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ORIGINAL PAPER

Effects of the Mindfulness-Based Childbirth and Parenting (MBCP) Program Among Pregnant Women: A Randomized Controlled Trial

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Abstract

Objectives To evaluate the efficacy of the Mindfulness-Based Childbirth and Parenting (MBCP) program in improving the mental well-being of pregnant women as compared to an attention-matched active control group (i.e., an Antenatal Childbirth Education and Support program).

Method This was a two-arm 1:1 randomized controlled trial with 183 pregnant women in Hong Kong. Assessments were conducted at baseline (T1), at the last prenatal session (T2), 6–8 weeks postpartum (T3), and 6 months postpartum (T4). The primary outcome was the Mental Component Score (MCS) of the 12-item Short Form Survey (SF-12) at T4. Secondary outcomes included depressive and anxiety symptoms, stress, catastrophizing thoughts about pain, disordered mother–infant relationships, mindfulness, and clinical outcomes related to childbirth. Analysis of covariance (ANCOVA) was used as the primary analysis based on the intention-to-treat (ITT) principle.

Results MBCP demonstrated superiority over the control at T4 in improving mental health–related quality of life (increased MCS score), reducing depression symptoms and state anxiety, and increasing mindfulness levels at T2, T3, and T4. No significant differences were shown in other outcomes. No serious adverse events were reported.

Conclusions MBCP showed positive mental health effects and was perceived as a safe intervention for pregnant women in Hong Kong. Future studies may look into its mechanisms and cost-effectiveness.

Pre registration Chinese Clinical Trial Registry ChiCTR-TRC-13004070.

Keywords Mindfulness-based intervention · Prenatal and postnatal · Pregnant · Randomized controlled trial · Mental health

A mother's mental health during pregnancy is important in determining her pregnancy outcome, her child's health and development, and the father's mental health. Better maternal mental health is associated with improved learning, academic achievement, and physical health of the child (Meltzer et al., 2003). Conversely, pregnancy-related mood disorders are associated with increased adverse pregnancy outcomes (such as preterm birth, low birth weight, and more difficult childbirth), as well as lifelong adverse mental and cognitive outcomes for the child, with effects persisting into their adolescent years (Meltzer et al., 2003; Murray et al., 2011; Sutter-Dallay et al., 2011). Regarding the father's health, a study has shown that maternal postnatal depression (PND) is associated with paternal PND in Hong Kong Chinese (Chung et al., 2011). As factors before birth affect a person's lifelong well-being, a life course approach should be taken

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to improve the mental health of pregnant and postpartum women.

Pregnancy can be a stressful and vulnerable period. It is a period when about one in six women with depression experience their first episode, with a 15% prevalence of antenatal and postnatal depression being similarly reported in Hong Kong and worldwide (Gavin et al., 2005; Lee et al., 1998; Leung et al., 2011). A systematic review found the prevalence of self-reported anxiety symptoms was 18.2% (95% CI 13.6–22.8) in the first trimester, 19.1% (95% CI 15.9–22.4) in the second trimester, and 24.6% (95% CI 21.2–28.0) in the third trimester (Dennis et al., 2017). The study also reported the overall prevalence to be 4.1% (95% CI 1.9–6.2) for a generalized anxiety disorder and 15.2% (95% CI 9.0–21.4) for any anxiety disorder. More than 70% of pregnant women have reported stress during pregnancy (Pais & Pai, 2018), and about 12% have experienced high levels of perceived stress (Kingston et al., 2012). Pregnant women with catastrophizing thoughts about pain have been observed to be at an increased risk for depression, anxiety, and developing acute and persistent perineal pain (Dogru et al., 2018; Soares et al., 2013). Furthermore, pregnancy is also a time when women are motivated to improve the well-being of themselves and their babies. Non-pharmacological mind-body interventions are appealing options for these mothers because they offer potential benefits without the substantial adverse effect profiles often associated with medication.

Mindfulness-based interventions (MBIs) are mind–body programs with mindfulness skills that can be systematically taught over 8 to 10 weeks through group educational programs to cultivate non-judgmental, moment-to-moment awareness, acceptance, and non-avoidance of one's present-moment inner experience (Kabat-Zinn, 1982). Accumulating evidence shows that MBIs improve mental health, reduce psychosomatic symptoms, and increase relationship satisfaction with overall good safety (Hughes et al., 2009; Wong et al., 2018; Zhang et al., 2021). Studies suggested that MBIs contribute to improvements in mindfulness, rumination, worry, self-regulation, compassion or meta-awareness, emotional reactivity, and momentary positive and negative affect, which predict or mediate the treatment effects (Zhang et al., 2021). Systematic reviews found antenatal distress during pregnancy increases the likelihood of preterm birth (Staneva et al., 2015), low birth weight (Littleton et al., 2010), obesity, infantile colic, and autism spectrum disorder in offspring (Caparros-Gonzalez et al., 2021). These effects might be due to more engagement in alcohol drinking, smoking, and skipping meals or other poor eating habits, as well as neuroendocrine responses to stress (e.g., increases in corticotropin-releasing factor, catecholamine, and glucocorticoids affecting peripheral blood vessels and cellular immunity) (Littleton et al., 2010). Mindfulness may improve childbirth-related clinical outcomes by reducing depression, anxiety, and stress and improving mental well-being.

The Mindfulness-Based Childbirth and Parenting (MBCP; Bardacke, 2012) program, which has gained popularity in recent years (Shorey et al., 2019), is an adaptation of the widely applied Mindfulness-Based Stress Reduction (MBSR) program (Kabat-Zinn, 2006). In the MBCP program, participants learn to cultivate mindfulness skills to cope with the stress, fear, and pain related to pregnancy, childbirth, and parenting. This program actively encourages partner participation and intentionally builds a sense of community among course participants. Therefore, in addition to promoting the well-being of the expectant mother, MBCP also aims to promote family health and well-being and enhance social support for new parents.

Qualitative studies and observational research on MBCP or its adaptions conducted in the UK, the USA, Sweden, and Germany support its feasibility and acceptability (Duncan & Bardacke, 2010; Kantrowitz-Gordon et al., 2018; Lönnberg et al., 2018; Malis et al., 2017; Warriner et al., 2012, 2018). Couples have commented that they have gained "indispensable" mindfulness techniques and "lifelong skills that can be adapted in many situations besides parenting," and that "fear and pain can be broken down into manageable pieces" (Warriner et al., 2012). Experimental studies in Sweden, the USA, Taiwan, Iran, and Sri Lanka also showed MBCP's effectiveness in reducing stress, anxiety, and depressive symptoms, leading to a positive state of mind and increased self-efficacy (Agampodi et al., 2018; Duncan et al., 2017; Khoshayand et al., 2019; Lönnberg et al., 2020; Pan et al., 2019a, b; Price et al., 2019). However, these previous studies had either a very small sample size ($n = 12–43$) (Agampodi et al., 2018; Duncan et al., 2017; Khoshayand et al., 2019; Price et al., 2019), a short follow-up period following immediately after the intervention (Lönnberg et al., 2020), less power in the 3-month postpartum follow-up, or a comparison group that was not matched with the MBCP group in terms of time, format, homework, etc. (Pan et al., 2019a, b). Furthermore, no evidence had yet been presented on the beneficial effects of MBCP on childbirth-related clinical outcomes (e.g., complications, newborns' weights).

The health and economic burden of poor maternal mental health for the current and future generations cannot be overlooked. There is a need to find interventions that promote mental well-being and are feasible, cost-effective, and community-based. The MBCP program is a holistic intervention that may improve the well-being of expectant parents and their infants. The aim of this randomized controlled trial (RCT) is to test the long-term effectiveness of MBCP among Chinese pregnant women in Hong Kong as compared to a matched active control, with a follow-up

period of 6 months postpartum. We hypothesized MBCP would sustainably improve mental health–related quality of life (primary hypothesis) and reduce depression, anxiety, stress, and catastrophizing thoughts about pain, as well as lead to better clinical outcomes of pregnancy and childbirth (e.g., birth weight, mode of delivery, duration of labor, birth complications, number of hospital days) (secondary hypotheses), as compared to the matched active control group.

Method

Participants

Pregnant women and one support person (usually the husband) were recruited from community and primary care settings through posters, leaflets, mass emails, and newsletters in Hong Kong. Inclusion criteria were as follows: (1) women with a singleton pregnancy in the second trimester at the beginning of the course and at 37 weeks or less gestation at the last session of the course, who were (2) able to communicate in Cantonese, (3) able to give informed consent, (4) had no previous meditation experience, and (5) did not practice any other mind–body modalities (e.g., yoga, tai-chi) on a daily basis. Participants were excluded if they (1) had a DSM-IV Axis 1 diagnosis or recent diagnosis of depression during the last 12 months, (2) were currently seeing a psychiatrist or mental health professional, or (3) were receiving any form of treatment for any mental condition. A research assistant first introduced the study details and screened for initial eligibility. Participants' eligibility was further determined during scheduled interviews with the investigator (KWKT) with study objectives further explained and written informed consent obtained.

At the time of the trial design, no other similar large RCTs had compared the effects of MBCP with an active control group. Thus, the sample size was calculated based on a previous trial of MBSR with an average MCS-12 score at baseline similar to that reported in trials among pregnant women (Hartmann et al., 2012). Using the reported effect size ($d = 0.54$) (Hartmann et al., 2012), increasing the power to 0.90 to account for a higher placebo effect from an active comparison group, it yielded an estimated target sample size of 148 ($\alpha = 0.05$). We set the total needed sample size at 178 with 89 women in each group to allow for a 20% dropout rate, using the software G*Power (version 3.1.5).

Out of 450 pregnant women screened, 263 were eligible for the study. A total of 183 pregnant women were then successfully recruited (Fig. 1). Baseline characteristics are provided in Table 1.

Procedure

This was an RCT with two arms: an MBCP group and an attention-matched active control group. Both interventions consisted of 9 weekly sessions of 2¾ h, a half-day retreat delivered prenatally, and a postnatal reunion session. Data were collected at baseline before the intervention (T1), at the last prenatal session (T2), at the reunion 6 to 8 weeks after childbirth (T3), and 6 months after childbirth (T4). All data were collected between May 2015 and April 2017. Ethics approval was obtained from the Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee before commencement.

Randomization and masking

Pregnant women and their support persons in pairs were randomly assigned by simple randomization with a 1:1 ratio to one of the two groups, using a list of computer-generated random numbers. The randomization was performed by a statistician who was not part of the research team. Allocation was concealed until all the subjects were recruited for the specified intervention period. Randomization results could not be changed after disclosure by the statistician. Due to the nature of the intervention, participants could not be blinded. However, the research assistants who conducted the medical data acquisition and data analysis were blinded to group allocation and participants were blinded to the study hypotheses and did not know whether the group they attended was the experimental condition.

Intervention: Mindfulness-Based Childbirth and Parenting (MBCP)

The intervention involved training in mindfulness through various meditation practices (Table S1) including mindful awareness of the breath, body, feelings, thoughts, and emotions; body scan meditation; a mindful movement sequence; and loving-kindness meditation. In addition, the MBCP intervention included specific exercises for coping with stress, pain, and fear associated with pregnancy, childbirth, and early parenting. A focus was on shifting participants' relationships with negative thoughts and emotions (Bardacke, 2012; Duncan & Bardacke, 2010). Participants were invited to practice mindfulness meditation at home for 30 to 45 min each day using audio recordings of 5 to 30 min for formal mindfulness practices or to practice mindful movement or informal daily mindfulness practices without audio recordings. A pilot MBCP program was conducted before the formal RCT under the supervision of and in discussions with the program developer Nancy Bardacke and a senior mindfulness teacher in Hong Kong. Only minor cultural adaptation was made for delivery of MBCP in Hong Kong, e.g., imagining a stone thrown into

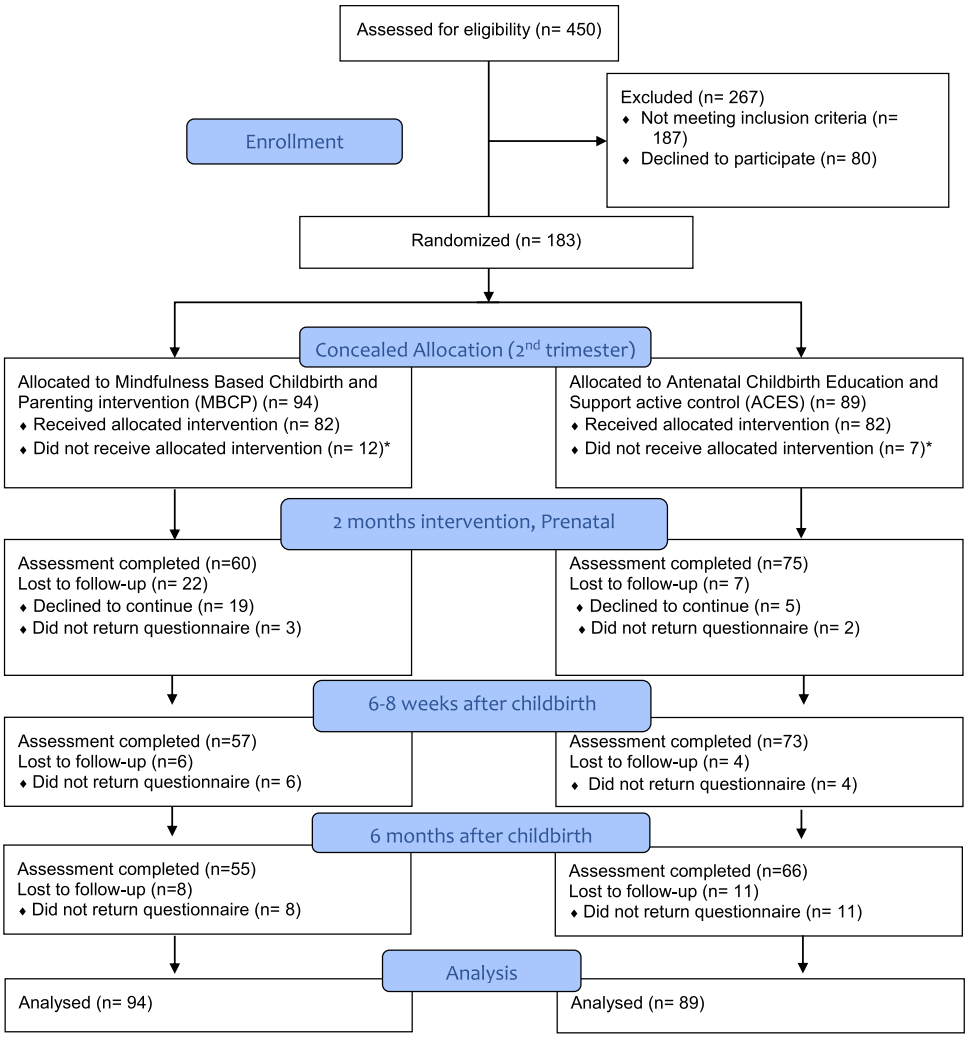

Fig. 1 The CONSORT (Consolidated Standards of Reporting Trials) flow diagram of the study (*did not attend any session)

a "heart lake" instead of imagining in or near a well because Chinese pregnant women found the latter uncomfortable, and examples related to perinatal care in the Hong Kong healthcare system were used. Two trained MBCP instructors were responsible for co-leading a total of seven MBCP groups, involving up to 18 pairs (i.e., pregnant women and their partners) per group. The purposes of having two instructors were to increase external validity and generalizability and to avoid attributing the treatment effects to a specific instructor. Both instructors had pregnancy- and childbirth-related clinical experience and personal mindfulness practices for more than 5 years and training in teaching mindfulness for more than 2 years. They both received specific teacher training and supervision from senior MBCP instructors.

Control: Antenatal Childbirth Education and Support (ACES)

As advocated by some researchers (MacCoon et al., 2012), studies on MBIs should control for non-specific group effects and social interaction effects. The 9-week ACES course was designed as a psychosocial placebo comparable to MBCP in terms of program structure, instructor contact hours, content regarding pregnancy and childbirth, class activities, and homework assignments of similar nature and duration. Participants were invited to do 30 to 45 min of homework assignments. The homework assignments included a pregnancy diary, a dietary record for 3 days and sharing with the support person, walking, pelvic floor exercises, birthing position exercise, breastfeeding benefit review, planning/shopping for birth, and breastfeeding-related materials. ACES aimed to enhance the well-being of pregnant women by means other than the mindfulness components (Table S1). Three health professionals with pregnancy-related clinical experience and experience facilitating educational group sessions delivered seven ACES groups of up to 18 pairs of participants.

Fidelity Check

First, developing and using the MBCP training manual was in consultation with experts from the MBCP team and the use

Table 1 Baseline characteristics for MBCP and ACES

	Total ($n=183$)	MBCP ($n=94$)	ACES ($n=89$)
Age	32.5 ± 3.9	32.3 ± 4.4	32.6 ± 3.4
Education			
F7 or below	57 (31.1%)	30 (31.9%)	27 (30.3%)
College or above	126 (68.9%)	64 (68.1%)	62 (69.7%)
Occupation			
Housewife	25 (13.7%)	10 (10.6%)	15 (16.9%)
Employed	158 (86.3%)	84 (89.4%)	74 (83.1%)
Religion[a]			
With religion	57 (31.3%)	31 (33.0%)	26 (29.5%)
Without religion	125 (68.7%)	63 (67.0%)	62 (70.5%)
Marital status			
Married or co-habit	180 (98.4%)	92 (97.9%)	88 (98.9%)
Single, divorced, or widowed	3 (1.6%)	2 (2.1%)	1 (1.1%)
Personal income[b]			
$10,000 below	32 (17.9%)	14 (15.4%)	18 (20.5%)
$10,000 to $19,999	60 (33.5%)	32 (35.2%)	28 (31.8%)
$20,000 to $29,999	43 (24.0%)	22 (24.2%)	21 (23.9%)
$30,000 or above	44 (24.6%)	23 (25.3%)	21 (23.9%)
Medical history	$n=134$	$n=64$	$n=70$
No. of chronic diseases			
0	59 (44.0%)	24 (37.5%)	35 (50.0%)
1	42 (31.3%)	24 (37.5%)	18 (25.7%)
2	23 (17.2%)	12 (18.8%)	11 (15.7%)
3 or more	10 (7.5%)	4 (6.3%)	6 (8.6%)
No. of psychiatric disorders			
0	130 (97.0%)	63 (98.4%)	67 (95.7%)
1	4 (3.0%)	1 (1.6%)	3 (4.3%)
No. of pregnancy terminations			
0	110 (82.1%)	53 (82.8%)	57 (81.4%)
1 or more	24 (17.9%)	11 (17.2%)	13 (18.6%)

Table 1 (continued)

	Total ($n=183$)	MBCP ($n=94$)	ACES ($n=89$)
No. of spontaneous abortions			
0	114 (85.1%)	56 (87.5%)	58 (82.9%)
1 or more	20 (14.9%)	8 (12.5%)	12 (17.1%)
No. of live births			
0	124 (92.5%)	60 (93.8%)	64 (91.4%)
1	10 (7.5%)	4 (6.3%)	6 (8.6%)
SF-12 (mental component)	49.4 ± 8.8	49.3 ± 8.9	49.6 ± 8.8
EPDS	6.9 ± 3.9	6.9 ± 3.9	6.9 ± 3.9
CESD	9.8 ± 6.8	9.4 ± 6.8	10.2 ± 6.8
Non-depressed	151 (82.5%)	80 (85.1%)	71 (79.8%)
Depressed	32 (17.5%)	14 (14.9%)	18 (20.2%)
PSS	20.8 ± 6.6	20.6 ± 6.7	20.9 ± 6.4
STAI—State	34.8 ± 8.9	34.5 ± 9.4	35.1 ± 8.3
STAI—Trait	39.0 ± 7.7	38.7 ± 7.9	39.3 ± 7.5
FFMQ	125.6 ± 11.7	125.3 ± 12.3	126.0 ± 11.0
MAIA	89.9 ± 18.6	90.7 ± 20.0	89.1 ± 17.1
PCS	15.5 ± 10.3	13.6 ± 9.5	17.4 ± 10.8
PPA	20.8 ± 4.5	20.5 ± 4.7	21.0 ± 4.3
PBQ[c]	28.9 ± 11.7	29.0 ± 11.7	28.9 ± 11.9

Mean ± SD and count (%) for continuous and categorical variables respectively

MBCP Mindfulness-Based Childbirth and Parenting, *ACES* Antenatal Childbirth Education and Support, *SF-12* The 12-Item Short-Form Health Survey, *EPDS* Edinburgh Postnatal Depression Scale, *CES-D* Center for Epidemiologic Studies Depression Scale, *PSS* Perceived Stress Scale, *STAI* The State-Trait Anxiety Inventory, *FFMQ* Five Facet Mindfulness Questionnaire, *MAIA* Multidimensional Assessment of Interoceptive Awareness, *PCS* The Pain Catastrophizing Scale, *PPA* Prenatal Pregnancy Anxiety, *PBQ* Postpartum Bonding Questionnaire

[a]182 participants answered for this item

[b]179 participants answered for this item

[c]T3 as baseline data because only after the mother gave birth could the data be collected

of a training manual for the education control group developed was in consultation with local maternal and child health experts (e.g., midwives from the Maternal and Child Health Centre directors and obstetricians), and using education materials from the MCHC websites. Second, facilitator training sessions were undertaken in consultation with Nancy Bardacke prior to the intervention, followed by continual supervision of the trained instructors by Nancy Bardacke and the Mindful Birthing and Parenting Foundation MBCP teacher training team. Facilitator training sessions for the ACES facilitators were conducted by experienced midwives and nurses. Third, audio recordings of all sessions from both arms of the study were randomly assessed for intervention fidelity to the manual by a senior mindfulness teacher (for the MBCP group) or an investigator (for the ACES group) to make sure the interventions adhere to the manual.

Measures

Participants' demographic information and medical, obstetric, and psychiatric history were collected at baseline. All questionnaires were completed by participants independently and returned either in person, by post, or by email, with at least three telephone or text message reminders. Trained research assistants with health-related degrees collected data from medical records using both written and electronic medical record systems of the public hospitals. Except for a few, almost all assessments were conducted at T1 to T4 for both groups. Except for clinical outcomes and course evaluations, all the measures are validated scales.

Mental Health–Related Quality Of Life (Primary Outcome) The primary outcome was measured by the Mental Component Score (MCS) of the validated Medical Outcomes Study Short-Form Health Survey (SF-12) Chinese (Hong Kong specific) version at 6 months after childbirth (T4) (Lam et al., 2005). MCS-12 includes mental health perception (MH); role–emotional (RE), or limitation in daily role functioning caused by emotional problems; and social functioning (SF) and vitality (VT). A higher score indicates a better outcome. The Chinese (HK) SF-12 has high internal consistency (0.90 for MCS) and explained 90% of the total variances of the Chinese (HK) specific SF-36 MCS (Lam et al., 2005).

Depressive Symptoms The 20-item Center for Epidemiologic Studies Depression Scale (CESD) (Cheung & Bagley, 1998; Lee et al., 2008) was used to measure depressive symptoms. The scale adopts a 4-point Likert-type scale ranging from 0 (*rarely or none of the time*) to 3 (*most or all of the time*). The Chinese version of the CESD has been validated in the Hong Kong population with a high internal consistency ($\alpha = 0.90$) and moderate concurrent validity against life stress ($r = 0.62$) and anxiety symptoms ($r = 0.64$). The 10-item validated Chinese Edinburgh Postnatal Depression Scale (EPDS) was also used to measure depressive symptoms (Lee et al., 1998; Leung et al., 2011). It has 10 self-reported items scored from 0 to 3, a total score of 0–30, with a higher score indicating more severe depressive symptoms. Postpartum EPDS scores exceeding 10 were considered "probable depression" (sensitivity 82%, specificity 86%, positive predictive value 44%), and if so, the women would be referred for a clinical interview.

Anxiety Anxiety was measured by the Prenatal Pregnancy Anxiety (PPA) scale (Guardino et al., 2014; Wadhwa et al., 1993) and the State-Trait Anxiety Inventory (STAI) (Shek, 1993) which consists of both trait and state scores. PPA was measured at T1 and T2. It consists of 10 items that assess the extent to which respondents worry or feel concerned about their health, their baby's health, labor and delivery, and caring for a baby. Responses were made on a 4-point scale (*not at all*, *somewhat*, *moderately*, *very much*; or *never*, *sometimes*, *most of the time*, *almost all of the time*). The PPA scale has good internal reliability (Cronbach's $\alpha = 0.78$) (Wadhwa et al., 1993). The STAI consists of a state subscale and a trait subscale. It was developed to measure both state and trait anxiety. Each subscale consists of 20 items that are based on a 4-point Likert-type scale ranging from 1 (*not at all*) to 4 (*very much so*). The Chinese version of the STAI (C-STAI) has been tested and validated for use in the Chinese community with Cronbach's alpha scores as high as 0.90 and 0.81 for state anxiety and trait anxiety respectively (Shek, 1993).

Stress Perceived stress was measured by the 14-item Global Measure of Perceived Stress Scale (PSS) (Leung et al., 2010). Each item was rated on a 5-point Likert-type scale from 0 (*never*) to 4 (*very often*), covering the preceding month. A higher score indicates more perceived stress. The validation of the Chinese version of the PSS showed high reliability ($\alpha = 0.83$) and good concurrent validity.

Catastrophizing Thoughts About Pain This was measured by the validated Pain Catastrophizing Scale (PCS; Yap et al., 2008). PCS is a 13-item self-report questionnaire consisting of three subscales: rumination, magnification, and helplessness. Respondents were instructed to rate the frequency with which they experience different pain-related thoughts and feelings on a 5-point scale, with the endpoints 0 (*not at all*) and 4 (*all the time*). Higher scores suggest higher levels of catastrophizing thoughts about pain. HK-PCS has been proven a valid and reliable instrument for measuring pain catastrophizing in Chinese patients with chronic pain with excellent internal consistency ($\alpha = 0.93$).

Disordered Mother–Infant Relationship This was measured with the validated Chinese Postpartum Bonding Questionnaire (PBQ; Siu et al., 2010) at T3 and T4. It has four subscales of

impaired bonding, rejection and anger, anxiety about care, and risk of abuse comprised of 25 statements rated on a 6-point Likert scale (from *always* to *never*). High total scores suggest difficult mother–infant bonding and a cut-off of 39/40 had a sensitivity of 83% and a specificity of 96% in identifying severe impairment in the mother–infant relationship (Siu et al., 2010).

Mindfulness Dispositional mindfulness was measured with the validated 39-item Chinese version of the Five Facet Mindfulness Questionnaire (FFMQ) (Hou et al., 2014a). FFMQ is a 39-item questionnaire that measures five facets of mindfulness: observing, describing, acting with awareness, non-judging, and nonreacting. Items were scored on a 5-point Likert-type scale ranging from 1 (*never or very rarely true*) to 5 (*very often or always true*). Scores were summed up, and higher scores indicate higher levels of mindfulness. A study indicated the reliability and internal consistency of FFMQ-C were 0.88 and over 0.80, respectively (Hou et al., 2014a). The Multidimensional Assessment of Interoceptive Awareness (MAIA) scale was used to measure mindful body awareness (Lin et al., 2017; Mehling et al., 2012). The original MAIA includes 32 items which are scored on a 6-point Likert scale, ranging from 0 (*never*) to 5 (*always*), with higher scores indicating more positively appraised interoceptive awareness. Cronbach's α of the Chinese version of MAIA was 0.91 overall. In addition, Cronbach's α for inter-item consistency and McDonald's omega (ω) for reliability (Peters, 2014) for the above scales in the present study are presented in a supplementary table (Table S2).

Clinical Outcomes and Course Evaluation Other secondary measures included maternal and neonatal clinical outcomes. Evaluation (interestingness, helpfulness, organization, recommendation to others) of the particular program attended was also collected at the last prenatal session (T2). Serious adverse events (SAE) were passively monitored by participants' self-reports and checking the public medical records. If the participants had any psychological or physical health concerns, they would be referred by nurses and doctors for further assessment under the Comprehensive Child Development Scheme which has a multi-disciplinary team involving midwives, pediatricians, psychiatrists, and social workers providing care to the mothers and their babies.

Data Analyses

Analysis of covariance (ANCOVA) was used for primary and secondary outcome analyses, adjusting for baseline values, based on the intention-to-treat (ITT) principle. It was supplemented by linear mixed models (LMMs) using ITT. LMMs provide the full likelihood estimation by incorporating all available data points, e.g., including individuals who only provided baseline data, and investigate significant changes over time. Each outcome variable was included as the dependent variable in the LMMs, and treatment group status, time point, and the interaction term between them served as fixed factors using an unstructured covariance pattern. Assuming missing at random, the missing data were left as missing and no imputation method was employed since LMMs have been proven to handle missing data in equivalence to the imputation technique (Chakraborty & Gu, 2009). Discrepancies in outcomes within different instructors in the MBCP group or the ACES group at different time points were compared using LMMs. Attritions were compared between the two groups using logistic regression (1 = withdrawal/dropped out at the study end point, 0 = remained/non-dropout). Comparisons of characteristics between the groups were also done using two-sample *t*-tests for continuous variables, and chi-squared tests, Fisher's exact tests, or binary logistic regression for categorical variables. A p-value < 0.05 (two-sided) was considered statistically significant. All statistical analyses were performed using SPSS Statistics version 24.0 (IBM Corp).

Results

Course Attendance and Evaluation

Course attendance was higher in ACES than in MBCP (87.6% vs. 68.1% attended 4 or more sessions, $p = 0.002$), but no statistically significant differences at baseline were found between those who attended at least 4 sessions and those who did not in both groups. The mean number of lessons attended by the participants of MBCP and ACES was 6.0 (standard deviation (SD) = 3.8) and 7.8 (SD = 3.1), respectively. Similar to the mentioned percentage difference between the two groups, course attendance was higher in ACES than in MBCP ($p = 0.001$ by two-sample *t*-tests). Average homework practice frequency and total duration during the intervention period were similar between the two groups (p-values > 0.05). The program evaluation results showed that more than half the expectant mothers thought the programs to be interesting (64.9% in ACES vs. 55.9% in MBCP), helpful (87.8% vs. 74.6%), and well organized (82.4% vs. 74.6%). The majority of them would recommend the program to others (88.9% vs. 82.8%). No statistical differences were observed in course evaluation results (p-values > 0.05) (Table S3).

Primary Outcome (SF-12 MCS)

Within-group changes showed that participants in MBCP had higher MCS scores at T2 but not T3 and T4 and participants in ACES had lower MCS scores at T3 and T4, compared to scores at T0. Between groups, ANCOVA results showed that participants in MBCP had higher MCS scores at T4 (mean difference (95% CI): 3.2 (0.1, 6.3), $p = 0.045$), which suggested the

better mental health–related quality of life compared to ACES (Table 2, $p=0.045$). Statistically significant differences in mental

Table 2 Analysis of covariance (ANCOVA) for pregnant women in MBCP and ACES groups

	n	MBCP[a]	*p* value[b]	ACES[a]	*p* value[b]	Mean difference (95% CI)	*p* value[c]
SF-12 (MCS)							
T2	128	52.9 (1.0)	0.018*	51.0 (0.9)	0.246	1.9 (−0.8, 4.7)	0.171
T3	114	47.3 (1.2)	0.149	44.6 (1.1)	< 0.001*	2.7 (−0.6, 5.9)	0.106
T4	112	49.7 (1.2)	0.677	46.5 (1.1)	0.009*	3.2 (0.1, 6.3)	0.045*
EPDS							
T2	131	6.4 (0.5)	0.375	7.4 (0.5)	0.273	−1.1 (−2.4, 0.3)	0.121
T3	128	6.4 (0.5)	0.287	7.9 (0.5)	0.065	−1.5 (−2.9, −0.1)	0.034*
T4	118	5.8 (0.6)	0.090	7.0 (0.5)	0.758	−1.3 (−2.8, 0.2)	0.099
CESD							
T2	135	8.6 (1.0)	0.264	11.2 (0.9)	0.189	−2.6 (−5.2, −0.1)	0.045*
T3	129	10.1 (1.1)	0.920	13.1 (0.9)	0.004*	−3.0 (−5.8, −0.2)	0.034*
T4	121	9.4 (1.0)	0.604	12.5 (0.9)	0.009*	−3.1 (−5.7, −0.5)	0.018*
PSS							
T2	135	19.6 (0.7)	0.404	20.7 (0.7)	0.922	−1.1 (−3.1, 0.9)	0.270
T3	130	21.1 (0.8)	0.798	22.5 (0.7)	0.072	−1.4 (−3.5, 0.6)	0.165
T4	121	19.7 (0.8)	0.588	20.5 (0.8)	0.750	−0.7 (−2.9, 1.5)	0.524
STAI_State							
T2	134	32.5 (1.0)	0.049*	35.8 (0.9)	0.362	−3.2 (−5.8, −0.7)	0.013*
T3	129	35.5 (1.1)	0.368	39.8 (1.0)	< 0.001*	−4.3 (−7.1, −1.4)	0.004*
T4	120	34.4 (1.1)	0.962	38.9 (1.0)	< 0.001*	−4.5 (−7.4, −1.7)	0.002*
STAI_Trait							
T2	133	37.7 (0.7)	0.150	39.2 (0.6)	0.787	−1.6 (−3.3, 0.2)	0.085
T3	129	39.2 (0.9)	0.682	41.3 (0.8)	0.025*	−2.0 (−4.3, 0.2)	0.077
T4	120	38.6 (1.0)	0.955	40.7 (0.9)	0.085	−2.1 (−4.7, 0.5)	0.113
FFMQ—total							
T2	135	131.0 (1.2)	0.002*	126.1 (1.1)	0.919	4.9 (1.6, 8.2)	0.004*
T3	130	126.8 (1.3)	0.470	122.8 (1.2)	0.043*	4.0 (0.5, 7.4)	0.026*
T4	121	127.8 (1.3)	0.339	122.7 (1.2)	0.007*	5.2 (1.6, 8.8)	0.005*
MAIA—total							
T2	133	98.7 (1.6)	< 0.001*	92.0 (1.5)	0.042*	6.7 (2.4, 11.1)	0.003*
T3	129	93.3 (2.2)	0.223	88.0 (1.9)	0.684	5.3 (−0.4, 11.0)	0.070
T4	121	94.2 (2.5)	0.462	89.1 (2.3)	0.949	5.1 (−1.5, 11.8)	0.131
PCS—total							
T2	135	13.7 (1.0)	0.285	14.4 (0.9)	0.022*	−0.6 (−3.4, 2.2)	0.663
T3	126	12.7 (1.2)	0.077	14.5 (1.1)	0.050	−1.8 (−5.0, 1.4)	0.275
T4	116	10.6 (1.4)	0.015*	11.9 (1.3)	0.001*	−1.3 (−5.1, 2.4)	0.480
PPA (T2)	135	18.7 (0.5)	0.002*	20.1 (0.4)	0.085	−1.4 (−2.6, −0.1)	0.030*
PBQ (T4)	113	21.2 (1.8)	< 0.001*	21.5 (1.5)	< 0.001*	−0.4 (−5.0, 4.3)	0.873 [d]

T2 last prenatal session, *T3* 6–8 weeks after childbirth, *T4* 6 months after childbirth, *MBCP* Mindfulness-Based Childbirth Parenting, *ACES* Antenatal Childbirth Education and Support, *SF12* The 12-Item Short Form Health Survey, *EPDS* Edinburgh Postnatal Depression Scale, *CES-D* Center for Epidemiologic Studies Depression Scale, *PSS* Perceived Stress Scale, *STAI* The State-Trait Anxiety Inventory, *FFMQ* Five Facet Mindfulness Questionnaire, *MAIA* Multidimensional Assessment of Interoceptive Awareness, *PCS* The Pain Catastrophizing Scale, *PPA* Prenatal Pregnancy Anxiety, *PBQ* Postpartum Bonding Questionnaire

*p-value < 0.05

[a]Estimated mean (standard error)

[b]p-value for paired t-test to compare within-group differences between baseline and follow-up

[c]p-value between two groups with adjustment for baseline values

[d]p-value between two groups with adjustment for T3 data

health–related quality of life at T4 and depression (EPDS at T3 and CES-D at all follow-ups) using ANCOVA were not found using LMMs. In addition, participants in two ACES classes instructed by one trainer had lower MCS scores at T4; no significant differences were seen in the below outcomes between the individual instructors in each group (Table S4).

Depression and Anxiety (CES-D, EPDS, STAI, and PPA)

EPDS scores at T3 and CES-D scores at T2, T3, and T4 of the MBCP group were significantly lower in MBCP, indicating lower depression levels (all $p < 0.05$). STAI state scores were significantly lower in MBCP at T2, T3, and T4 (all $p < 0.05$), indicating lower anxiety levels. The Prenatal Pregnancy Anxiety (PPA) score was also lower in the MBCP group at T2 ($p = 0.03$).

Mindfulness (FFMQ and MAIA)

An increase in FFMQ total score at T2, T3, and T4 was observed in the MBCP group, which suggested higher mindfulness levels (all $p < 0.05$). The results of linear mixed models were consistent with the ANCOVA results in STAI state subscale, FFMQ, and MAIA (Fig. 2).

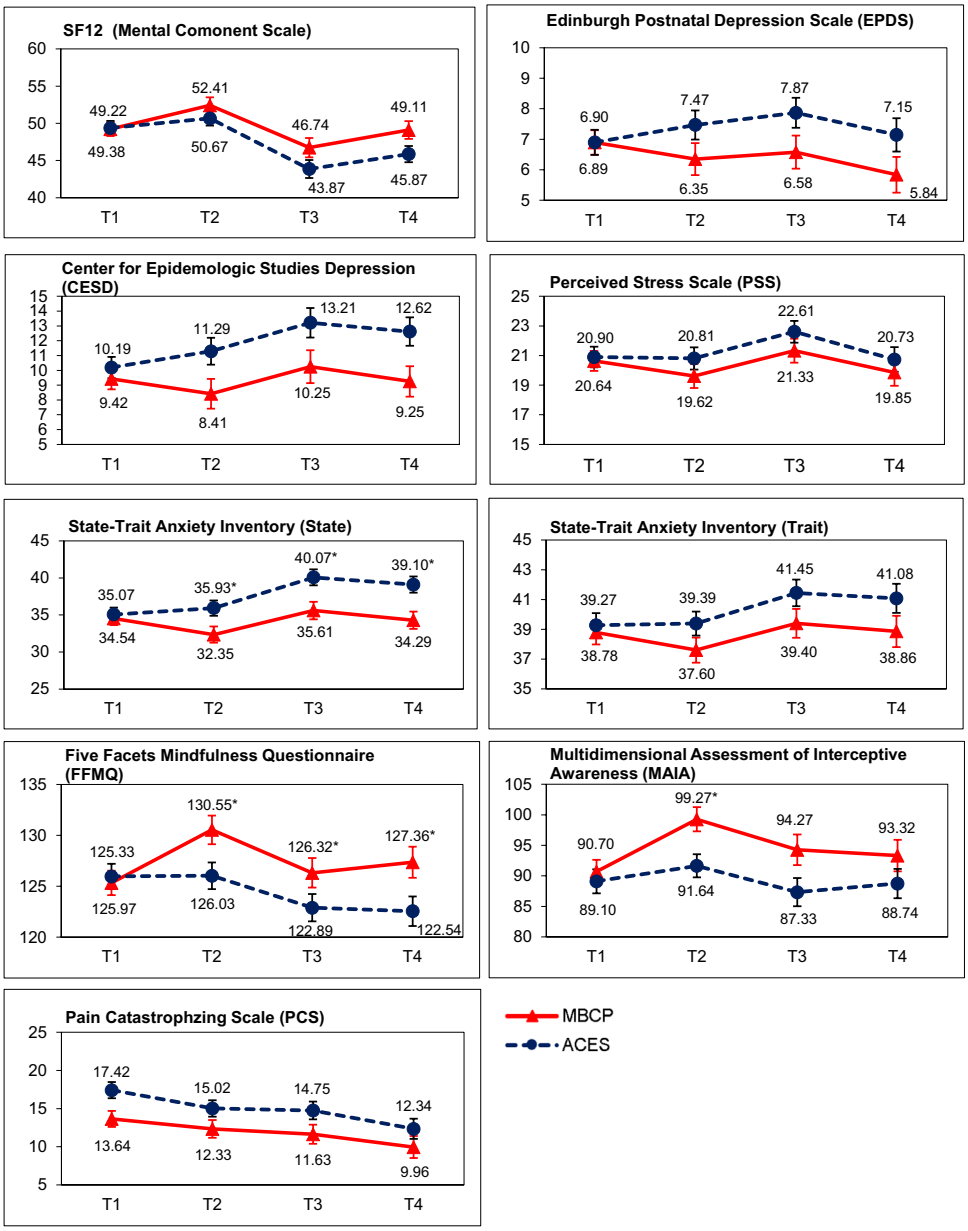

Fig. 2 Estimated changes using linear mixed models in primary and secondary outcomes from baseline to 6 months after childbirth. Note: Data are presented as estimated mean and standard error from linear mixed models. * indicates significant between-group difference at $p < 0.05$

Perceived Stress (PSS), Catastrophizing Thoughts About Pain (PCS), and Disordered Mother–Infant Relationships (PBQ)

No statistically significant within-group changes in PSS were observed in either the MBCP or the ACES group. A within-group decrease in disordered mother–infant relationship (PBQ score) was seen in both groups at T4, comparing to T3. A within-group decrease in PCS score was observed in MBCP at T4 and in ACES at T2 and T4, respectively. No statistically significant between-group differences were observed among these outcomes at any time point.

Childbirth-Related Clinical Outcomes

No statistically significant differences in medical, psychiatric, or obstetric history were seen at baseline between those who had ($n=110$) or did not have the records ($n=73$) due to some participants being unwilling to grant access to their medical records and some participants having delivered in private hospitals. No statistically significant differences in clinical outcomes related to childbirth were seen between the MBCP and ACES groups, except for greater use of a birth ball in the ACES group ($n=5$; 11.6% vs. $n=21$; 44.7%; $p=0.001$) (Table S3).

Course Compliance

Nineteen subjects (12 in MBCP and 7 in ACES) never attended any intervention sessions, and 24 women (19 in MBCP and 5 in ACES) withdrew from the study after completion of intervention sessions, yielding an overall attrition rate of 23.5%. The attrition rates were 33.0% and 13.5% in the MBCP and ACES groups, respectively, with a corresponding odds ratio of 3.16 (95% CI = 1.50 to 6.65) indicating that subjects in the MBCP group were more likely to drop out. Among those who withdrew, there were no statistically significant differences in baseline characteristics between the MBCP and the ACES groups (Table S5). Similarly, no statistical differences in the baseline characteristics were noted between those who were lost to follow-up and those who continued at T4, either within or between the MBCP and ACES groups, except that those who continued were about 2 years older (overall: 33.2 ± 3.6 vs. 31.0 ± 4.2, $p < 0.001$; MBCP: 33.3 ± 4.0 vs. 30.8 ± 4.5, $p = 0.006$; ACES: 33.1 ± 3.2 vs. 31.3 ± 3.6, $p = 0.023$) (Table S6). Post-hoc analysis showed that age only had a weak association with PCS ($r = 0.186$, $p = 0.045$) at T4 but not at baseline nor other outcome measures. Apart from the age differences, there were no other statistically significant differences between MBCP and ACES within withdrawal and lost to follow-up groups, so bias by differential attrition was unlikely with respect to those variables. Results from logistic regression confirmed that for both withdrawal and drop-out, no significant interaction between intervention and all demographics was found (all $p > 0.05$).

Serious Adverse Events

No fetal death was found in the medical records. Three preterm births were seen in the MBCP group. Three preterm births and one very preterm birth were seen in the ACES group. No serious adverse events due to MBCP or ACES were reported by the participants.

Discussion

MBCP appeared to have beneficial effects on mental health–related quality of life at 6 months after childbirth (T4). Reduction in levels of depression and anxiety, and an increase in mindfulness levels among expectant mothers, were also seen immediately after intervention (T2), at the reunion 6 to 8 weeks after childbirth (T3), and lasted up to 6 months after childbirth (T4). No serious adverse events and fetal deaths were reported in the MBCP group. No beneficial effects were found for perceived stress, catastrophizing thoughts about pain, disordered mother–infant relationships, or obstetrical outcomes related to pregnancy and childbirth such as duration of labor or birth weight. MBCP was overall well accepted by the participants with an acceptable attendance rate, course evaluation results, and homework practice time and frequency.

Although previous qualitative studies and non-randomized controlled trials had suggested potential benefits of MBIs during the perinatal period, systematic reviews of randomized controlled trials (RCTs) so far have not provide support (Dhillon et al., 2017; Shorey et al., 2019; Taylor et al., 2016), which might be due to small sample sizes and the relatively low quality of the study designs of previous studies (Dhillon et al., 2017; Taylor et al., 2016). This randomized controlled trial included a relatively large sample size that compared a tailored MBI (i.e., MBCP) with an active control group that was matched in terms of time, format, homework, etc., as well as a relatively longer-term follow-up. Furthermore, obstetrical outcomes related to pregnancy and childbirth were examined and subgroup analyses were explored.

It is promising that MBCP has beneficial psychological effects for expectant mothers with effects sustained from pregnancy to 6 months after childbirth. The mechanisms of beneficial effects of MBIs have not been fully understood yet. Researchers have suggested that reduced rumination and worry, increased mindfulness, acceptance,

compassion, and cognitive flexibility might contribute to these positive changes (Gu et al., 2015; Lee & Orsillo, 2014; Nyklíček & Kuijpers, 2008). One study on MBCP found that two mindfulness subscales, "non-reactivity to inner experience" and "non-judging of experience," might have mediated effects on the positive results of MBCP (Lönnberg et al., 2020). The current trial showed an increase in mindfulness level which might have mediated the positive results (Greeson et al., 2015; Song & Lindquist, 2015). With a greater increase in mindfulness state after repeated mindfulness practices, one would expect a greater increase in mindfulness trait and a greater decrease in stress (Kiken et al., 2015). If mothers continued their mindfulness practices after the program, it would be likely that they would continue to experience better mental health (Kiken et al., 2015; Lönnberg et al., 2020) and also yield better outcomes for their children, as mindful parents are more involved in their children's lives and are more aware of their children's needs (Keaulana et al., 2019; Siu et al., 2016). With the active involvement of their partners in MBCP, it might also benefit the couples by reducing anger and supporting a better relationship with each other (Zhang et al., 2020).

Previous studies found a decrease in stress (Lönnberg et al., 2020; Pan et al., 2019a), and a trend toward less pain medication use in labor, but not less perceived labor pain or less use of epidural anesthesia in the MBCP group (Duncan et al., 2017). The current study showed non-statistically significant results in stress, catastrophizing thoughts about pain, disordered mother–infant relationships, obstetrical outcomes, etc., although within-group improvements were seen in catastrophizing thoughts about pain and disordered mother–infant relationships. As catastrophizing thoughts about pain could happen any time, even after childbirth, we kept measuring PCS at T3 and T4. Although the MBCP group had an overall lower PCS score at T2, T3, and T4, no between-group differences were observed. At the same time, a within-group decline was observed in the ACES group at T2 and T4 and in the MBCP group at T4. This overall inferred both interventions might be effective or there might be some natural reduction in catastrophizing thoughts about pain. The non-significant between-group results might be largely explained by the adoption of an active control group and a relatively healthy population which means less room for improvement. The baseline MCS score in this trial was similar to the score among the general population in Hong Kong (mean: 50.0, standard deviation: 9.5) (Lam et al., 2005), and antenatal depression scores were lower than what had been reported in local epidemiological studies (Gao et al., 2009; Lee et al., 2007). This might also partly explain that statistically significant differences were seen in EPDS scores at T3 only. Furthermore, we are not able to discern whether there may be beneficial effects of MBCP which were obscured when compared to an active control. The active control provided psycho-education, practical parenting skills, peer support, and prescribed exercises which might also have improved the overall health of the expectant parents who were mostly first-time parents. Within-group improvements were also seen in ACES. The active control might have made some beneficial effects of MBCP more difficult to detect in this study, though such effects on stress were observed for the subgroup who were at a higher risk for depression.

Regarding the safety of MBCP, we did not find any specific serious adverse event or fetal death reported by participants or in the retrieved medical records. The study in Sweden found one woman in the MBCP group had increased anxiety and discontinued participation, and eleven women discontinued participation due to pregnancy complications, fatigue, scheduling problems, or disliking the intervention (Lönnberg et al., 2020). Although MBCP is regarded as relatively safe in this study and also in other previous studies, and is widely implemented among thousands of couples in the USA and other countries in the past decades, future studies and services are still strongly encouraged to take precautionary efforts to record and treat potential adverse effects due to the intervention for prevention and ethical reasons (Wong et al., 2018).

Limitations and Future Research

Given the above merits, the study had a major limitation—attrition. Although different strategies, e.g., at least three telephone or text reminders were provided, about one-third of the participants did not complete their last assessment. The attrition rates were comparable to those of other perinatal studies which showed attrition rates from 16 to 30% in the prenatal period (Bruno et al., 2017; Tough et al., 2007) and from 17 to 63% at 3 to 24 months postpartum (Foulon et al., 2015). The MBCP dropout rate was slightly higher than the rates in other MBI studies in Hong Kong (Hou et al., 2014a, 2014b; Wong et al., 2017) as well as the adapted MBCP study in Taiwan which had only eight sessions (Pan et al., 2019a), although it was comparable to the attendance in another MBCP intervention study (Dunn et al., 2012). The non-compliance might be due to lower interest in MBCP, and participants were more familiar with a conventional educational course that had been offered for a long time, whereas the mindfulness course was fairly new. A higher dropout rate was observed in the mindfulness group when compared to the active control group (e.g., psycho-education or psycho-education with physical exercise) in previous studies as well (Wong et al., 2016, 2017). Another reason might be that due to a very fast-paced lifestyle, some people may find it quite difficult to slow down and do the requested mindfulness practices. Future studies need to examine ways

to improve compliance with mindfulness programs. Despite the overall attrition and uneven attritions between the intervention and control groups, it is fair to state that the results of this trial are reliable due to three reasons. First, different statistical analyses (ANCOVA and LMM) based on the ITT principle showed similar findings supporting the beneficial effects. Second, almost no statistically significant differences were found between those who were lost to follow-up and those who were not, either within or between the MBPC and ACES groups. Third, the final number of participants in the analysis was close to the required sample size since dropout was accounted for in the initial sample size determination. These considerations suggest that the results of this randomized controlled trial were unlikely to have been influenced by attritions. Another limitation could be the common method bias (Podsakoff et al., 2012). This bias is prevalent when information on multi-item scales is obtained from the same person using the same method. Due to response styles, social desirability, priming effects, mood, acquiescence, etc., it could produce spurious correlations among the scale constructs when participants self-reported the answers in the same survey (Podsakoff et al., 2012). However, as this was a randomized controlled trial and both groups underwent similar procedures, the between-group differences should be mainly explained by the difference between the two interventions.

MBCP appears to improve mental health–related quality of life, reduce depression and anxiety, and increase levels of mindfulness among expectant mothers in Hong Kong, with beneficial effects lasting up to 6 months after childbirth. Future studies can further examine the cost-effectiveness of MBCP as well as its efficacy for mothers with psychiatric symptoms and disorders (e.g., depression or anxiety). Potential reasons for non-compliance and mechanisms of the positive changes can also be further explored. In addition, it would be worthwhile to prospectively follow the mothers, their partners, and their babies to see if these mothers will continue their mindfulness practices after the program, and to examine whether there are any long-term effects of MBCP within families.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s12671-022-02046-8.

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Author Contribution KWKT, SYSW, TWH, BHKY, and LGD contributed to the conceptualization, funding acquisition, and methodology. KWKT, SYSW, LGD, and NB contributed to the supervision of the overall study and intervention. DZ contributed to the writing (original draft) and methodology. DCCC contributed to the formal analysis and methodology. TTG and DCCC contributed to the investigation and project administration. WHT, KYL, and WHT contributed to project administration. All authors contributed to the writing (review and editing).

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Data Availability The data has been deposited to CUHK Research Data Repository: https://researchdata.cuhk.edu.hk/dataset.xhtml?persistentId=doi:10.48668/KT1ZZR.

Declarations

Ethics Ethics approval was obtained from the Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee (date of approval: 2 October 2013, Reference Number: CRE-2013.463-T). Written informed consent was obtained from all participants.

Conflict of Interest Nancy Bardacke founded the not-for-profit Mindful Birthing and Parenting Foundation (MBPF) that provides Mindfulness-Based Childbirth and Parenting (MBCP) professional trainings. She receives royalties from the sale of a book and guided audio meditation materials from the MBCP program tested in this study. Larissa Duncan serves as an unpaid board member of the MBPF. The other authors report no conflicts of interest.

Trial Registration The trial was registered in one of the WHO primary registries: Chinese Clinical Trial Registry before recruitment. Identifier Number: ChiCTR-TRC-13004070. http://www.chictr.org.cn/historyversionpuben.aspx?regno=ChiCTR-TRC-13004070

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