

Research paper

Effects of a mindfulness based childbirth and parenting program on pregnant women's perceived stress and risk of perinatal depression—Results from a randomized controlled trial



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ABSTRACT

Objectives: The aim of this study was to test the efficacy of a Mindfulness-Based Childbirth and Parenting Program (MBCP) in reducing pregnant women's perceived stress and preventing perinatal depression compared to an active control condition.

Method: First time pregnant women ($n = 197$) at risk of perinatal depression were randomized to MBCP or an active control treatment, which consisted of a Lamaze childbirth class. At baseline and post-intervention, participants filled out questionnaires on perceived stress, depressive symptoms, positive states of mind, and five facets of mindfulness.

Results: Compared to the active control treatment, MBCP significantly reduced perceived stress ($p = 0.038$, $d = 0.30$) and depressive symptoms ($p = 0.004$, $d = 0.42$), and increased positive states of mind ($p = 0.005$, $d = 0.41$) and self-reported mindfulness ($p = 0.039$, $d = 0.30$). Moreover, change in mindfulness possibly mediated the treatment effects of MBCP on stress, depression symptoms, and positive states of mind. The subscales “non-reactivity to inner experience” and “non-judging of experience” seemed to have the strongest mediating effects.

Limitations: The outcomes were self-report questionnaires, the participants were not blinded to treatment condition and the condition was confounded by number of sessions.

Conclusions: Our results suggest that MBCP is more effective in decreasing perceived stress and risk of perinatal depression compared to a Lamaze childbirth class. The results also contribute to our understanding of the underlying psychological mechanisms through which the reduction of stress and depression symptoms may operate. Thus, this study increases our knowledge about efficient intervention strategies to prevent perinatal depression and promote mental wellbeing among pregnant women.

1. Background

Postnatal depression is the most common complication after childbearing (WHO, 2008), and an estimated 11.9% of women experience antenatal or postnatal depression globally (Woody et al., 2017). In Sweden, there is a similar prevalence of antenatal depression (13.7%) and postnatal depression (11.1%) (Rubertsson et al., 2005). Widarsson and colleagues have warned that existing health-care services may fail

to meet the psychological and emotional support needs of expectant parents (Widarsson et al., 2012). In addition to the suffering of the mother, there is also substantial global evidence for the negative impact of perinatal depression on a broad range of child outcomes, and this has led to a call to prioritize the development of effective health promoting prenatal interventions (Stein et al., 2014).

Interventions with a potential to reduce stress among expectant parents have been developed and typically include elements of psycho-

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education and peer support. A meta-analysis demonstrated that perinatal psychosocial interventions given by non-mental health specialists are effective in reducing depression and anxiety (Clarke et al., 2013). One of the working mechanisms in these interventions is peer support since expectant parents have a strong need to discuss relevant topics with their peers (Norling-Gustafsson et al., 2011).

The risk factors for depression around the time of childbirth have been linked to previous history of depression, prenatal anxiety, low levels of support and exposure to stressful life events (Robertson et al., 2004). Early life adversity such as abuse and neglect in the mother's own childhood, is also associated with elevated risk for postpartum depression (Jonas et al., 2013). Furthermore, current stressors like partner conflict and work-related stress are also predictors of depression in any period of life, including pregnancy. If the stressor is related to the fetus it is significantly associated with antenatal depression (Dayan et al., 2010). Evidence regarding risk factors for perinatal depression have been summarized as follows (Howard et al., 2014): Prior history of psychopathology including depression, anxiety and PTSD and previous abuse and domestic violence are characterized as strong risk factors. Life stress and major/negative life events and anxiety during pregnancy are characterized as medium to strong risk factors while absence of social support is characterized as a medium risk factor (Howard et al., 2014).

Given these risk factors an antenatal Mindfulness-Based Intervention (MBI) may be a promising prevention approach for this group, since it combines peer support and psycho-education with tools for self-regulation. Also, dispositional mindfulness seems to work as a buffer as it is associated with lower depression symptoms in pregnancy among mothers and fathers who are exposed to adversity (Hicks et al., 2018). In the past decades, the use of MBIs has increased in clinical practice. Mindfulness-Based Stress Reduction (MBSR) and Mindfulness-Based Cognitive Therapy (MBCT) are the two most empirically supported and commonly used programs offered in clinical settings to reduce stress and depression in non-pregnant women and in men. An overview of 23 systematic reviews and meta-analyses of RCTs in which MBSR and MBCT were compared to a waiting-list control or an active control treatment group showed improvement in depressive symptoms, anxiety, stress, quality of life and physical functioning (Gotink et al., 2015). Of importance, MBIs are not intended to replace standard psychiatric care (Van Dam et al., 2018) but show promise mainly in the prevention of depression relapse and in depression and anxiety symptom reduction (Gotink et al., 2015). However, there is a scarcity of randomized controlled studies comparing MBIs to active control conditions, warranting further research (Dimidjian and Segal, 2015).

A number of authors have suggested models to explain the mechanisms underlying the positive effects of mindfulness-based interventions (Brown et al., 2007; Carmody et al., 2009; Shapiro et al., 2006). Hötzel et al. (2011) have proposed a theoretical framework that integrates earlier models. This framework proposes that there are four main mechanisms: 1) attention regulation; 2) body awareness; 3) emotion regulation and 4) change in perspective of the self – and that these components together improve self-regulation (Holzel et al., 2011). Bränström and Duncan (2014) have added further evidence supporting this model, suggesting that mindfulness is related to a more adaptive modification of attention and increased ability to adjust cognitions, which leads to decreased negative and increased positive emotions.

Mindfulness-Based Childbirth and Parenting (MBCP) is based on MBSR and tailored for expectant couples. A small pilot study of MBCP showed reduced pregnancy anxiety and stress from baseline to post-intervention (Duncan and Bardacke, 2010b). A number of similar interventions, all encompassing 8 weekly sessions each 2 h long (except for Woolhouse et al. having 6 sessions and Byrne et al. having 2.5 h long sessions), with the aim to reduce or prevent stress, anxiety and depression symptoms during pregnancy and the early parenting period have been developed (Byrne et al., 2014; Dimidjian et al., 2015;

Goodman et al., 2014; Vieten and Astin, 2008; Woolhouse et al., 2014). However, the efficacy of these interventions has only been assessed in small pilot studies and several reviews call for well-designed RCTs to study the effectiveness of antenatal MBIs (Badker and Misri, 2017; Hall et al., 2016; Matvienko-Sikar et al., 2016; Taylor et al., 2016).

To the best of our knowledge, the present study is the first large scale randomized controlled trial that tests the efficacy of MBCP in reducing pregnant women's perceived stress and preventing perinatal depression compared to an active control condition. It is part of a larger research project in which our main outcomes are maternal perceived stress, depression, childbirth self-efficacy, breastfeeding and quality of mother-child relationship (as stated in ClinicalTrials). In the present study our first aim was to investigate the change in the following outcome variables; pregnant women's perceived stress, depression symptoms, positive states of mind and mindfulness skills, from baseline to post-intervention. The second aim was to explore if our data is consistent with a proposed causal process; being that increased mindfulness skills would mediate improvements on our outcome measures, in line with the suggested mechanism through which mindfulness training improves psychological outcomes. Our third aim was to examine the effect of intervention adherence on the outcomes.

2. Method

2.1. Sample

Statistical power analysis was calculated based on perceived stress as main outcome and data from a pilot study by Duncan and colleagues (Duncan and Bardacke, 2010a). The Stockholm Regional Ethics Committee approved the study and written informed consent was obtained from all participants. Participants were blinded to the study hypothesis and received no compensation other than free participation in the MBCP or Lamaze course. They were recruited through eight maternity health clinics (MHCs) in Stockholm County from 2014 to 2016. Considering the risk factors for perinatal depression and our aim to target an at-risk-population, we selected women with a history of depression or anxiety and/or early life adversity and/or current high levels of perceived stress through the following procedure: A letter was mailed to all first-time pregnant women listed at the participating MHCs around gestational week 15–22. The letter explicitly invited women with a felt need of extra support to participate. Those who were interested completed a brief online screening questionnaire for eligibility. Eligibility was defined as a) scoring six points or higher on the 4-item Perceived Stress Scale (Cohen et al., 1983), or b) having previously sought health care for mental health problems (yes/no, if yes then they were asked to describe when and for what), or c) previous experience of depression or anxiety (yes/no), or d) scoring six points or higher on three selected items from the Childhood Trauma Questionnaire (Bernstein et al., 2003) using a 5-point scale from 0 to 4 with a high score indicating early life adversity, as well as e) fluent in Swedish, f) no previous experience of mindfulness training or meditation (yes/no), g) no current psychotic symptoms or major depressive episode reported in their response to criteria b (given the focus on prevention, not on acute intervention) and h) at least 18 years old. In total, the letter of invitation was sent to 1647 primiparous women. Of those, 347 women were assessed for eligibility and 193 met the inclusion criteria and agreed to participate; 96 were randomized to the MBCP group and 97 to the Lamaze group. For further information on participation see flowchart (Fig. 1).

2.2. Procedure

Non-eligible participants received an email thanking them for their interest and informing them that they did not meet the inclusion criteria. Eligible participants were contacted by phone; they were informed about the study and scheduled for an appointment with a

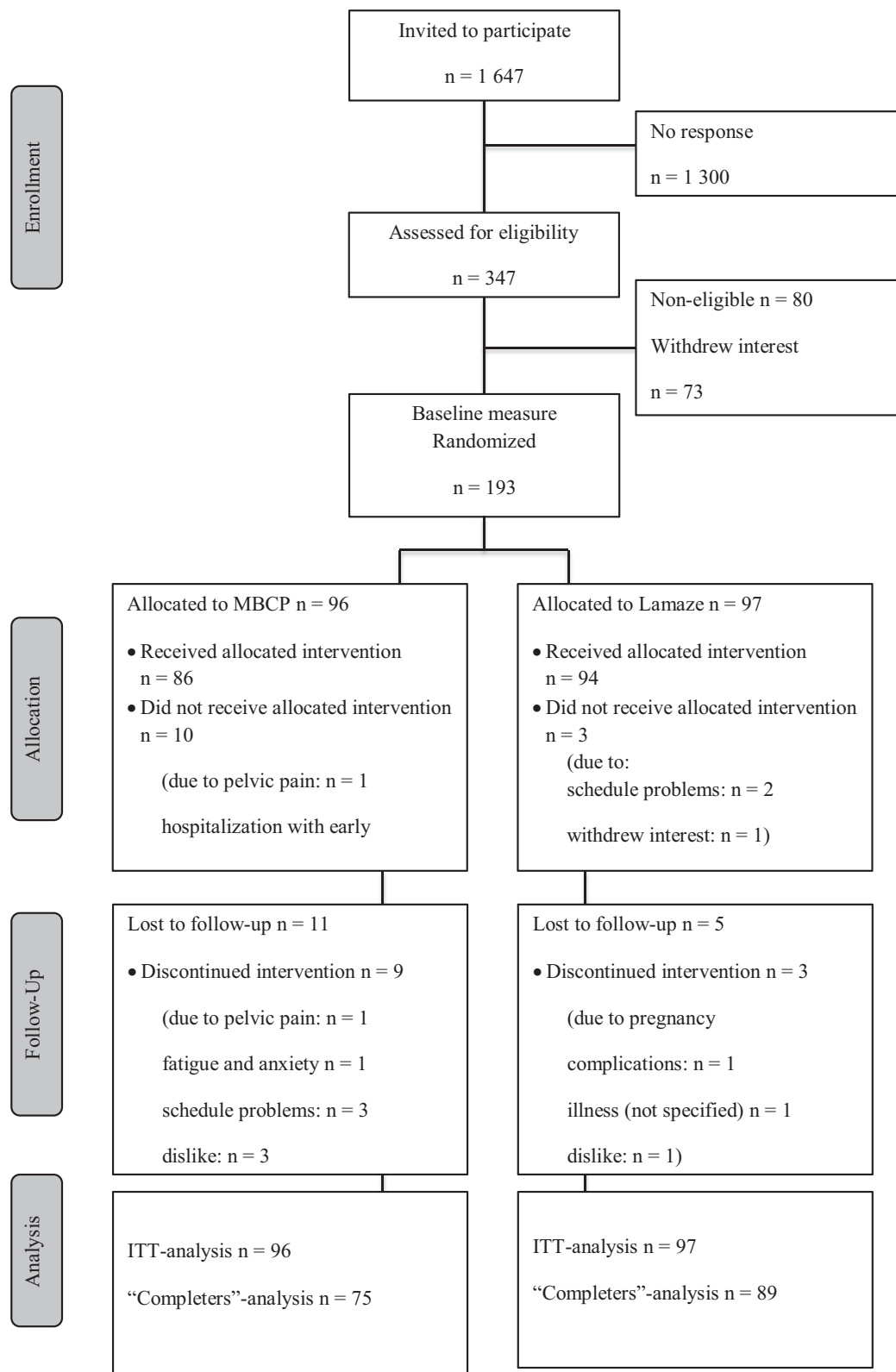


Fig. 1. Flowchart of participants invited, screened, enrolled, and completing the study (CONSORT figure).

researcher, during which they gave written informed consent to participate. An online link with the baseline questionnaires was emailed to them which was filled out when the participants were in gestational week 19–26. After completion of the questionnaires, an administrator, who was not part of the research team, randomised the participants to either MBCP or active control. The randomisation sequence was

generated in SPSS in blocks of 10 to reduce the effects of time.

Participants assigned to the MBCP condition started their intervention within two weeks after a baseline assessment. Participants who were assigned to the active control condition participated in a shorter program based on Lamaze techniques, which started between three and five weeks after the baseline assessment. At ten to twelve weeks after

the baseline assessment both groups received an email with a link to the post-intervention questionnaires which they filled in online when they were in gestational week 27–34. During the study, a total of 13 MBCP programs were run for the intervention participants and 13 Lamaze programs for the control participants.

2.2.1. Intervention

The original MBCP program was developed in the USA and consists of nine 3-hour long weekly sessions, a full day retreat and a reunion (Bardacke, 2012). In the current trial we adapted the curriculum to the conditions in Sweden, to take into account feasibility and differences in culture and health care systems. Firstly, we shortened the program to eight sessions and a reunion, each 2 h and 15 min long. This made it more feasible for participants with busy schedules to attend. Moreover, if effective, these adaptations could make future implementation more cost-effective. The sessions were also shortened because the groups only numbered 8–14 persons, which is fewer than in the original program (usually including 24–30 participants). Also, since our personal experience of teaching MBCP to Swedes is that they are not as prone to speak at length in group settings, the group discussions during the sessions were shortened. Furthermore, expectant parents in Sweden have free access to maternity health care, consisting of a program with visits to a midwife who provides support and information. Thus, we shortened some informative parts regarding childbirth. On the other hand, exercises that encouraged participants to reflect on gender-roles and their expectations on co-parenting were added.

Throughout this program, the practice of mindfulness was integrated with antenatal education. The practices were similar to MBSR and MBCT with body scan, mindful movement, sitting and walking meditation, loving kindness meditation and informal meditation in daily life. Special for the MBCP curriculum were the practices of interpersonal mindful speaking and listening inquiry, methods to increase awareness of the baby and to cope with pain during labour. All sessions included a 15 min snack break, which opened up for networking and peer support. For each session, an informative text was handed out which included home-practice assignments and links to audio-files with guided mindfulness practices. Participants were asked to do formal practice 30 min per day throughout the program as well as informal practice whenever they sensed foetal movements and during various other daily activities. The practices were reflected upon and discussed within the group. (See Table 1 for a more detailed description.)

2.2.2. Session attendance and compliance with practice at home

At each session, the participants filled out a form regarding how often and for how long they had been practicing formal and informal mindfulness meditation during the week.

2.2.3. Treatment supervision and fidelity

Three different teachers delivered the intervention. They had gone through teacher training in MBCP (Bardacke, 2019) and had 10 to 20

years of experience with meditation as well as attendance at a number of silent meditation retreats. The first teacher had long experience of teaching both MBCP and MBSR, the second teacher had long experience of teaching MBSR, and the third teacher had no previous experience of teaching mindfulness. The newly trained teacher co-taught two courses before teaching by herself. Throughout the project, the teachers met frequently to discuss their teaching, in order to ensure fidelity to the intervention. They were not blinded to the experimental hypothesis.

2.2.4. Active control

In order to control for the effects of social support and psycho-education, as well as for feasibility reasons, the active control condition consisted of a Lamaze program (AnnasProfylax, 2019) that is widely available in Stockholm.

The focus of this program was to learn methods to cope specifically with stress and pain during labor and it consisted of three group meetings, each three hours long. During the first two sessions the couples learned breathing and relaxation techniques, how to prepare mentally for birth and how the partner can be supportive during labor by coaching and giving calming massage for pain relief. The participants were encouraged to practice the breathing and relaxation techniques at home before birth. The theme of the third session was ‘parenting an infant’ and focused on breastfeeding, sleeping and eating routines, as well as the couple relationship. Three different teachers, all trained by ProfylaxGruppen, taught the program and they were not blinded to experimental hypothesis.

2.2.5. Adverse events

The instructors logged any adverse events that occurred.

2.3. Outcome measures

2.3.1. Perceived Stress Scale (PSS)

The PSS is a scale consisting of fourteen items that measure perceptions of stressful experiences during the past month (Cohen et al., 1983). We used the validated Swedish translation (Eklund et al., 2014). Participants rate items on a 5-point Likert scale, ranging from 0 (“never”) to 4 (“very often”). PSS scores range from 0–56, with higher scores indicating greater perceived stress.

2.3.2. Edinburgh Postnatal Depression Scale (EPDS)

The EPDS has ten items measuring the intensity of depressive symptoms during the past week. Each item is scored on a four-point scale ranging from 0 to 3 with minimum scores of 0 and maximum scores of 30. High scores indicate more depressive symptoms (Cox et al., 1987; Rubertsson et al., 2011).

2.3.3. Positive States of Mind (PSOM)

The PSOM is a six-item scale measuring positive experiences regarding focused attention, productivity, responsible caretaking, restful

Table 1
Overview over the MBCP-curriculum adapted for the present study.

Session	Theme and practices
1	Introduction to mindfulness and introduction of the teacher and the participants. Practice: mindfully eating a raisin and body scan.
2	Mind-body perspectives of childbirth regarding pain and fear, stress-hormones and the role of oxytocin and endorphins. Practice: body scan.
3	Coping with pain. Information about medical and non-medical analgesics. Practice: mindful yoga and pain-practice holding ice-cubes and exploring how pain and time is experienced differently depending on how and where one pays attention.
4	The role of the partner and how to best support a woman in labour. Practice: sitting meditation and pain-practice in couples supporting each other while holding one hand in ice water.
5	The needs of a newborn and new parents, secure attachment and child-development. Practice: sitting meditation and reflection on one's own childhood and expectations of parenthood and gender-roles.
6	Mindful communication. Practice: sitting meditation, lovingkindness meditation and interpersonal mindful speaking and listening inquiry reflecting on fear and joy.
7	Breastfeeding and the mind/body connection regarding prolactin, oxytocin, the let-down reflex and stress/anxiety versus calmness. Practice: sitting meditation.
8	Review of the course. Encouragement to continue practicing mindfulness, especially informal meditation with the baby after the birth. Practice: body scan.
Re-union	Experiences of childbirth and early parenthood are shared and approached with kindness and curiosity. Practice: sitting meditation/being with the baby.

repose, sharing, and sensuous nonsexual pleasure (Adler et al., 1998; Horowitz et al., 1988). Scores range from 5 to 30, where high scores indicate a high capacity to experience positive states of mind.

2.3.4. Five-Facet Mindfulness Questionnaire (FFMQ)

The Swedish Version of the FFMQ is a 29-item scale measuring five factors representing elements of mindfulness (Lilja et al., 2011). The items are rated on a 5-point Likert scale ranging from 1 (“never/almost never”) to 5 (“always”). Scores range from 29–145 and can be divided into sub-scores for each facet. The five facets are non-reactivity to inner experience, observing, acting with awareness, describing and non-judging of inner experience (Baer et al., 2006). High scores indicate a higher capacity to be mindful.

In the current study, internal consistency was good in all four measures (Cronbach alpha for PSS = 0.82, for EPDS = 0.85, for PSOM = 0.83, for FFMQ = 0.85 and FFMQ subscales = 0.82, 0.75, 0.84, 0.88 and 0.84). All four measures were used as continuous variables.

2.4. Statistical analyses

Data on interval scale levels are presented as means and either standard deviation (SD) or 95% Confidence intervals (CI) and hypotheses were tested using Student's *t*-test for independent samples. Cohen's *d* effect size was calculated with the formula $d = t * \sqrt{(96 + 97)/(96 * 97)}$.

As descriptive measure of sociodemographic data on nominal level, absolute and relative frequencies were used and Chi-Square or Fishers exact test were calculated.

Due to missing data from the post-intervention assessments, we used two strategies for analyzing the intervention effect. First, we performed an intention-to-treat (ITT) analysis, where outcome data lost to follow-up was imputed using multiple imputation with five iterations, which we ran in SPSS. All variables (demographic data and scores on baseline questionnaires) were included in the imputation model. Second, a “completer-analysis” was conducted including only those subjects who completed the questionnaires post intervention. We calculated a pre- to post difference (Δ = pre-treatment score – post-treatment score) for all outcome variables, such that more positive values in Δ PSS (Perceived Stress Scale) and Δ EPDS (Edinburgh Postnatal Depression Scale) suggest greater symptom improvement, and more negative values in Δ PSOM (Positive State of Mind) and Δ FFMQ (Five Facets of Mindfulness) indicate an increase in positive state of mind and mindfulness after treatment. Then we used independent samples *t*-tests to compare the pre- to post difference in PSS, EPDS, PSOM and FFMQ between intervention and active control.

2.4.1. Mediation analyses

First, we ran three models examining the mediating effects of changes in FFMQ (Δ FFMQ) in the association of treatment condition with changes in Δ PSS, Δ EPDS, and Δ PSOM in the completers dataset (one model per outcome measure). We also repeated these tests in the five iterations in the imputed dataset to check if results were robust. We hypothesized that receiving MBCP (coded as 1) versus Lamaze (coded as 0) would be linked to a stronger increase in FFMQ from the baseline to the post assessment. In turn, increased mindfulness (Δ FFMQ) would then predict more pronounced decreases in perceived stress (Δ PSS) and symptoms of postnatal depression (Δ EPDS) and increased positive states of mind (Δ PSOM) from the pre- to the post time point. To test these three models, we conducted bootstrap mediation models (Preacher and Hayes, 2008), which estimate direct and indirect effects of a predictor on an outcome measure using bias-corrected 95%-confidence intervals for all estimated effects generated from 10,000 bootstrap samples. We also generated a Sobel-test for each mediation model to obtain *p*-values based on normal theory tests for specific indirect effects.

Second, we tested the pre- to post differences in the five subscales of the FFMQ as parallel mediators in the association between treatment and the three outcome variables if we found significant indirect effects of the total FFMQ score.

For all mediation models, model residuals were visually explored for normality distribution and homoscedasticity in a full linear regression model with Δ PSS, Δ EPDS or Δ PSOM as outcome variables, and treatment and pre- to post difference in FFMQ as predictor variables. Furthermore, we ran models including potential covariates that were significantly associated with treatment and the respective outcome variable.

Last, we explored whether compliance with the MBCP-program associated with changes in psychological outcomes for the participants allocated to MBCP. This was analysed using four linear regression analyses, entering either Δ PSS, Δ EPDS, Δ PSOM, or Δ FFMQ as outcome variables and the number of sessions attended or the amount of informal or formal mindfulness practice in between sessions (minutes per week), as independent variables in all four regression analyses.

All analyses were performed using IBM SPSS Statistics Software (release 25.0.0.0; IBM New York, USA), including the SPSS macro Process for estimating indirect effects in mediation models (Hayes, 2012; Preacher and Hayes, 2008).

3. Results

The final analytic sample consisted of 193 women of which 85% had completed the post-intervention measure. Fig. 1 describes the sample size throughout all the study phases. Ten women allocated to MBCP and three women allocated to Lamaze dropped out after randomization but before the start of the intervention. The reasons for dropping-out at this point were either loss of interest, scheduling problems, or complications related to the pregnancy. Furthermore, 11 women from the MBCP-arm and five participants from the Lamaze-arm discontinued participation during the intervention due to pregnancy complications, fatigue, scheduling problems or disliking the intervention (Fig 1). There were also two women from each study-arm who completed the intervention but failed to respond to the post-intervention questionnaire. Regarding adverse events, one woman in the MBCP arm experienced increased anxiety during group meetings and therefore discontinued participation. There were no significant differences in socio-economic background or scores on the baseline questionnaires, between completers and dropouts.

3.1. Participants' characteristics

Table 2 presents the socio-economic background of the participating women. The majority of women were highly educated and lived with their partner. There were no significant differences in socio-economic background or scores on the baseline questionnaires between the two groups. Thus, sociodemographic background data were not included in our further analyses.

3.2. Intention to treat analysis

The MBCP group reported a larger reduction in perceived stress ($p = 0.038$, $d = 0.30$) and in depressive symptoms ($p = 0.004$, $d = 0.42$) compared to the Lamaze group. Furthermore, they reported a larger increase in positive states of mind ($p = 0.005$, $d = 0.41$) and in five facets of mindfulness ($p = 0.039$, $d = 0.30$). The change was largest in subscale 1 “Non-reactivity to inner experience” ($p = 0.001$, $d = 0.48$) (Table 3a).

3.3. Completers analysis

Similar to the ITT-analysis, the MBCP group reported a larger reduction in perceived stress ($p = 0.028$, $d = 0.35$) and in depressive

Table 2
Socio-economic background characteristics of all participants ($n = 193$).

Variable	MBCP ($n = 96$)	Lamaze ($n = 97$)	Condition Comparisons	df	p
Age, years					
Mean	32	32	$t = -0.52$	191	0.602
SD	3.86	4.14			
Civil status	n (%)	n (%)	$FET = 2.102$	3	0.607
Single	3 (3.1%)	2 (2.1%)			
Co-living	57 (59.4%)	60 (61.7%)			
Married	36 (37.5%)	33 (34.0%)			
Living apart	0 (0%)	2 (2.1%)			
Nationality			$FET = 1.267$	3	0.776
Swedish	86 (89.6%)	83 (85.6%)			
Swedish & other	3 (3.1%)	6 (6.2%)			
European	5 (5.2%)	6 (6.2%)			
Non-European	2 (2.1%)	2 (2.1%)			
Education ^a			$FET = 2.579$	3	0.636
Elementary	1 (1.0%)	0 (0%)			
Secondary	12 (12.5%)	12 (12.6%)			
College	83 (86.5%)	83 (86.6%)			
Work hours ^b			$\chi^2 = 5.199$	3	0.158
Up to 40 h/week	69 (72.6%)	70 (72.2%)			
More than 40 h/week	26 (27.4%)	27 (27.8%)			
Household income/month ^a			$FET = 4.247$	4	0.345
< 25 000 SEK	2 (2.2%)	0 (0%)			
25 - 40 000 SEK	15 (16.0%)	14 (14.4%)			
40 - 60 000 SEK	30 (31.9%)	27 (27.8%)			
> 60 000 SEK	47 (50.0%)	56 (57.7%)			
Prescribed drug use			$FET = 2.71$	4	0.589
None	66 (68.8%)	72 (74.2%)			
ADHD medication	0 (0%)	1 (1.0%)			
SSRI medication	8 (8.3%)	5 (5.2%)			
Sedatives	1 (1.0%)	2 (2.1%)			
Non-psychotropic	21 (21.9%)	17 (17.5%)			

^a Data is missing for two participants.

^b Data is missing for one participant. *FET*: Fisher's Exact Test.

symptoms ($p = 0.002$, $d = 0.48$) compared to the Lamaze group. Also, they reported a larger increase in positive states of mind ($p = 0.002$, $d = 0.50$) and in five facets of mindfulness ($p = 0.004$, $d = 0.46$) with the largest change in subscale 1 “Non-reactivity to inner experience” ($p < 0.000$, $d = 0.61$) (Table 3b).

3.4. Mindfulness as a possible mediator for intervention effects

Here we report the mediation analyses which were performed with the completers dataset as well as across the iterations in the imputed dataset as a check of result robustness. The correlation matrix showed that all outcome variables showed high inter-correlation. With regard to outcome variables, we found an association between work hours and

Table 3

Pre- and post intervention scores of the outcome measures; perceived stress (PSS), depressive symptoms (EPDS), positive states of mind (PSOM) and five facets of mindfulness (FFMQ). FFMQ is presented with subscales and sum. Group comparisons were performed by t -tests for independent samples of the pre- to post difference in score. Standard Deviation is only given in Completers-analysis since it is not available for datasets with multiple imputations, which was used for ITT-analysis.

Outcome measures	MBCP Pre-score Mean (SD)	Post-score Mean (SD)	Lamaze Pre-score Mean (SD)	Post-score Mean (SD)	Group effect p	df	d
3a) ITT-analysis							
PSS	26.85	20.76	26.97	23.33	0.038	352	0.30
EPDS	9.92	6.37	10.10	8.42	0.004	1790	0.42
PSOM	19.69	23.30	19.22	20.77	0.005	290	0.41
Subscale 1	15.81	18.86	16.34	17.61	0.001	142	0.48
Subscale 2	22.45	24.43	22.58	23.74	0.137	1342	0.21
Subscale 3	15.0	15.94	15.13	16.10	0.944	230	0.01
Subscale 4	21.83	22.83	21.40	22.30	0.841	236	0.03
Subscale 5	15.55	18.09	14.78	16.47	0.106	489	0.23
Sum FFMQ	90.65	100.15	90.24	96.22	0.039	145	0.30
3b) Completers-analysis							
PSS	26.85 (7.17)	20.78 (6.54)	26.97 (7.52)	23.17 (7.85)	0.028	163	0.35
EPDS	9.92 (4.83)	6.31 (4.10)	10.10 (5.10)	8.33 (5.48)	0.002	162	0.48
PSOM	19.69 (4.03)	23.05 (3.77)	19.22 (4.57)	20.81 (4.72)	0.002	163	0.50
Subscale 1	15.81 (4.19)	18.96 (3.19)	16.34 (4.09)	17.69 (4.32)	0.000	163	0.61
Subscale 2	22.45 (4.92)	24.49 (4.56)	22.58 (4.20)	23.83 (4.68)	0.054	163	0.30
Subscale 3	15.0 (2.86)	15.88 (2.61)	15.13 (3.68)	16.27 (3.53)	0.703	163	0.06
Subscale 4	21.83 (4.60)	22.76 (4.13)	21.40 (4.46)	22.42 (4.12)	0.414	163	0.13
Subscale 5	15.55 (4.05)	18.48 (4.22)	14.78 (3.80)	16.50 (4.07)	0.047	163	0.31
Sum FFMQ	90.65 (12.41)	100.57 (12.60)	90.24 (13.29)	96.71 (13.56)	0.004	163	0.46

The five subscales in FFMQ are 1) non-reactivity to inner experience, 2) observing, 3) acting with awareness, 4) describing and 5) non-judging of inner experience.

$\Delta PSS\ t(163) = -2.300$; $p = 0.023$; more work hours were related to greater decrease in PSS from pre to post. Secondary analyzes in which we statistically controlled for work hours did not reveal any changes in the interpretation of the results regarding the total, the direct and the mediation effects.

3.4.1. Perceived stress

The effect of participating in MBCP on perceived stress was fully mediated by the five facets of mindfulness (Effect = 1.623; SE (bootstrapping) = 0.675; 95%- confidence interval (bootstrapping) = 0.487 to 3.169; $\beta = 0.107$; $p = 0.008$; $R^2(\text{mediation}) = 0.027$). This result was repeated in four of the five iterations. The mediation was driven by the subscales “non-reactivity to inner experience” and “non-judging of experience”. Full regression models suggested that residuals were normally distributed with no standardized residual values $> |3.0|$. Secondary analyzes in which we statistically controlled for work hours did not reveal any changes in interpretation of the results regarding the total, the direct and the mediation effects, except for the mediation through the subscale “non-judging of experience” of the FFMQ questionnaire, which lost significance (Effect = 0.442; SE(bootstrapping) = 0.333; 95%- confidence interval (bootstrapping) = -0.001 to 1.335; $\beta = 0.031$). (Table in appendix)

3.4.2. Symptoms of depression

Again, the intervention effect on symptoms of depression was fully mediated by FFMQ (Effect = 0.972; SE (bootstrapping) = 0.391; 95%-confidence interval (bootstrapping) = 0.317 to 0.399; $\beta = 0.109$; $p = 0.008$; $R^2(\text{mediation}) = 0.041$). This result was repeated in four of the five iterations. Here, the effect was driven by the “non-judging of experience” sub score of the FFMQ questionnaire (Table in appendix). Regression models suggested two participants with model residuals $> |3.0|$, whose exclusion did not change interpretation of the results.

3.4.3. Positive states of mind

Finally, we also found that the increase in positive states of mind was mediated by FFMQ and this was also the case in four of the five iterations. Although there was a significant indirect effect through FFMQ (effect = -0.898; SE (bootstrapping) = 0.375; 95%-confidence interval (bootstrapping) = -1.711 to -0.238; $\beta = -0.098$; $p = 0.012$; $R^2(\text{mediation}) = 0.040$), the direct effect remained significant (Table in appendix), suggesting that the indirect path did not fully mediate the association between treatment and $\Delta PSOM$ (partial mediation). Exclusion of two participants with model residuals $> |3.0|$ did not change interpretation of the results. See Fig. 2 for a visual presentation of the mediation models.

3.5. Compliance

Finally, compliance was studied among the completers in the MBCP group. Of the eight sessions in the MBCP-intervention participants attended an average of 6,81 sessions ($SD = 1,202$). In between sessions they practiced formal mindfulness for an average of 62,2 min per week ($SD = 46,89$) and informal mindfulness for 41,03 min per week ($SD = 43,8$). Linear regression analysis of compliance in the MBCP group showed that none of the assessed compliance measures (attendance, formal and informal mindfulness practice) had any significant effects on the changes in outcome scores on PSS, EPDS, PSOM or FFMQ.

4. Discussion

This study found that participants randomized to MBCP reported significantly larger reduction in perceived stress and depressive symptoms compared to participants randomized to an active control treatment (Lamaze). MBCP participants also reported significantly larger increase of positive states of mind and mindfulness, as assessed with the FFMQ. The largest between group differences were found for the FFMQ

sub-scale “non-reactivity to inner experiences” with the largest increase among participants in MBCP. The treatment effects of MBCP on perceived stress, depression symptoms, and positive states of mind were possibly mediated by the five facets of mindfulness, of which the facet “non-reactivity to inner experience” indicated the strongest mediating effect on perceived stress, and the facet “non-judging of experience” the strongest mediating effect on depression symptoms.

To the best of our knowledge, this study is the first to compare the effects of MBCP with an active control group and a sample size providing enough power to detect medium to large effects. Furthermore, this study explores the mediating effects of mindfulness on psychological outcomes.

The original MBCP-program consists of nine sessions and a full day (Bardacke, 2012). We wanted to test if eight meetings could be effective in improving psychological wellbeing and preventing perinatal depression and stress, while also being feasible in an arena with constrained provider resources. When considering the length of the program we also have to consider the participants’ ability to take part in it. It is worth noting that there were more participants lost to follow-up from the intervention (MBCP) condition (22%) compared to the control condition (8%), partly due to scheduling difficulties, indicating that a shorter program was more feasible for the participants. Whether or not a further shortening of the MBCP program would result in higher completion rates with comparable effectiveness remains to be examined in future studies.

Our findings are in line with previous studies that indicate that antenatal MBI’s may have a positive impact on perceived stress and depression (Badker and Misri, 2017; Hall et al., 2016; Matvienko-Sikar et al., 2016; Taylor et al., 2016). We also extend previous findings by showing increases in positive states of mind. This is of interest in light of evidence showing that increased positive affect may have a stronger association with positive health outcomes compared to decreased negative affect (Danner, 2001; Ostir et al., 2001). Smith and Stephens have also found that maternal positive affect may buffer the effect of parental stress on maternal sensitivity (Smith and Stephens, 2018). Interventions that not only decrease negative affect but also promote positive affect during the perinatal period could therefore be particularly valuable.

The mediation analyses imply that the change in FFMQ-scores possibly had a mediating effect on the changes in the other psychological outcomes. More specifically, it was the increase in the subscale “non-reactivity to inner experiences” and “non-judging of inner experiences” that was significant with respect to the mediation of the decrease in perceived stress. Likewise, the subscale “non-judging of inner experiences” was significant regarding the mediation on the decrease in depressive symptoms.

This suggests that MBCP influences psychological well-being through increased mindfulness, which is in line with previous studies in other populations (Bränström et al., 2010).

The active control group also increased their score in FFMQ from baseline to post-intervention, which raises the question of whether the Lamaze intervention also caused an increase in mindfulness or if simply pregnancy in itself brings about changes, which increase mindfulness as the gestational weeks go by.

Tracking the amount of home practice completed by the participants in MBCP made it possible to explore if this moderated the positive effects of the intervention. The participants reported a large variation in the amount of home practice that they engaged in between sessions, and the average level was only 35% of what the program asked of the women. Our study did not find any association between amount of practice or level of attendance at group sessions and change in the outcomes. This finding suggests that it is of value to participate in MBCP even with a low amount of home practice, and even if it is not possible to attend all eight sessions. However, finding ways of motivating participants in MBCP programs to engage more may still lead to larger effects, since a small but significant association between the

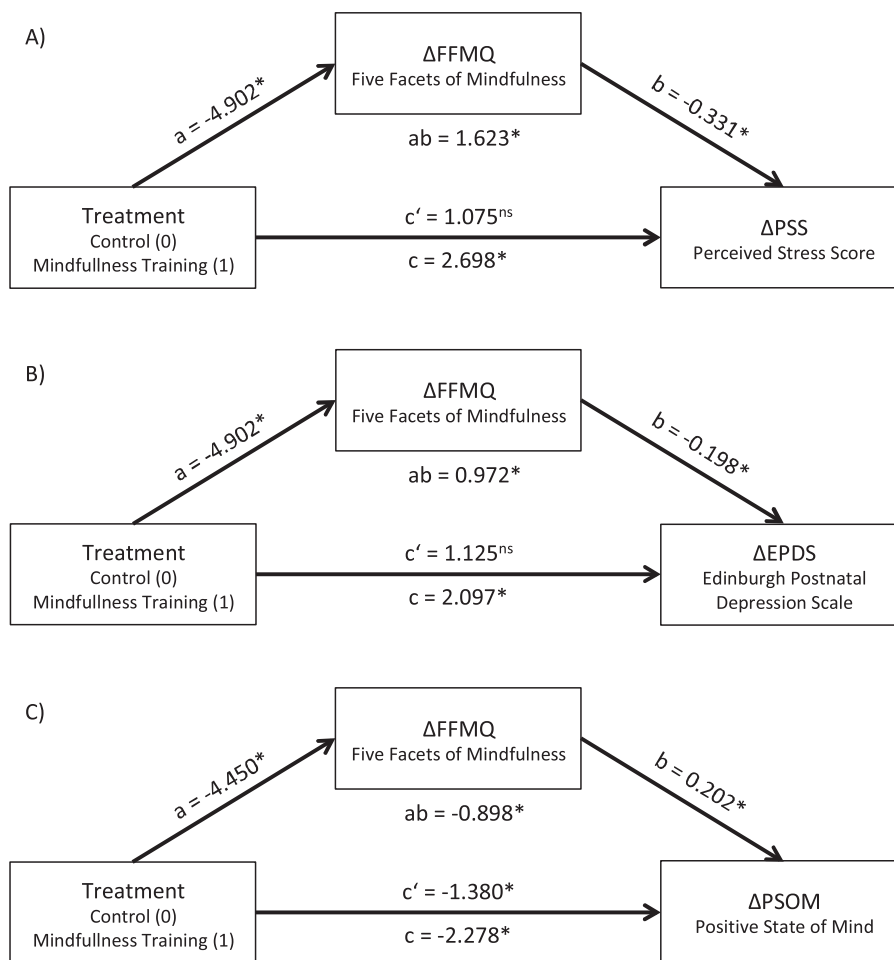


Fig. 2. Increased FFMQ-score mediating the difference between MBCP and Lamaze in A) decrease in stress, B) decrease in depression and C) increase in positive states of mind. Provided are unstandardized path coefficients with asterisk indicating significant effects ($*p < 0.05$). a = effect of treatment on FFMQ, b = effect of FFMQ on outcome, ab = indirect effect of treatment on outcome through FFMQ, c = total effect of treatment on outcome, c' = direct effect of treatment on outcome. Abbreviations: Δ : difference pre-assessment - post-assessment; β : completely standardized effect; CI: confidence interval; EPDS: Edinburgh Postnatal Depression Scale; PSOM: Positive State of Mind; PSS: Perceived Stress Scale; SE: Standard error.

amount of formal practice and positive intervention outcomes has been found in other studies (Parsons et al., 2017).

5. Limitations

In our mediation analyses, the mediator and the outcome were both measured at the same point in time. However, Hayes (2013) emphasizes that the measures of the mediator should precede the outcome measures in time. Thus, we cannot eliminate alternative explanations for the relationship between changes in mindfulness and changes in stress and depressive symptoms, since we lack temporal precedence of mediator over outcome. Consequently, our study does not provide sufficient evidence to conclude that increased mindfulness is the causal mechanism explaining the improvements in psychological outcomes observed among the MBCP participants. However, our results give partial support for such a proposed causal process.

Further limitations of this study are that the participating women mainly consisted of highly educated urban residents. It is warranted to evaluate this program with a more diverse population. Also, the number of sessions when the groups met differed between conditions and this could possibly have affected the findings. Furthermore, our outcome variables were measured using self-report questionnaires which may be subject to reporting bias, and this can be particularly problematic regarding the measurement of mindfulness (Goldberg, 2016). Participants with and without mindfulness training may interpret the questions differently and it is unclear in what direction a better understanding of mindfulness could influence these self-reports. It is possible that the intervention group could have over-reported mindfulness in the follow-up due to wishful thinking or their score could be more accurate compared to the control group's score, due to them having become

more aware of when they are truly mindful.

6. Conclusion and clinical relevance

Our results suggest that MBCP is more effective in decreasing perceived stress and perinatal depression symptoms compared to a Lamaze childbirth program. The results also contribute to our understanding of the underlying psychological mechanisms through which the reduction of stress and depression symptoms may operate. Thus, this study increases our knowledge about efficient intervention strategies to prevent perinatal depression and promote mental wellbeing among pregnant women.

We aimed to target pregnant women at risk of depression and an ongoing major depressive episode was an exclusion criterion. However, evidence suggests that MBI's may also be an effective treatment for postpartum depression and anxiety for patients with current clinical diagnoses (Shulman et al., 2018). Thus, for future implementation, MBCP could be considered as a universal health promoting intervention or as a prevention strategy for women at risk, as well as a possible treatment for those suffering from stress, depression or anxiety disorders during pregnancy. An advantage of MBCP is that it provides a non-pharmacological option for pregnant or lactating women who are less inclined to consider anti-depressive medication.

Future studies should use assessments of outcome and potential mediators at multiple time points, so that they can take the temporal component into account in analyses of causality of the mechanisms suggested by this study. Moreover, it is also of interest to evaluate if the beneficial effects of MBCP persist over time, if they are generalizable to more vulnerable populations (e.g., high risk pregnancies), and to explore whether or not there are any effects on childbirth self-efficacy,

breastfeeding, child health outcomes and behavioural efficacy measures, such as the relationship between mother and baby.

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Declaration of Competing Interest

Regarding conflicts of interest in the study two of the authors: Niemi and Lönnberg, are MBCP providers.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at [doi:10.1016/j.jad.2019.10.048](https://doi.org/10.1016/j.jad.2019.10.048).

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