($\beta = 0.20$, t (135) = 2.22, $p < 0.05$), with an estimated between-group effect difference of 0.34 (95% CI = [0.00, 0.68]). No statistically significant between-group differences were found in the levels of infants' maturity (i.e., born before or after 37 weeks of gestation) ($\beta = -0.11$, t (136) = − 1.24, $p = 0.217$) or infants' birth weights ($\beta = -0.05$, t (136) = − 0.57, $p = 0.573$).

Table 2 Intervention effects by linear mixed-effects analysis

Outcome variables	Estimated mean (*SE*)		Between-group differences			
			Group × time interaction			Cohen's *d*, with 95%CI
	MBI group	Education group	*F*	*p*-value	Partial eta squared	
Pregnancy-specific stress						
Overall time × group			**4.98****	**0.008**	0.08	
Post-intervention (T1)	29.44 (6.47)	34.17 (6.68)	0.29	0.589	0.01	0.08 (− 0.25, 0.41)
37th week of gestation (T2)	29.25 (6.20)	33.26 (6.86)	**4.07***	**0.048**	0.06	0.50 (0.02, 0.96)
Mindfulness						
Overall time × group			2.00	0.116	0.04	
Post-intervention (T1)	67.69 (10.47)	63.45 (7.51)	**4.58***	**0.034**	0.03	− 0.35 (− 0.69, − 0.01)
37th week of gestation (T2)	67.73 (8.43)	63.55 (7.92)	**3.91**	**0.052**	0.06	− 0.42 (− 0.90, 0.02)
5 weeks postpartum (T3)	66.19 (9.11)	62.32 (9.85)	2.99	0.086	0.02	− 0.16 (− 0.49, 0.18)

*$p < 0.05$; **$p < 0.01$; ***$p < 0.001$

Table 3 Intervention effects on neonatal outcomes by hierarchical regression analysis

Variables	Total participants			Intervention group			Control group			Regression analysis					Cohen's *d*
	Mean(*n*)	(*SD*)/(%)	*n*	*Mean*	(*SD*)	*n*	*Mean*	(*SD*)	*n*	*B*	*SE*	*β*	*t*	*p* value	
APGAR score	8.12	1.28	135	8.34	0.74	66	7.91	1.61	69	0.51	0.23	0.20	**2.22***	**0.028**	0.34 (0.004, 0.68)
Level 1: 2 points	3	2.2%		0	0.0%		3	4.3%							
Level 2: 5 points	9	6.7%		3	4.5%		6	8.7%							
Level 3: 8.5 points	123	91.1%		63	95.5%		60	87%							
Infant maturity (gestational weeks at birth)	1.08	0.27	136	1.04	0.21	67	1.12	0.32	69	−0.06	0.05	−0.11	−1.24	0.217	0.26 (−0.08, 0.59)
Before 37 weeks of gestation	125	91.9%		64	95.5%		61	88.4%							
After 37 weeks of gestation	11	8.1%		3	4.5%		8	11.6%							
Infant birth weight	1.95	0.39	136	1.94	0.39	67	1.96	0.40	69	−0.04	0.07	−0.05	−0.57	0.573	0.04 (−0.29, 0.37)
Less than 2.5 kg	14	10.3%		7	10.4%		7	10.1%							
2.5–4 kg	115	84.6%		57	85.1%		58	84.1%							
More than 4 kg	7	5.1%		3	4.5%		4	5.8%							

*$p<0.05$; **$p<0.01$; ***$p<0.001$

Mediation Analyses

For mediation analysis, results revealed that the improvement in mindfulness levels (the difference between baseline (T0) and post-intervention (T1)) among women in the MBI group significantly mediated the intervention's effect on reducing their PSS levels at their 37th week of gestation (the difference between T0 and T2) (indirect effect: $\beta = -0.51$, 95% CI = [−1.37, −0.01]), which accounted for 25.5% of the total intervention effect. Additionally, the total intervention effect on the participants' PSS in the 37th week of gestation remained significant when their mindfulness enhancement at T1 was entered into the mediation model (direct effect: $\beta = -0.24$, t (69) = −2.07, $p < 0.05$, 95% CI = [−2.94, −0.05]). This suggests that mindfulness improvement had a partial mediating effect. The paths and the standardized coefficients for the mediation model are shown in Fig. 2.

Discussion

The results showed that participants in the mobile-delivered MBI group exhibited greater declines in the PSS levels, improvement in mindfulness levels, and higher Apgar scores of newborn babies compared with those in the control group. In their 37th week of gestation (T2), the women's PSS level (the primary outcome) had dropped significantly for the participants in the MBI group. In addition, we found a significant difference between the MBI group and the control group in their mindfulness improvement immediately after the intervention (T1). However, we found no significant difference in the participants' mindfulness improvement over time between the women in the MBI group and those in the control group when we compared the changes between baseline (T0) and the second follow-up time point (at 5 weeks postpartum). Moreover, the mindfulness enhancement that occurred immediately after completion of the intervention significantly mediated the intervention effect that the MBI had on the reduction of the women's PSS at their 37th week of gestation. Furthermore, participation in the mobile-delivered MBI was associated with an increased probability of delivering an infant with a comparatively higher Apgar level.

The results of our study indicate a significantly greater decrease in PSS levels over the intervention assessment time points in the women in the MBI group, as compared to the control group. The MBI group had a significant reduction in PSS levels over time, while no such significant reduction of PSS was obtained within the control group over time.

Our study provides corroborative evidence for the burgeoning literature that posits MBIs as efficacious modalities for mitigating PSS during gestation. The MBI effect on the reduced PSS at T2 (37 gestation weeks) in this study

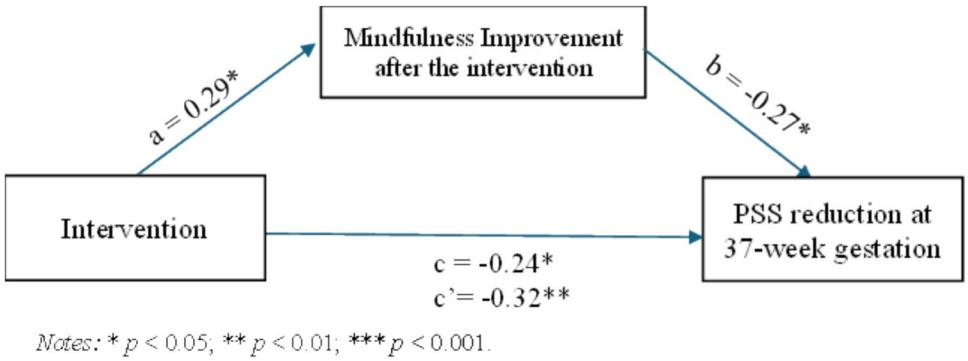

Fig. 2 Mediation model

(adjusted $d = -0.50$) was comparable to the preventive effects found from previous digital MBIs that targeted both a general population (Farris et al., 2021; Zhang et al., 2021) and healthy perinatal women (Goetz et al., 2020; Yan et al., 2022), such as the mobile-delivered MBI Thrive-Pregnancy program ($d = -0.60$) (Leng et al., 2023a, b), and a WeChat-delivered MBI program for pregnant people ($d = -0.37$ to 1.51) (Zhang et al., 2023). Several possible factors could potentially account for the relatively significant maintenance effects found in the current research. Firstly, participants in our intervention and control group were able to receive guidance and support from a clinical social worker through email. Previous studies have reported a positive correlation between professional support for participants and adherence to the interventions (Spijkerman et al., 2016). Second, reduction of PSS has been found to be associated with enhanced mindfulness (Gu et al., 2015)**.** Specifically, we found that mindfulness mediated the relationship between the intervention effect and the reduction of PSS. This suggests that the enhanced maintenance of intervention effect before the delivery can be attributed to the improvement of mindfulness skills. Mindfulness can effectively improve one's non-judgmental and nonreactive acceptance of all experiences, and that, in turn, results in positive mental health outcomes, including PSS reduction (Kabat-Zinn, 2023). Furthermore, the MBIs originally developed with the intention of treating recurrent mental health problems (e.g., depression) are theorized to decrease people's distress by enhancing their awareness of self or their disengagement from repetitive passive thinking loop about their emotional distress (Kabat-Zinn, 2023). Hence, in this study, the MBI was likely to reduce the pregnant women's PSS through improving mindfulness that encouraged the participants to be aware of their current status and try to be accepting of their negative concerns and emotional distress without avoiding them.

However, we found no difference between the MBI group and the control group in the degree of reduction of their PSS immediately after the intervention (T1). One possible explanation for that result could be a delay having occurred in achieving the full effect of the MBI on the women's PSS. We did find a significant between-group difference between the MBI group and the control group in the women's PSS reduction by the time of the women's 37th week of gestation (T2). Prior research has revealed a pattern of delayed effect, in which an earlier improvement in mindfulness levels during an MBI period was associated with a later reduction in distress symptoms (Baer et al., 2012). Echoing the prior findings (see a meta-analysis by Gu et al., 2015), we found that mindfulness levels at T1 partially mediated the relationship between the intervention effect and PSS reduction at T2. It is possible that the improvement of mindfulness levels at an earlier time (T1) partly contributed to the later reduction of PSS levels at the 37th gestation week (T2) in the MBI group.

Our results regarding the effectiveness of a mobile-delivered MBI in enhancing mindfulness levels among pregnant women's mindfulness immediately post-intervention corroborate prior research that reported MBIs to be effective in the immediate post-intervention assessment period (Goetz et al., 2020; Krusche et al., 2018; Leng et al., 2023a, b; Sun et al., 2021; Yang et al., 2023).

Nevertheless, although our MBI enhanced the women's mindfulness significantly at T1 and T2 for those in the intervention group, the effects of that mindfulness enhancement were not maintained into the postpartum period (i.e., at T3, the follow-up 5 weeks after delivery). That the effect of enhanced mindfulness was not sustained could be interpreted in several ways. One possibility concerns the fluctuations in women's emotional status in their postpartum phases. Many changes occur during a woman's postpartum period, as a result of which the individual may develop other practical needs compared with the needs during pregnancy. For example, women in the postpartum period may have a new set of health concerns related to such issues as physical recovery from delivery, breastfeeding, baby care, changes in the relationship dynamic, and transition issues (e.g., being a working mother) (Kanotra et al., 2007; Walker & Murry, 2022). Another possible reason could be that the new mothers may have new priorities (such as preparing for their recovery, caring for their newborns, dealing with weight

retention, and concerns about the economic costs of hospital stays) rather than focusing on their own mental health status (e.g., practicing mindfulness) (Ruderman et al., 2021). In that light, future research should also consider interventions for reducing postpartum-specific stress, such as providing one or two additional sessions of a mindfulness-based intervention within the delivery and postpartum periods and assessing the effects of the MBI at several follow-up time points (e.g., 5 weeks, 8 weeks, and 12 weeks after delivery) instead of just one, early timepoint in the postpartum period.

Moreover, our study also contributes to the currently limited evidence of the effects of MBIs on neonatal outcomes (Azimah et al., 2023; Leng et al., 2023a, b). Specifically, our results support the previous finding that MBIs can lead to better Apgar scores (Leng et al., 2023a, b; Veringa-Skiba et al., 2022). For example, Veringa-Skiba et al. (2022) found that newborns' 1-min Apgar scores were higher in their MBI group than in their control group. Apgar outcomes are a reputable and feasible measure for indicating the status of the newborn infant immediately after birth and the baby's response to resuscitation if needed. Thus, the Apgar score is associated with neonatal health quality, and a low Apgar score (commonly defined as below 7) is often an effective predictor of neonatal mortality (Cnattingius et al., 2017; Iliodromiti et al., 2014). Since pregnant women with high levels of PSS are found to deliver infants with lower Apgar scores (Sun et al., 2021), together with our current finding, we suggest that effective early prevention (e.g., with an MBI) is essential and imperative to reduce PSS and to support healthy childbirth.

Study Strengths, Limitations, and Future Directions

The current study had several strengths and limitations. The study's major strengths included the relatively high completion rate, a relatively large sample size at baseline, and its rigorous RCT design with an active education-oriented control group. Sixty-nine of the 93 (74.2%) participants in the MBI group fully completed the eight-session intervention (including the post-test (T1) and the follow-up test (T3, 5 weeks after delivery)). Thus, the rate of completion in our study aligns with the rates documented in previous intervention studies that have implemented in-person MBI for perinatal individuals, with reported completion rates averaging around 80% (Felder et al., 2017; Goodman et al., 2014). In addition, our completion rate was comparable to those reported for similar online delivery modes of MBIs, which reported even lower compliance rates of 15 to 57% (Goetz et al., 2020; Hulsbosch et al., 2023; Krusche et al., 2018). For instance, Hulsbosch et al. (2023) reported a completion rate of 15% among a cohort of 109 participants who engaged in an online MBI program. The researchers attributed the low completion rate to the absence of real-time support and the lack of instructor availability for consultation on issues encountered by the participants. In our study, the mobile-delivered MBI was designed to ameliorate these limitations from prior research, partly offering a viable avenue for perinatal women to access mindfulness practices and educational content through digital platforms. It also facilitated ongoing interactions between mindfulness professionals and the participants when needed. Perinatal women are easily able to gain access to a mobile MBI. In addition, our mobile-delivered MBI provided our perinatal participants with a more feasible and less stigmatized mode for participating in mindfulness practices and improving their mental health status.

Despite these study strengths, our findings have several limitations. First, although roughly 75% of the participants in the MBI group completed the whole session and the post-tests at T1 and T3, only 35 of 69 (50.7%) participants in the MBI group completed the first follow-up test (at T2, in the 37th week of gestation). One reason for the low participation at T2 can be explained by the women's busy status before delivery, as disclosed by the participating women "not having the time or right mood to finish the follow-up test." Another reason given for the missing data at T2 was that, for some participants who were in the later stages of pregnancy (e.g., 27 to 28 weeks) at the baseline timepoint (T0), the time of the post-testing after completing the 8-week course occurred almost at the 36th to 37th week of gestation. Therefore, the T2 follow-up was not conducted for these participants, and they were only asked to complete the post-test (T1) and the final follow-up (T3, at 5 weeks postpartum).

The study's second limitation was that, although we facilitated the online MBI by using email support so that participants could obtain access to support from mental health professionals, we did not consider the moderating role of such support. We suggest future intervention studies to resolve the issue by keeping records of participants' subjective experiences, of both intervention involvement and professional support.

Third, our sample was predominantly low-risk, middle-income, well-educated women, and that could restrict the generalizability of the MBI's effectiveness. To increase the recruitment scope and social impact of the programs, we did not conduct screening of PSS among the applicants. However, as a result, the participant sample may include pregnant women with relatively lower levels of PSS, which could lead to an increase in the attrition rate. Future research should consider re-examining the effects of the MBI in a more diversified sample (e.g., recruiting women in low-socioeconomic status families and screening for women with relatively high PSS scores).

Fourth, in the final data analysis, we utilized a completer analysis in which we only included participants who had fully reached the intervention endpoint although the

completer analysis allowed us to investigate the efficacy of intervention under a rigorous and ideal situation (Tripepi et al., 2020). However, the completer analysis may fail to demonstrate the comprehensive picture of intervention settings. For instance, it is challenging to draw conclusive and rigorous conclusions about whether the incomplete intervention is due to the ineffectiveness of the intervention itself or the personal choices of the non-completed participants. Hence, to improve the internal validity of the intervention studies and maintain the benefits of randomization, future studies should consider utilizing intent-to-treat analysis.

Fifth, while many studies have demonstrated the challenges that postpartum women face (e.g., Ruderman et al., 2021; Walker & Murry, 2022), our intervention program did not address the potential benefits of MBI during postpartum. We recommend that future research consider a two-phase MBI, with the first phase focusing on perinatal-specific distress and the second phase targeting post-partum distress. This approach may provide pregnant and postpartum women with more effective, sustained support and guidance.

Sixth, although we found that participants' increased mindfulness level mediated the relation between intervention effect and decreased PSS, the current study did not explore the specific factor of mindfulness that plays the most crucial role underneath such mechanism. Future studies could utilize more nuanced measurement tools, such as conducting qualitative interviews and measuring sub-concepts of four Immeasurables (e.g., self-compassion, joy) to better understand the potential mechanisms of mobile-delivered MBIs.

In summary, this study investigated the effectiveness of a mobile-delivered MBI program for reducing PSS and improving pregnant women's mindfulness and their neonatal outcomes. With a reasonably low dropout rate (25.8%), the current MBI delivered by mobile phone proved acceptable and effective for reducing PSS at the 37th week of gestation (T2, the first follow-up assessment). In addition, the mobile-delivered MBI proved effective in improving mindfulness immediately after the intervention. The association between the intervention effect and changes in the participants' PSS was mediated by changes in their mindfulness. Moreover, the study's mobile-delivered MBI also effectively enhanced the participants' newborn infants' Apgar scores. The findings contribute significantly to the evidence supporting the benefits, feasibility, and acceptability of a mobile-delivered MBI during pregnancy. We, therefore, suggest that perinatal care providers include mindfulness interventions as an essential component of psychological care for women during the perinatal period.

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Data Availability The participants of this study did not give written consent for their data to be shared publicly, so due to the sensitive nature of the research, supporting data is unavailable.

Declarations

Ethics Approval Ethical approval for the research was granted by the Ethical Review Board of The University of Hong Kong.

Informed Consent Prior to their participation, all participants provided written informed consent, signifying their understanding and agreement to be part of this research endeavor.

Conflict of interest The authors declare no competing interests.

Use of Artificial Intelligence We did not use any AI tools in our research.

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