

KAROLINSKA INSTITUTET Institutionen för kvinnor och barns hälsa Enheten för reproduktiv hälsa Kurs: Examensarbete i sexuell, reproduktiv och perinatal hälsa, 15hp

Effekter av en mindfulness-baserad föräldraförberedande intervention på mor-barn samspel

En randomiserad kontrollerad studie

Effects of a mindfulness-based childbirth and parenting intervention on mother-child interaction

A randomized controlled trial

Examensarbete i sexuell, reproduktiv och perinatal hälsa, 15 hp (Avancerad nivå), år

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Sammanfattning

Bakgrund: Depression under graviditet kan ha negativa effekter på moderns och barnets hälsa samt mor-barn samspelet. Tidigare forskning efterfrågar fler prenatala interventioner för att reducera stress och depression, således har Mindfulnessbaserade interventioner (MBI) visat sig ge resultat. Det föreligger kunskapsluckor huruvida mindfulness under graviditet påverkar mor-barn samspel.

Syfte: Primära syftet var att utforska om en mindfulnessbaserad föräldraförberedande intervention under graviditeten hade effekt på mor-barn interraktion 12 månader efter barnets födelse. Det sekundära syftet var att se om moderns psykologiska tillstånd kunde relateras till mor-barn samspelet.

Metod: En randomiserad kontrollerad studie, där interventionsgruppen deltog i en MBI och jämfördes med en profylaktisk föräldraförberedande kurs (Lamaze). Studien bestod av ett delurval från en större studie. Deltagarna fyllde i självskattande formulär med psykologiska skalor vid interventionens start, efter interventionen, sex, nio och 12 månader efter förlossning. Därefter videofilmades 65 mor-barn par under lek som varade i fem minuter. Filmerna observerades av erfarna kodare och skattades med hjälp av "Parent Child Early Relational Assessment" (PCERA), ett verktyg som utvärderar samspelet från föräldra-, barn- och dyadperspektiv.

Resultat: Det var ingen skillnad i resultatet mellan grupperna utefter PCERA, dock fanns signifikanta korrelationer mellan de psykologiska skalorna och PCERA klustren: "Positive affect parent" (P=<0,01) och "dyadic mutuality" (P=<0,01).

Slutsats: Resultatet indikerade att vissa aspekter av mor-barn samspel påverkades positivt av hög självskattning i mindfulness och positiv sinnesstämning hos mödrarna. Effektstorleken var liten, därför var slutsatser svåra att dra, varför starkare grundad forskning uppmuntras.

Nyckelord: Graviditet, intervention, mindfulness, mor-barn samspel

Abstract

Background: Depression during pregnancy can have negative effects on maternal and child health outcomes as well as mother-child interaction. Previous research has requested further prenatal interventions aiming to reduce stress and depression and Mindfulness based interventions (MBI) have proven successful. There is a lack of research into how mindfulness during pregnancy affects mother-infant interaction.

Aim: The primary aim was to investigate whether a mindfulness-based parenting intervention provided during pregnancy had an effect on mother-infant interaction at twelve months postpartum. The secondary aim was to see whether mothers' psychological measures related to the mother-child interaction.

Method: A randomized controlled trial, where an MBI group was controlled with a Lamaze prophylactic course. This study had a subsample of a larger study. Participants filled out psychological scales questionnaires at baseline, post intervention, six, nine and twelve months postpartum. Thereafter 65 participants were filmed during free play with their infants for five minutes. The video footage was observed by experienced coders and assessed with the "Parent Child Early Relational Assessment" (PCERA), evaluating interaction from the parent's, child's and dyad's point of view.

Results: No significant differences in PCERA outcomes between groups, however there were significant correlations between the psychological scales and the PCERA clusters: "Positive affect parent" (P=<0,01) and "dyadic mutuality" (P=<0,01).

Conclusion: The results indicated that the mothers' self-reporting higher scores of mindfulness and positive states of mind positively affect some aspects of mother-child interaction. However, low effect size inhibited abilities to draw conclusions and further studies with stronger power are encouraged.

Keywords: Pregnancy, intervention, mindfulness, mother-child interaction

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Introduction

Mindfulness is "the awareness that emerges through paying attention on purpose, in the present moment, and nonjudgmentally to the unfolding of experience moment by moment" (Jon Kabat-Zinn, 2003, p 145).

With roots in China, Vietnam, India, Nepal, Japan and other parts of east Asia, mindfulness originates from ancient meditation. In short, one practices mindfulness by focusing on the thoughts presenting themselves and acknowledging their existence nonjudgmentally, with the aim to incorporate this strategy in everyday life in order to become *mindful* (Kabat-Zinn, 2003).

Over the past decades Mindfulness, along with other related practices of eastern origin, such as yoga and meditation, has grown to be a popular exercise - both praised and heckled (Bratt, 2007; Hilton, 2019; Lofors & Lerner, 2010). The method and its therapeutic potential have been studied since the 1970's and praised for its versatile use (eg psychiatric therapy, combat training and business management) (Pickert, 2014). These appraisals have not arrived unnoticed nor non opposed (Purser, 2019; The Guardian, 2019). Purser (2019) points to the overzealous mindfulness supporters spreading its' panacea-like effects and warns of how the non-judgmental awareness in mindfulness won't solve ones' issues, just learn to live with them and "disable ones' moral intelligence". Often referred to as the founding father of modern mindfulness, Jon Kabat-Zinn, has been criticized for selling a fast food-version of meditation, McMindfulness, as an all round quick fix (Neale, 2011). Williams and Kabat-Zinn (2011) refers to it as repackaging a useful product, meditation, for people who might not be so keen on meditation. Evidently, mindfulness continues to intrigue. The amount of research on its effects has exploded (Williams & Kabat-Zinn, 2011) and Sweden has seen it being implemented into health care on a steadily growing rate. The recent finds presented in our study sparks curiosity and enthusiasm to probe further into the prospects of mindfulness in maternal health care.

As midwives to be, the need for (and right to) preventive care is clear when looking at the expanse and harm of maternal mental illness and the risk of adverse effects on children in a longer perspective. Therefore, the present study reviews a mindfulness-based intervention for pregnant women who experience stress and/or are at risk of depression in the perspective of its possible effects on mother-child interaction. Our hypothesis is that mindfulness can help improve the prospects of preventing the mother's from developing depression and thus reduce the risk of negative outcomes in the child.

1. Background

1.1. Stress and depression

Worldwide, depression affects 300 million people, which makes it one of the main threats to global health (World Health Organization [WHO], 2017). In Sweden, depression is one of the most common diagnoses and the Swedish public health agency confirms that more women than men are diagnosed with depression, nearly one in four women (24 %) claim to have been diagnosed with depression at some stage in their lives (Folkhälsomyndigheten, 2017). Over the years, the same agency confirms that there has been an increased incidence of depression and depressive symptoms, such as anxiety and stress (Folkhälsomyndigheten, 2016a).

Levi (2005) describes that stress represent a globally growing problem on both a societal and individual level. In addition, Folkhälsomyndigheten (2019) states that the prevalence of stress increases in the Swedish population, and in 2018, 16 percent (age 16-84) reported feelings of stress, of whom women in early adolescence (16-29) was target as the group with highest frequencies (35 percent). There is no uniform definition of stress, but several studies refer to stress as the "revving" of an organism and often this revving is purposeful and useful, but not always (Levi, 2005). A chronic stress set in the human body will inhibit recovery of organs and biological processes, which will eventually lead to the occurrence of both physical and mental damage (Leopardi, 2016). Furthermore, stress can to varying degrees cause or exacerbates mental illness of various kinds, including depression (Leopardi, 2016; Levi, 2005). Similary, Rickert-Olsson (2019) states that depression and stress are two conditions that are tightly linked to one another, where stress can trigger depression and depression can trigger stress.

1.2. Stress and depression during pregnancy and the effects on the newborn baby There is evidence that shows that the relationship between mother and child establishes during pregnancy. The mother undergoes several psychological phases that help her prepare to become a mother and help her attach to the fetus and later to the newborn baby (Ryding, 2014). Studies show that a woman with depressive symptoms can have difficulties going through these psychological phases completely, which can impede the connection with the newborn baby (Ryding, 2014; Stein et al., 2014). In turn, research indicates that newborns with poor attachment to their mothers are less equipped for cognitive and emotional development; the child can develop depressive symptoms, anxiety problems or behavioral disorders later in life (Chase-Brand, 2008; Stein et al., 2014). Futhermore, Stein et al. (2014) note that postnatal depression can (influence is low to moderate in extent) lead to language difficulties and have a negative effect on IQ-scores as well as ability to learn and achieve goals for the child.

1.2.1. Stress, depression and mother-child interaction

Attachment is the secure base a caregiver provides for its child, which allows the child to explore the world and thereafter return to the caregiver to seek safety and comfort. Attachment is built on the caregivers' responsiveness, continuity in behaviours and sensitivity for the child and its key signals (Stein et al., 2014). These features of behavior are essential for developing a good mother-infant relationship, including bonding and attachment in the mother-infant dyad (Ainsworth et al., 1978). On the contrary, an insecure and disorganised mother-child pattern of behaviours have been noticed when mothers suffer from antenatal depression, depressive symptoms or anxiety (Hakanen et al., 2019; Stein et al., 2014). After birth, postnatal depression can be characterized by insensitivity, less responsiveness and continuity from the mother in the mother-child interaction (Stein et al., 2014).

1.3. A way to prevent and treat

Due to the extensive evidence pointing towards long lasting negative consequences of prenatal depression, such as adverse child outcomes and maternal suffering, Stein et al. (2014) and Hakanen et al. (2019) further advocate the need to start prioritizing health promoting prenatal interventions. According to the Public Health Agency of Sweden, Swedish municipalities are increasingly aware of how a pregnant woman's health may impact the developing fetus (Folkhälsomyndigheten, 2016b). The agency further clarifies that the municipalities should strive to work preemptively to support families where one or two parents are suffering from depression (Folkhälsomyndigheten, 2017). Furthermore, the Public Health Agency of Sweden published a literature review, in which they conclude that preventive interventions aimed for the parents (especially the mother) may reduce the risk of depression and depressive symptoms for the child (Folkhälsomyndigheten, 2016b).

1.3.1. Mindfulness based interventions (MBI)

Research has shown that MBIs has the potential not only to support one family member suffering from mental or psychological conditions, but also to help whole families (Bögels & Emerson, 2019; Duncan & Bardacke, 2010). More specifically, the evidence points to mindfulness not only affecting how we relate to ourselves, but how we relate to others (Bögels & Emerson, 2019).

Mindfulness-Based Stress Reduction (MBSR) and Mindfulness-Based Cognitive Therapy (MBCT) are common therapeutic treatments in health care and have shown to decrease the risk of relapse into depression as well as provide relief of depression, anxiety and stress related health issues (Baer, 2003; Khoury et al., 2013). Socialstyrelsen (2017) recommends MBSR and MBCT as additional therapy (combined with for example cognitive behavioral therapy) for patients diagnosed with anxiety and depression related illnesses.

As stated in Duncan and Bardacke (2010) the Mindfulness Based Childbirth and Parenting (MBCP) program was developed by Nancy Bardacke in 1998 to promote family health and well being by introducing mindfulness during pregnancy, childbirth and early parenting. The study showed that MBCP improved stress handling and alleviated pregnancy-induced anxiety. A review (Lavender, Ebert, & Jones, 2016) further shows MBCP to hold promising effects on pregnant women's thought patterns, by offering methods to tackle negative thoughts and challenging situations, which led to a decrease in depressive symptoms. Similarly, another study showed that the participants in the MBCP intervention had a larger decrease of depressive symptoms, compared with an active control group (Lamaze prophylactic course). Besides that, MBCP led to a greater increase of mindfulness and positive states of mind (Lönnberg et al., 2020).

1.4. Mindful parenting and mother-child interaction

Duncan, Coatsworth and Greenberg (2009) developed a five-dimensional model in which mindful parenting can be explanied as an extension of mindfulness in the context of parent-child relationships. More specifically, the parent, no matter the situation, brings awareness to the parent-child relationship by listening with full attention while interacting with the child, and shows emotional awareness and compassion by holding a non-jugmental and accepting attitude during the interactions. There is much research showing that high self-reported feelings of mindfulness in the parent has a variety of positive outcomes for the child and the mother-child relationship (Bögels & Emerson, 2019; Duncan et al., 2009; Hertz, Laurent & Laurent, 2014; Siu, Ma & Chui, 2016). For example, an observentional study investigating the mother-child interaction in relation to mothers' self-reported levels of mindful parenting, showed that mothers with higher mindful parenting ratings exhibited more positive mother-child interactions (Duncan, Coatsworth, Gayles, Geier & Greenberg, 2015).

1.5. Problem definition

Research indicates that pregnant women who are stressed and depressed do not interact with their child to the same extent as non-depressed/stressed mothers. Adverse mother-child interaction can negatively affect child outcomes and some children end up showing signs of poor attatchment. Mothers who are stressed and run a risk of developing depression may benefit from receiving an intervention to improve interaction with their child. However, little is known about what interventions might work best on this population. Thus, a prenatal MBI for women who exhibit or are at risk of developing depressive symptoms, may contribute to improve these women's health, which indirectly might decrease the risk of adverse consequences for the child and support mother-child interaction.

2. Aim

-The primary aim was to examine whether a mindfulness-based parenting intervention provided during pregnancy has an effect on mother-infant interaction at twelve months postpartum.

-The secondary aim was to study whether mothers' psychological outcomes during pregnancy and the first year postpartum relate to some aspects of mother-infant interaction at twelve months postpartum.

3. Method

3.1. Study design

A Randomized Controlled Trial (RCT) with an experimental parallel design was conducted aiming to compare the effects of an MBCP intervention with an active control group, Lamaze prophylactic course. With regards to the study purpose, RCTs are highly regarded for their ability to establish causal effect of an intervention by comparing its outcomes with the outcomes of a control group (Kabisch, Ruckes, Seibert-Grafe, & Blettner, 2011; Stang, 2011). RCTs are considered the gold standard of experimental research (Harbour & Miller, 2001; Jüni, Altman, & Egger, 2001).

3.2. Procedures and sample

Prior to the study, a power analysis was conducted according to data from Duncan and Bardacke (2010). A power analysis calculates the number of participants required to saturate the results and reduce the margin of error in order to reject the null hypothesis (Cohen, 1992). In accordance with M. Niemi (personal communication, 15th februari 2020): In the power analysis a medium to large effect size (2/3 standard devations) was desired and calculated n = 15.7 (1/.66) = 36.04 (rounded to 40). The adjusted group is $n^* = n/(1-.10)2 = 49.38$, which rounds to 50 participants in each group. However, adjusting for attrition, a 40% participation rate from the whole sample was anticipated for videofilming.

Between 2014 and 2016, recruitment took place in eight maternity health clinics in Stockholm County. In cooperation with the clinics, letters introducing the project were sent to these pregnant women around gestational age 15-22 weeks (Appendix 1). The women who were interested filled in an online questionnaire from which the researchers were able to determine if the women met the inclusion criteria for the study. In the letters, the researchers asked specifically for women who felt the need of extra support during pregnancy to participate, as the main outcome of the study was to evaluate if MBCP could reduce stress in nulliparous women with depressive symptoms, who had an increased risk of perinatal stress and depression. Thus, women were selected if they had a history of depression or anxiety and/or early life adversity and/or current high levels of perceived stress.

The eligibility criteria was defined as a) rating six points or higher on the perceived stress scale (S. Cohen, Kamarck, & Mermelstein, 1983), b) had contact with health care concerning their own mental health (yes/no, if yes - two following questions were asked about when and for what), c) experience of depression or anxiety earlier in life (yes/no, yes being an eligibility criteria), or d) a total rating of six points or higher (on three selected items) in the childhood trauma questionnaire (Bernstein et al., 2003), in which high scores indicate early life adversity, e) fluent in Swedish, f) no experience of mindfulness training or meditation (yes/no), g) no present psychotic symptoms or major depressive episodes reported in criteria b (given the focus on prevention rather than treatment, presently diagnosed women were excluded), h) a minimum age of eighteen years. If not eligible, the women were informed of exclusion from the study by email and thanked for showing interest in the study. If eligible, women were contacted via telephone and invited to meet a research team member along with their partner (if applicable). During the meeting, the participants recived information that they would be a part of a larger study and signed a written informed consent to participate (Appendix 2). The participants were blinded for the hypothesis of the study, and they did

not receive any reimbursement, other than a free MBCP or Lamaze class (depending on randomization). When the assessment was finished, an external administrator, who was completely blinded to the study, randomized participants to groups with help from a randomization sequence in the SPSS software. In total, there were 193 participants in the RCT, 96 in the MBCP group and 97 in the Lamaze group. Finally, a total of 65 participants were included in the present study, 26 from MBCP and 39 from Lamaze groups (for an overview of the selection process, please see Figure 1). Drop out was most commonly due to outdated contact details and participants having moved out of Stockholm. For a detailed description of the sample and the complete study protocol, please see Lönnberg et al. (2020).

3.2.1. Intervention group - A Mindfulness Based Childbirth and Parenting Class

The MBCP program was adapted for Swedish settings (Lönnberg et al. 2020). The course was held by three MBCP educated teachers who had numerous years of experience in meditation. The teachers held regular meetings to uphold consistency in methodology and procedure to ensure fidelity to the intervention. The groups consisted of eight to twelve women, where the majority (89%) participated accompanied by their partner. The intervention was divided into eight course sessions lasting for two hours and fifteen minutes, once every week. For detailed content of the sessions, please see Appendix 3. Birthing education was interwoven with mindfulness exercises. Apart from participating in the course, the participants were encouraged to be conscious of fetal movements and to meditate thirty minutes a day with audio-recorded assistance. After childbirth, a reunion was arranged for the course participants.

3.2.2. Control group– Lamaze Prophylaxis Course

To be able to compare the course results, this study was conducted with an active control group (Mohr et al., 2009). Lamaze prophylaxis courses are common and well-appreciated parturition preparatory courses in Stockholm. The Lamaze course in this study took place at three occasions, lasted for three hours each and included the partner to the birth mother. The Lamaze courses provided education in breathing and relaxing exercises which have been shown to affect different aspects during childbirth; for example physiological aspects where breathing exercises increase oxygen intake and relaxes the muscles; cognitive aspects through focus on breathing and relaxation; and psychological aspects to relieve fear and increased sensation of control. This can aid the woman/mother to cope with pregnancy/birth pains and increase the antenatal and perinatal experiences. The program also included information on breast-feeding as well as the infant's sleep

and eating routines. The Lamaze course teachers were educated and experienced in Prophylaxis (AnnasProfylax, 2019).



Figure 1. Flowchart showing the sample procedure. Modified version of Lönnberg et al. (2020) flow diagram.

3.3. Pre-data collection

At inclusion to the study, participants provided information on their age, civil status, nationality, education, work hours, household income and prescribed drugs. The women also filled in psychological scales in questionnaires at baseline, post intervention and at six, nine and twelve

months postpartum. There were four questionnaries, of which two were considered to concern mindfulness (Postive States Of Mind (PSOM) questionnaire and Five-Facets of Mindfulness Questionnaire (FFMQ)) and were therefore chosen for the present study.

3.3.1. Positive States Of Mind (PSOM)

The PSOM six-item scale measures positive experiences. Focused attention, restful repose, sharing, productivity, repsonsible caretaking and sensuous nonsexual pleasure are scored. Total score ranges from five to thirty (Adler, Horowitz, Garcia, & Moyer, 1998; Horowitz, Adler, & Kegeles, 1988). Higher scores indicate higher capacity to experience positive states of mind and vice versa.

3.3.2. Five-Facets of Mindfulness Questionnaire scale (FFMQ)

The Swedish version of the FFMQ measures five factors representing elements of mindfulness, on a 29-item scale (Lilja et al., 2011). On a five-point Likert-scale, the items are rated from one ("never/almost never") to five ("always") with a score total of 29-145, where high scores indicate high capacity to be mindful. The five facets are observing, acting with awareness, non-judging of inner experience, non-reactivity to inner experience and describing. Each facet represents a set of sub-scores which can be individually evaluated (Baer, Smith, Hopkins, Krietemeyer, & Toney, 2006).

3.4. Data collection

Data collection took place from 2016 until 2018 (MBCP and Lamaze classes were given to groups of approximately ten participants and their partners at a time). The families were contacted via email with an invitation to participate in the last part of the trial at twelve months after birth. The invitation included ethical considerations and assurance of confidentiality. The families were asked to contact the research team to arrange a suitable time for the video recording to take place. If letters were unanswered, additional contact was pursued via telephone.

All recordings of mother-infant interaction took place in the same room at Karolinska Institutet, Stockholm. Mothers were videotaped for five minutes while playing in an unstructured manner with her twelve-month-old child. All mothers and their children got the same set of toys to play with during the recording. Toys included a ball, Duplo Lego, Pop-Up Farm Animal and a soft toy.

3.5. Outcome measure

3.5.1. Parent-Child Early Relational Assessment (PCERA)

The PCERA (Clark, 1985) is an instrument designed and used to evaluate the affect and behavior in parent-child interactions, from the parent's, child's and dyad's perspective. A five-minute video recording is made of the mother and child during free play (as in the current study), feeding, and/or a structured task is performed. The video recording is then observed where a variety of behaviors are assessed. PCERA has been revised in 2006, 2010, and 2015. It is considered to have high validity and reliability. The 65 variables of Clark's (1985) PCERA manual are presented in Appendix 4, and have, by Clark, been categorized into eight clusters; Parent's positive affect, parent's negative affect, parent's intrusiveness, infant's positive affect, infant's quality of play, infant's dysregulation, dyadic mutuality and dyadic disorganization. The same clusters were used for the present study. Cronbach's alpha values were calculated for these eight clusters. They are presented in Table 3. According to Tavakol and Dennick (2011), Cronbach's alpha is a measure of internal consistency, that is, how closely related a set of items are as a group. It is considered to be a measure of scale reliability. What constitutes an acceptable Cronbachs alpha can differ, but generally 0.7 and above is considered to be acceptable, 0.8 and above is good, 0.9 and above is best (Brace, Kemp & Snelgar, 2016; Tavakol and Dennick, 2011).

3.5.2. Procedure of the PCERA

According to J. Lindstedt (personal communication, 28th February 2020): The PCERA-situations were rated according to the manual of Clark (1985) by two trained coders who were blind to participants' treatment group status, background variables and any information concerning the children (except the age of the children). The main coder (J.L.) analyzed all the videotapes (n=65) and twenty percent of the tapes were double-scored by the second coder (S.A.-B.). Drift sessions were held during the assessment process, to maintain inter-rater agreement. The items of the PCERA were rated on a five-point Likert scale, where one presents a lack of the evaluated phenomenon and five presents frequent occurrence of the phenomenon. Clinically the scores one and two indicate an area of concern, a score of three an area of *some* concern, and the scores four and five indicate an area of strength. Before performing inter-rater reliability calculations, the items were recoded into a three-point Likert scale: the scores one and two were combined into one, three into two, and four and five were combined into three. The inter-rater agreement between the two coders was 80.2 percent, which according to McHugh (2012) is substantial agreement, close to

near perfect agreement (>81 percent). The original five-point PCERA-scores were used in the data analyses. Before the analyses, the items were combined into scales based on the original scales of Clark (1999).

3.6. Statistical analyses

After receiving the assessment scores in an excel file, the authors worked in the following way: Following the CONSORT, step one of the comparative analysis was gathering all the unidentified data from the PCERA outcomes along with maternal and child background data and compile into one file (Schulz, Altman, & Moher, 2011). Step two was serial manual checks to confirm correct table values. When the data was clarified and cleaned, the final step was transferring data into SPSS version 26, where ID's were combined with allocation and prepared for analyzing.

For comparing the group of women who did not do the PCERA follow up with the women who attended the pcera follow upå, t-tests were performed. Because the PCERA study subgroups were small and showed a skewed distribution, we applied nonparametric statistical methods for all other analyses (Brace, Kemp & Snelgar, 2016; Bell, Kenward, Fairclough & Horton, 2013; Olsson & Sörensen, 2011). Socioeconomic data, measures from the psychological scales and PCERA were measured by Descriptive Statistics-Frequences and reported as median and interquartile ranges. Pearson's Chi-Square test was used for categorial variables. To perform comparison between the groups Mann-Whitney u-test was performed. Further Spearman's rang correlation coefficient (r_s) was used for testing correlations between PCERA clusters and psychological scales outcomes (Brace et al., 2016). As many correlation tests were performed, the authors decided to interpret *p*-values below 0.01 as significant to avoid mass significance (Cohen, 1992). The Cronbach's alpha was calcuted through a reliability analysis in SPSS (Brace et al., 2016). two Independent sampled t-test

3.7. Non-responsive analyses

A non-responsive analysis compared the RCT sample (MBCP n=96, Lamaze n=97) with PCERA subsample (MBCP n=26, Lamaze n=39), there were no significant differences between the mother-child dyads who participated in the PCERA and those who did not in terms of age, civil status, nationality, education, work hours, income, and prescribed drug use.

4. Ethical considerations

In a report from the Swedish Research Council (2017), research ethics are declared as a not welldefined subject, and the Council refers to ethics in two different directions; *ethical research* and *professional ethics. Ethical research* concerns the participants and aim to protect them from harm. In the present study, the participants received clear information, signed a written consent and were allowed to discontinue the study at any time. Furthermore, participants were coded and identification was exclusively accessible by an authorized main author. The Lamaze Prophylactic course was included as control so, from an ethical point of view, participants, regardless of randomization, received a prenatal intervention free of charge. The second direction, *professional ethics*, applies to and comprises the researchers' obligations towards the research, avoiding misconducting of results and plagiarism. The researchers who conducted the RCT have discussed preconceptions of the subject and noted that two authors are mindfulness instructors. The authors of this master thesis hold no preconception of the subject and are not bias to the results of the study. The study was approved by the Stockholm Regional Ethics Committee (2012/400-31/4). Trial registration, ClinicalTrials.gov ID: NCT024415955.

Results

5.1. Participants characteristics

A total of 65 women and their infants participated in the study, 26 participants from MBCP and 39 participants from Lamaze. The subsample for the present study had similar sociodemographic background data when compared to the sample included in the RCT. With respect to sociodemographic background information of all participants, the median age was 32 years, a majority (63 percent) of the participants were co-living with their partner, twenty were married, three were single and one lived apart with their partner. Most participants were Swedish (91 percent). A majority of participants (85 percent) had a higher level of education (university or college degree) while eight women had a secondary school degree. There were 72 percent who worked up to forty hours per week and 28 percent worked more than forty hours per week. A majority of the participants (54 percent) had a household income over 60 000 SEK. Household income was the only sociodemographic background data where a difference between groups was found, where Lamaze group participants had a significantly higher income (p = 0.024) than the

MBCP group participants. The majority of the women had no prescribed drugs (68 percent). Please see Table 1 for an overview of the sociodemograpic characteristics.

5.2. Comparison of maternal scores and psychological outcome

Table 2 shows a comparison of mothers self-reported ratrings of psychological outcomes at baseline, post intervention, six, nine and twelve months postpartum (between MBCP and Lamaze). There was no significant difference between groups at baseline, but an increase in PSOM and FFMQ scores post intervention with a significant difference (PSOM p = 0.039 and FFMQ p = 0.013) in favor of MBCP.

5.3. Comparsion of PCERA outcomes measures

The primary aim of the study was to examine whether a mindfulness-based parenting intervention provided during pregnancy has an effect on mother-child interaction at twelve months postpartum. There were no significant differences in PCERA outcomes between MBCP and Lamaze (Table 3).

5.4. Mindfulness associated with mother-child interaction

The secondary aim was to study whether mothers' psychological outcomes after the first year postpartum relate to some aspects of mother-infant interaction at twelve months postpartum. Results are presented in Table 5a and Table 5b. In MBCP, high outcome in *Positive affect parent* correlated strongly ($p = \langle 0,01 \rangle$) with high scores in both FFMQ and PSOM. High scores in FFMQ also correlated strongly ($p = \langle 0,01 \rangle$) with high outcome in *Dyadic mutuality*. No strong correlations between PCERA outcomes and psychological scales scores were found in Lamaze.

Variable	MBCP	Lamaze	Condition	df	р
	<i>n</i> = 26	<i>n</i> = 39	Comparisons		
Age, years					
Median	32	31	<i>z</i> = -0.490		0.624
Q25-Q75	29.75-35	29-35			
Civil status	n (%)	n (%)	Chi square=1.572	3	0.666
Single	2 (7.7)	1 (2.6)			
Co-living	16 (61.5)	25 (64.1)			
Married	8 (30.8)	12 (30.8)			
Living apart	0 (0)	1 (2.6)			
Nationality			Chi square=1.847	2	0.397
Swedish	25 (96.2)	34 (87.2)			
Swedish & other	0 (0)	2 (5.1)			
European	1 (3.8)	3 (7.7)			
Education ^b			Chi square=0.054	1	0.817
Secondary	3 (11.5)	5 (13.5)			
College	23 (88.5)	32 (86.5)			
Work hours			Chi square=0.205	1	0.651
Up to 40 h/week	18 (69.2)	29 (74.4)			
More than 40 h/week	8 (30.8)	10 (25.6)			
Household income/month ^a			Chi square=9.430	3	0.024*
< 25 000 SEK	1 (4.0)	0 (0)			
25 - 40 000 SEK	3 (12.0)	3 (7.7)			
40 - 60 000 SEK	13 (52.0)	9 (23.1)			
> 60 000 SEK	8 (32.0)	27 (69.2)			
Prescribed drug use			Chi square=2.568	3	0.463
Non	15 (57.7)	29 (74.4)			
SSRI medication	3 (11.5)	2 (5.1)			
Sedatives	1 (3.8)	2 (5.1)			
Other	7 (26.9)	6 (15.4)			

Table 1- Sociodemograpic characteristics of the all the study participants (n=65).

^a Data missing for n = 1 (MBCP).

^b Data missing for n = 2 (Lamaze).

*p ≤ 0.05 and **p ≤ 0.01 (2-tailed).

Sociodemographic background characteristics are reported as medians and interquartile range and frequencies (n and %). To test differences between groups, Pearson's Chi-Square test and Mann-Whitney u-test were used.

MBCP		Lamaze $(m-20)$			
(n=20) n	Median (Q25-Q75)	(n=39) n	Median (Q25-Q75)	Z	Asymp. Sig. (2- tailed)
26	18 (13.75-21)	38 ^a	19 (16-23)	-1.522	.128
25 ^a	24 (20.5-25)	38 ^a	22 (19.75-24)	-2.069	.039*
24 ^b	20.5 (17.25-24.75)	38 ^a	19.5 (16-24)	986	.324
23°	20 (18-23)	35 ^d	20 (13-22)	838	.402
24 ^b	20.5 (15-22)	35 ^d	18 (15-24)	333	.739
26	86 (75.25-97.25)	38 ^a	91.5 (83.75-96.25)	971	.331
25 ^a	103 (95-109)	38 ^a	95 (90.75-99.5)	-2.495	.013**
24 ^b	102.50 (86.25-109.75)	38 ^a	96 (87-102.75)	-1.099	.272
23°	96 (85-106)	35 ^d	92 (87-100)	875	.382
24 ^b	94 (88.5-105.5)	35 ^d	95 (85-106)	193	.847
	$\begin{array}{c} \text{MBCP}\\ (n=26) \\ n \\ 26 \\ 25^a \\ 24^b \\ 23^c \\ 24^b \\ 26 \\ 25^a \\ 24^b \\ 23^c \\ 24^b \\ 23^c \\ 24^b \end{array}$	MBCP ($n=26$)	MBCPLamaze $(n=26)$ Lamaze $(n=39)$ nMedian (Q25-Q75)n2618 (13.75-21)38a25a24 (20.5-25)38a24b20.5 (17.25-24.75)38a23c20 (18-23)35d24b20.5 (15-22)35d2686 (75.25-97.25)38a25a103 (95-109)38a24b102.50 (86.25-109.75)38a23c96 (85-106)35d24b94 (88.5-105.5)35d	MBCP $(n=26)$ Lamaze $(n=39)$ nMedian (Q25-Q75)nMedian (Q25-Q75)2618 (13.75-21)38a19 (16-23)25a24 (20.5-25)38a22 (19.75-24)24b20.5 (17.25-24.75)38a19.5 (16-24)23c20 (18-23)35d20 (13-22)24b20.5 (15-22)35d18 (15-24)2686 (75.25-97.25)38a91.5 (83.75-96.25)25a103 (95-109)38a95 (90.75-99.5)24b102.50 (86.25-109.75)38a96 (87-102.75)23c96 (85-106)35d92 (87-100)24b94 (88.5-105.5)35d95 (85-106)	$\begin{array}{c} \text{MBCP}\\ (n=26) \end{array} \qquad \begin{array}{c} \text{Lamaze}\\ (n=39) \end{array} \\ \hline n \text{Median} \left(\text{Q25-Q75} \right) \qquad n \text{Median} \left(\text{Q25-Q75} \right) \qquad \mathbb{Z} \\ \hline 26 18 \left(13.75 - 21 \right) \qquad 38^a 19 \left(16 - 23 \right) \qquad -1.522 \\ \hline 25^a 24 \left(20.5 - 25 \right) \qquad 38^a 22 \left(19.75 - 24 \right) \qquad -2.069 \\ \hline 24^b 20.5 \left(17.25 - 24.75 \right) \qquad 38^a 19.5 \left(16 - 24 \right) \qquad986 \\ \hline 23^c 20 \left(18 - 23 \right) \qquad 35^d 20 \left(13 - 22 \right) \qquad838 \\ \hline 24^b 20.5 \left(15 - 22 \right) \qquad 35^d 18 \left(15 - 24 \right) \qquad333 \\ \hline \end{array} \\ \hline \\ 26 86 \left(75.25 - 97.25 \right) \qquad 38^a 91.5 \left(83.75 - 96.25 \right) \qquad971 \\ \hline 25^a 103 \left(95 - 109 \right) \qquad 38^a 95 \left(90.75 - 99.5 \right) \qquad -2.495 \\ \hline 24^b 102.50 \left(86.25 - 109.75 \right) \qquad 38^a 96 \left(87 - 102.75 \right) \qquad -1.099 \\ \hline 23^c 96 \left(85 - 106 \right) \qquad 35^d 92 \left(87 - 100 \right) \qquad875 \\ \hline 24^b 94 \left(88.5 - 105.5 \right) \qquad 35^d 95 \left(85 - 106 \right) \qquad193 \\ \end{array}$

Table 2- Mothers scores on psychological scales (PSOM and FFMQ) at baseline, post intervention, and six, nine and twelve months post partum.

Grouping variable: Randomization. ^a Data missing for n = 1. ^b Data missing for n = 2. ^c Data missing for n = 3. ^d Dara missing for n = 4. * $p \le 0.05$ and ** $p \le 0.01$ (2-tailed).

Scores are repoted as medians and quartiles. Group differences were calculated by Non-Parametric two Independet sampled Mann-Whitney u-test.

	MBCP		Lamaze				
	(II-20)	Median	(II-37)	Median			
	IN	$(Q_{23}-Q_{13})$	IN	$(Q_{23}-Q_{13})$		Asymp. Sig.	Cronbach's
	Valid		Valid		Ζ	(2-tailed)	alpha
Positive affect							
parent	24 ^b	37 (33-40)	36°	35.5 (32.5-39.75)	364	.716	.831
Intrusiveness							
parent	26	32 (29.75–33)	39	32 (30-34)	904	.366	.693
Negative affect							
parent	26	23 (22-24)	38 ^a	23 (22-24)	265	.791	.744
Positive affect							
infant	25ª	27 (23.5–29)	38ª	25.5 (22–28.25)	-1.057	.290	.785
Quality of play	26		20		7 (0)	442	750
	26	37 (34–38.25)	39	36 (34-38)	/68	.443	.750
infant	26	29 (27-30)	38 ^a	29 (28–29.25)	064	.949	.734
Dvadic mutuality	26	12 (9.75-13.25)	39	12 (11-14)	-1.104	.270	.736
Dyadic		(,,					
disorganisation	26	17 (16.75–18)	39	17 (16-18)	117	.907	.680
A Grouping Variab	le:						
Randomization							

Table 3- outcome of the PCERA Clusters of the MBCP and Lamaze groups.

^a Data missing for n = 1.

^b Data missing for n = 2.

^c Data missing for n = 3.

Scores are repoted as medians and quartiles. Group differences were calculated by Non-Parametric two Independet sampled Mann-Whitney u-test.

a)	Positive affect parent	Intrusiveness parent	Negative affect parent	Infant positive affect	Infant quality of play	Infant Dysregulation	Dyadic mutuality	Dyadic disorganisation
Positive state of mind (PSOM)								
baseline	033	.361	.119	111	.131	.017	018	.141
PSOM 12 months postpartum	.610**	.282	220	.317	.383	076	.474	.253
Five facets of mindfulness (FFMQ)								
baseline	.158	.183	067	.187	.194	.190	.141	.026
FFMQ 12 months postpartum	.611**	.334	320	.419	.342	.119	.538**	.329
				Infant				
b)	Positive affect parent	Intrusiveness parent	Negative affect parent	positive affect	Infant quality of play	Infant Dysregulation	Dyadic mutuality	Dyadic disorganisation
Positive state of mind (PSOM)								
baseline	159	268	219	116	218	245	290	241
PSOM 12 months postpartum	055	.087	.261	033	062	061	.125	.333
Five facets of mindfulness (FFMO)								
The facets of minutumess (TTMQ)								
baseline	156	.014	118	.001	035	322	060	.086

Table 4 – Correlations between maternal psychological scales and PCERA clusters in the a) MBCP and b) Lamaze

Values are in Spearman's Rho correlation coefficients r(n=65). ** Correlation is significant at 0,01 level (2-tailed).

6. Discussion

6.1 Summary of the results

The present study's primary aim was to examine whether a mindfulness-based parenting intervention provided during pregnancy to women who experience symptoms of stress and depression had an effect on mother-child interaction at twelve months postpartum. The second aim was to study whether aspect of mindfulness as measured by two psychological scales assessed during pregnancy and postpartum related to aspects of mother-child interaction at twelve months postpartum. The results did not support evidence for an effect of MBCP on improved mother-child interactions when compared to a Lamaze group. However, some significant correlations between FFMQ and PSOM scales and aspects of mother-child interactions were found in the MBCP group.

6.2. A discussion of the findings in light of the literature

6.1.1 Primary aim

Table 3 shows that there were no significant differences in PCERA outcomes between groups, thus the null hypothesis cannot be rejected. However, in the event of a weak sample for instance, accepting the null hypothesis can lead to a type-2 error (ie the null hypothesis is wrongly accepted) (Cohen,1992). Our study groups were small and a larger sample size may have increased the power of the study and thus, enhanced the chances to reject the null hypothesis, that is, enhanced the chance to find existing differences between groups (Harbour & Miller, 2001; Jüni et al., 2001).

Another reason may be due to low rates of compliance decribed in Lönnberg et al. 2020 (of which sample our subsample was taken). That is, our study participants were instructed to self-practice mindfulness, but only thirty percent followed those recommendations. It could be that participating in a mindfulness course during pregnancy on its own is not enough, but also requires one to maintain the practice in one's spare time and thus possibly influence mother-child interaction. In relation to this, wide ranges of research emphasize the importance of regular practice of mindfulness (Siu et al., 2016; Duncan et al., 2015; Kim & Kwon, 2017; Kabat-Zinn, 2003; May, Ostafin, & Snippe, 2020).

Further, to measure effects on an intervention that takes place during pregnancy on events that happen considerably later is difficult. To give an example, in a Russian study by Bystrova et al.

(2009) children were randomized to either skin-to-skin contact with their mothers after birth, or the ordinary care of swaddeling with no skin-to-skin contact. The study showed differences in the mother-child interaction in dyads that been randomized to skin-to-skin contact, therefore, the conclusion was that strong stimulus of closeness of the mother and child postpartum had a long-time positive effect on mother-child interaction. Considering the conditions of skin-to-skin contact for Russians, one could say Sweden offers well-developed pre-and postnatal care which, after birth aims to not separate mother-and child, and to encourage skin-to skin contact. This could affect the interaction and hide possible effects of MBCP, compared to if the study was conducted in other settings, such as Russia.

Moreover, the question arises whether settings and Lamaze class could have had an effect on outcomes for the control group. The active control attended a Lamaze prophylactic course, which, to the best of our knowledge, is not well studied in its effects on interaction. Women who participate in parental classes are reported to appreciate their preparation for childbirth (Fabian, Rådestad, & Waldenström, 2005) and are self-reporting better mental health postnatal (Jakubiec et al., 2014). Therefore, it would be a conceivable assumption that even these outcomes could affect mother-child interaction, and even in this context conceal a possible effect of MBCP in Table 3.

6.1.2 Secondary aim

When we explored whether scores on different pscychological scales related to mindfulness (FFMQ and PSOM), correlates to any aspects of PCERA, some interesting observations were made. When stratifying the sample into two study groups we found that, even though psychological scales scores at twelve months and PCERA outcomes were similar between groups, there were significantly strong correlations scores on PSOM and FFMQ scales and PCERA clusters whithin the MBCP sample only (Table 4). In the MBCP group, there were strong correlations between PSOM and FFMQ and the PCERA clusters *positive parental affect* and *dyadic mutuality*. This finding may relate to the MBCP participants' self-reporting skills being more accurate on the positive spectrum of mental health. Mindfulness' therapeutic techniques aim to equip the participant to tackle negative emotions (Kabat-Zinn, 2003), which in the case of our intervention group could mean they rated truthfully as it correlated strongly with outcomes in two PCERA clusters. It could be argued that participating in an MBI develops one's abilities to rate one's feelings of mindfulness. Comparing self-reported variables in two groups, of which one group's intervention revolves around the reported variable while the other does not, there are difficulties drawing conclusions as to whether the outcome is due to the participants' difference in self-reporting skills or actual

feelings of mindfulness. A similar difficulty in data assessment was discussed in Lönnberg et al. (2020), as to which direction a mindfulness intervention influenced the self-reported measures.

However, when looking at Clark (1985), we can identify similarities between the PCERA variables and psychological scales but are due to lack of analyses restricted to drawing only hypothetical conclusions around these. FFMQ and PSOM assess certain items, which one would expect allows finer attunement to the child and corresponds well to one another. To explain, we will construct a scenario (which is based on the FFMQ, PSOM and PCERA clusters) in which a mother interacts with her child. She *observes* and *mirror* her child's expressions and signals, maintaining *visual contact*. She *acts with awareness, focuses her attention* and provide *responsible caretaking* for her child and through this behavior she allows for *reciprocity* and *state similarity* in the dyad. This scenario (which is based on our findings) is similar to the behaviors which are essential for developing a good mother-infant relationship, including bonding and attachment in the mother-infant dyad (Ainsworth et al., 1978; Stein et al. 2014). Furthermore, it has similarities with Duncan et al. (2009) multidimensional model of mindful parenting.

Speculating further, the self-aware and non-judgemental mindset of the mindful person as Kabat-Zinn (2003) defines it, one could argue being non-judging-and non-reactive to one's inner experience leads to acting not on impulse but more prudently, leading to a calmer approach. This approach is in usison with both the *positive affect parent* and *dyadic mutuality* clusters and relates to Siu et al. (2016) results showing that higher mindfulness in mothers correlates positively with attachment, involvement and parenting confidence. Duncan et al. (2015) found that mothers who reported high scores in mindful parenting exhibited more positive interactions with their children than low scoring mothers, which could imply substance to our speculations. Furthermore, high prenatal scores in mindfulness have been shown to correlate with mothers' responsiveness to their infants at seven to ten weeks and six months postpartum (Pickard, Townsend, Caputi, & Grenyer, 2017, 2018).

6.2. Methodology

RCTs are, as mentioned, "the gold standard" of group comparison in experimental research, and for the present study, an intervention of MBCP was suitable due to previous research requesting these types of interventions for mothers with depressive symptoms (Duncan et al., 2009; Hakanen, 2019; Stein et al., 2014). The present study is developed and based on the CONSORT statement (both checklist and flow diagram), which is regarded as a precaution for quality and transparency of the report (Schultz et al., 2011). Giraudeau et al. (2009) refers to CONSORT as a widely used tool for

boosting quality in reports, though often used at discretion, with substandard power analyses and misjudged control group effects. Therefore, Giraudeau and collaborators calls for easier ways on planning sample size to achieve transparency in RCT reports. However, as of today the CONSORT is globally used and there is nothing considered better on an international level, therefore the study is based on it, which we consider a strength.

6.2.1. Outcome measures - PCERA

The choice of free play as the assessed situation in the current study was made as it stimulates the spontaneous and emotional contact between mother and child. This is confirmed by Clark (1985) when describing the assessment of free play, as it views the parent's capacity to enjoy playing with their child, allowing it to explore and observing the capacity of the dyad in regards of for example mutuality. Therefore, we consider it a strength for our results that the clusters *positive affect parent* and *dyadic mutuality* correlated positively with mother's psychological scales, as they, as mentioned, are specifically notable in the chosen free play situation.

The PCERA can be used at different points in time after birth (Anke et al., 2019; Kivijärvi, Räihä, Kaljonen, Tamminen & Piha, 2005). The RCT by Bystrova et al. (2009) was using the PCERA method at twelve months postpartum and found that an intervention at birth had significant effect on mother-child interaction one year later. Clark (1999) further describes the free play situation as particularly useful for monitoring development at twelve months of age, which is when PCERA was assessed in the current study and thus, generates additional strength to our findings. Kemppinen et al. (2005) decided to investigate the PCERA method, in which five minutes of free play was compared to observations of mother-child interaction one hour per week, during a whole year (approximately forty hours). The result showed similarity and stability between the variables; Five minutes videotape of free play and observations during a year, which concluded that PCERA had high validity.

Furthermore, other studies showing that PCERA have high validity and sensibility (Clark, 1999; Lotzin et al., 2015), even in small sample sizes (Anke et al., 2019; Savonlahti el al., 2005). The authors suspect that the use of PCERA was not the main reason for large drop-out which might affect the result, since there are studies having lots of participants using the PCERA. Bystrova et al. (2009) had 144 participants at the one year follow up, and thereafter the PCERA method was used, and excluded only twenty participants. The dropout was reported as: two refusing PCERA, six had sick children, six were on vacation, three had schedule difficulties, two were unreachable and one mother was sick. Similarly, our mothers did their last self-report of psychological scales at twelve months postpartum, thereafter it was time for the video filming to take place, which was where we suffered the large drop-out. Speculative, one reason that may be crucial is that this study's sample was taken from a previous study, so the participants have been active in the project for a long time. Another reason might be that the location of the video filming changed to Karolinska Institutet instead of participants' homes. Either way, Bell, Kenward, Fairclough & Horton (2013) states that it is impossible to (during analysis) distinguish whether data are missing at random, or non-randomly missing data.

6.2.2. Limitations in accordance to bias

According to SBU (2015) there are many ways to distort a study's result. Therefore, all bias was discussed on the basis of an RCT evaluation form (SBU, 2019). The PCERA subsample was slightly smaller than expected especially in the intervention group (MBCP=26, Lamaze=39), based on the power calculation. Therefore, the results should be reviewed with caution. Attribution bias may occur in the absence of participants; large drop-out, or if drop-out results in skewed balance between intervention group and control group (SBU, 2015). To address this issue, we used adequate statistical methods with nonparametric analyses, reporting medians rather than means, which the authors regard as a strength and is supported by Bell et al. (2013).

Furthermore, SBU (2015) highlights that the risk of random error increases with a smaller number of observations in a study, more specifically the results are easily affected by change and can cause reduction in reliability, which has been considered. Two independent psychological scales were investigated instead of four, to restrict the width of analyses. A stricter level of significance ($p = \leq 0,01$) was used in the correlation analysis, further taking the possibility of mass significance as multiple analyses are made, into account. The two chosen were the two scales in which focus lies on mindfulness and positive states of mind (which are were considered most associated with the aims of the study). In a review by Goldberg et al., (2016), the FFMQ scale was investigated for risk of reporting bias, which is a weakness of the study. Aiming to minimize reporting bias and gain transparency in the report, we have shown results of both groups in the tables, irrespective of whether the findings benefit the hypotheses. The procedure is supported by SBU (2015) and Scultz et al. (2011).

6.2.3. Limitations in generalizability and applicability

Generalizability depends on how the quality of effect of the intervention on study participants (internal validity) compared with how it would affect target population (external validity), why the study sample should represent the target population (Stuart, Bradshaw & Leaf, 2015). Conducting the RCT in a bigger city offers a large population in a smaller area, but sociodemographics differs from that in rural areas and even other cities. As an example, the average annual income in Stockholm is 382 500 SEK compared with 318 200 SEK nationwide and 323 100 SEK in Gothenburg, second largest city in Sweden (Statistiska centralbyrån, 2018). The homogeneous sample in our study reduces generalizability of the findings, since the participants mainly originated from Sweden, were highly educated and lived with their partners. Thus, a more diverse sample sociodemographics would have increased external validity and hence increased generalizability for use in general population (Khorsan and Crawford, 2014). Another factor is that the participants who were included in the present study had depressive symptoms, which limits external generalizability to that target population. The non-responsive analysis showed no significant difference between the sample and subsample, which we consider a strength since it increases internal validity and therefore generalizability to the RCT sample.

Furthermore, conditions of the interventions differed, as MBCP received eight sessions compared to three for Lamaze. As mentioned, Lamaze is not well studied, and using a control intervention without knowledge of its effect on the outcome measures can be regarded as a limitation. Moreover, AnnasProfylax (2019), has since the RCT was conducted, restructured their courses and does not offer a comparable Lamaze class, which might be a limitation in transparency, reliability and generalizability. A review of Giraudeau, Dechartres, Baron and Ravand (2009) mention that an active control group is sometimes necessary for ethical reasons but considered a complicated variable to take into account, which might be the case in the current study. Conducting an RCT with an inactive control group would have eliminated the possibility of a control effect but was, with support in literature (Schultz et al., 2011; Statens beredning för medicinsk utvärdering [SBU], 2014, Appendix 9), considered unethical.

6.3. Inspiration to further studies

As the results find interesting correlations but are limited by power and sample size, we would like to see further similarly conducted studies with a larger and more diverse sample and a larger power. The correlations between psychological measure and PCERA clusters spark curiosity to investigate correlations between isolated items in the psychological measures and variables in the PCERA clusters. As mentioned earlier, Duncan et al. (2009) made a multidimensional model of mindfulness, suggesting that the participants adopt a mindful orientation for their parenting and continuously use mindfulness on daily bases. Meaning, it makes the parent undergo a fundamental change, in which the focus lies on truly being present with growth and development of, and relationship to the child. Bögels and Emerson (2019) result shows that mindful parenting gives less psychopathology in the child, such as: anxiety and depression, problem behavior, internalizing-and externalizing problems during development stages and reduces the likelihood of adolescents' risk behaviors. Along with the positive effects on depressive symptoms (Lönnberg et al., 2020), findings like these fuel our inquisitiveness into what mindfulness during pregnancy could yield for mother-child interaction.

Mindfulness as a recreational activity continues to grow and so is the empirical foundation (Williams & Kabat-Zinn, 2011) required to reach a wider population in health care. Our hope is that said foundation could add inspiration for the future of preventive maternal health care. Perhaps studies with a more valid power would show promising results in mother-child interaction and hence enable mindfulness to be intergrated in parenting preparing classes and/or maternal health care. Offering an effective preventive intervention to women at risk of depression would not only alleviate health care, but also enhance the basis of parenting and child upbringing.

7. Conclusions

In the present study, a larger loss to dropout than anticipated was observed. However, the authors have found that outcomes on the psychological scales relate to some PCERA clusters in the MBCP group and hence, encourage additional exploration of these correlations to further map the aids of mindful parenting.

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10. Appendix

10.1. Appendix 1: Information about the studyproject

- Recived and copied by Lönnberg et al. (2020).



KAROLINSKA INSTITUTET Institutionen för Kvinnors och Barns Hälsa

15-03-23 Vi söker deltagare till en studie om

föräldrautbildning, stress och livskvalitet under graviditeten och som föräldrar

Vi samarbetar med din mördravård och vill informera och bjuda in dig och din partner att delta i en studie. Delgarna i studien får gå en mer omfattande föräldrautbildning. Om du känner dig stressad eller oroad – om du exempelvis har ett stressigt jobb eller om du är oroad inför att föda barn och bli förälder – kan det här innebära en möjlighet till extra stöd.

Om du vill delta i studien kommer du att lottas till antingen en

(1) *mindfulnessbaserad* föräldrakurs eller en (2) föräldrakurs med *psykoprofylax*. Din partner eller en stödperson är också välkommen att gå kursen tillsammans med dig.

(1) Den mindfulnessbaserade kursen innehåller praktiska övningar i mindfulnessmeditation och teori kopplad till att föda barn och bli förälder. Den är 8 veckor lång med veckovisa träffar på 2,5 timmar. Den bygger också på att deltagarna avsätter ungefär en halvtimme per dag för hemövningar under kursens gång.

(2) *Kursen med psykoprofylax* lär ut andningstekniker som används för att slappna av och fokusera för att underlätta förlossningsarbetet, och den tar också upp föräldraskap. Den har tre kurstillfällen på 3 timmar vardera, och övningar som man kan göra hemma.

Vi genomför denna studie för att försöka ta reda på vilka effekter föräldrakurser kan ge på välmående under graviditeten och hur bra de kan förbereda föräldrar inför förlossningen och inför att få barn.

Föräldrakurserna är gratis! Det vi kommer be dig att göra är att

• Fylla i en enkät vid fem tillfällen (vilket tar ca 15 minuter per tillfälle); före och efter genomgången kurs, samt 3, 9 och 15 månader efter barnets födelse. Vi vill även att din partner fyller i enkäterna.

• Före och efter kursen kommer vi be dig att lämna ett blodprov.

• Vi kommer också vilja mäta din hjärtfrekvensvariabilitet (HRV). Det görs genom att tre små elektroder klistras på bröstkorgen och sitter där i 5 minuter efter 10 minuters vila.

• Vi kommer vilja få ta del av din förlossningsjournal och MVC och BVC journaler.

• Vi kommer också fråga några av våra deltagare om vi får göra en individuell djupintervju (vilket man kan tacka ja eller nej till separat). 2 (2)

En del av studien handlar om barnets välmående och samspelet mellan föräldrar och barn vid drygt ett års ålder. Vi kommer då fråga

• om vi får mäta HRV på ert barn (genom att tre små elektroder klistras på bröstkorgen och sitter där i 5 minuter)

• om ni kan fylla i en enkät om ert barns utveckling

• alternativt om vi får komma på hembesök och videofilma er vid ett tillfälle (3 filmsekvenser om 5 minuter).

Deltagandet är frivilligt och kan när som helst avslutas. Allt insamlat material kommer att behandlas konfidentiellt. Endast forskningsteamet kommar att ha tillgång till insamlad data och resultaten sammanställs på gruppbasis och redovisas så att det är omöjligt att identifiera individuella svar.

Ditt val att delta i studien eller ej påverkar inte din möjlighet att få annat stöd eller annan behandling.

Om du lämnade dina kontaktuppgifter på formuläret du fyllde i hos din barnmorska och om du möter våra inklusionskriterier kommer vi att ringa till dig och fråga om du vill delta.

Om du tackar ja kommer vi att boka in en tid för dig att göra HRV-mätningen, be dig lämna ett blodprov och fylla i den första enkäten. Därefter kommer du lottas till att antingen gå den mindfulnessbaserade föräldrakursen eller föräldrakursen med psykoprofylax.

Båda kurser kommer ges på kvällstid i BBSFamilys lokaler, antingen i Gamla Stan eller på Kungsholmen.

Du kan också läsa denna information och fylla i formuläret på ki.se/kbh/foraldrautbildning-forskningsstudie Om du har frågor om studien får du gärna kontakta oss!

Vänliga hälsningar,

Eva Nissen, Professor Maria Niemi, PhD Gunilla Lönnberg, doktorand

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10.2. Appendix 2: Written consent of the study

- Recived and copied by Lönnberg et al. (2020).



Informerat samtycke för studien om föräldrautbildning, stress och livskvalitet under graviditeten och som förälder

Vi genomför denna studie för att försöka ta reda på vilka effekter föräldrakurser kan ge på välmående under graviditeten och hur bra de kan förbereda föräldrar inför förlossningen och inför att få barn. Om du vill delta i studien kommer du att lottas till antingen en mindfulnessbaserad föräldrakurs eller en föräldrakurs med psykoprofylax. Din partner eller en stödperson är också välkommen att gå kursen tillsammans med dig.

Föräldrakurserna är gratis! Det vi kommer be deltagarna att göra är att:

• Fylla i en enkät vid fem tillfällen (vilket tar ca 20 minuter per tillfälle); före och efter genomgången kurs, samt 3, 9 och 12 månader efter barnets födelse. Vi vill även att partnern fyller i enkäterna.

• Komma på en intervju som tar mellan 45-60 minuter (bara du som är gravid).

• Vi kommer också vilja få ta del av förlossningsjournalen och MVC och BVC

journaler samt ditt barns PKU-prov (ett prov som tas på alla nyfödda i Sverige).

En del av studien handlar om barnets välmående och samspelet mellan föräldrar och barn vid drygt ett års ålder. Vi kommer då att fråga:

• om vi får komma på hembesök och videofilma er vid ett tillfälle (3 filmsekvenser om 5 minuter).

• om vi får mäta hjärtrytmsvariabilitet på ditt barn (genom ett EKG då tre små elektroder klistras på bröstkorgen, vid hembesöket).

Deltagandet är frivilligt och kan när som helst avslutas. Allt insamlat material kommer att behandlas konfidentiellt, vilket innebär att endast forskningsteamet kommar att ha tillgång till insamlad data. Resultaten sammanställs på gruppbasis och redovisas så att det är omöjligt att identifiera individuella svar. Alla personuppgifter som samlas genom mödrahälsovården (personnummer, kön, fullständig namn) hanteras enligt personuppgiftslagen (1998:204). Ansvarig för dina personuppgifter är Karolinska Institutet. Ditt val att delta i studien eller ej påverkar inte din möjlighet att få annat stöd eller annan behandling.

Medgivande: Jag har läst och förstått den ovanstående informationen och väljer att delta i studien om föräldrautbildning, stress och livskvalitet under graviditet och föräldraskap.

Datum och ort: _____

Namnförtydligande: _____ Tfn nr: _____

Underskrift: _____

Den senare delen av studien, som handlar om samspelet mellan föräldrar och barn kan du ge ditt samtycke till eller avstå ifrån separat från första delen av studien. Om du är osäker kan du bara lämna det blankt nedan. Jag samtycker till att mitt barn får delta i HRV-mätning och videofilmning om samspel.

Datum och ort: _____

Underskrift, förälder 1: _____

Underskrift, förälder 2: _____

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10.3. Appendix 3: Description of the MBCP sessions

Session	Theme and practices
1	Introduction to mindfulness and introduction of the teacher and the participants. Practices; mindfully eating a raisin and bodyscan.
2	Mind-body perspectives of childbirth regarding pain and fear, stress-hormones and the role of oxytocin and endorphins. Practices; bodyscan.
3	Coping with pain. Information about medical and non-medical analgesics. Practices; 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 and insight dialogue–explore listening and talking mindfully, reflecting on fear and joy.
7	Breastfeeding and the mind/body connection regarding prolactin, oxytocin, the let down reflex and stress/anxiety versus calmness.
8	Review of the course. Encouragement to continue practicing mindfulness, especially informal meditation with the baby after the birth.
Re- union	Experiences of childbirth and early parenthood are shared and approached with kindness and curiosity.

- Recived and copied by Lönnberg et al (2020).

10.4. Appendix 4: Cluster grouping of PCERA

- Recived from the experienced coders using the PCERA in the current study, copied from the manual (Clark, 1985).

Parent-Child Early Relational Assessment (Clark, 1985) **12 MONTH FREE PLAY FACTORS** (N = 359)

PARENT COMPONENT		
Factor I: Parental Positive Affective Involvement and V	/erbalization	Alpha: .91
2) Expressive, non-flat tone of voice	17) Quality of verbalizations	· ·
 Expressed positive affect 	18) Social initiative	
7) Lack of depressed, withdrawn mood	21) Structures & mediates envi	ronment
12) Enjoyment	24) Mirroring	
15) Visual contact	26) Creativity	
16) Amount of verbalization	, ,	
Factor II: Parental Negative Affect and Behavior		Alpha: .91
 Angry, hostile tone of voice 	11) Displeasure	
5) Expressed negative affect	20) Contingent responsivity to r	negative
6) Angry, hostile mood	behavior	_
Factor III: Parental Intrusiveness, Insensitivity, and Inc	onsistency	Alpha: .86
8) Anxious mood	22) Insensitivity/unresponsiven	ess to
14) Negative physical contact	child's cues	
16) Amount of verbalization	25) Rigidity	
21) Lack of structuring/mediating	27) Intrusiveness	
	28) Inconsistency/unpredictabil	ity
INFANT COMPONENT		-
Factor IV: Infant Positive Affect, communicative and So	ocial Skills	Alpha: .87
30) Expressed positive affect	39) Social initiative	
32) Happy, pleasant, cheerful mood	55) Visual contact	
33) No apathetic, withdrawn mood	56) Communicative competenc	e
36) No sober/serious mood	57) Readability	
Factor V: Infant Quality of Play, Interest, Attentional Sk	lills	Alpha: .87
33) No apathetic/withdrawn mood	47) Robustness	
38) Alertness/interest	48) Persistence	7
44) Motoric competence & quality	50) Self-regulation/organization	
45) Quality of exploratory play	56) Communicative competenc	e
46) Attentional abilities	57) Readability	
Factor VI: Infant Dysregulation and Irritability		Alpha: .83
31) Expressed negative affect	43) Aggressivity	-
35) Irritability/angry mood	49) Impulsivity	
37) Emotional lability	50) Lack of self-regulation/orga	nization
DYADIC COMPONENT		
Factor VII: Dyadic Mutuality and Reciprocity		Alpha: .87
59) No flat, empty, constricted affect	63) Reciprocity	-
61) Mutual Enthusiasm, Enjoyment, "joie de vivre"	65) State similarity	
Factor VIII: Dyadic Disorganization and Tension		Alpha: .78
58) Anger, hostility/irritability	64) Dyadic organization, regula	tion
60) Tension, anxiety	65) Lack of state similarity	

- 60) Tension, anxiety
- 62) Lack of joint attention, activity

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