On fear of childbirth and mindfulness

Irena Katarzyna Veringa

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Promotiecommissie

Promotor:	prof. dr. S.M. Bögels	Universiteit van Amsterdam
Copromotores:	dr. E.I. de Bruin	Universiteit van Amsterdam
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Faculteit der Maatschappij- en Gedragswetenschappen

For all new families.

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PROLOGUE

I remember, as if it happened yesterday, the first childbirth in life I ever saw. The enormous power of the labouring body and mind, the honesty of the birth process, the energy of a new-born entering this world and the extraordinary joy of the mother and spectators with this accomplished task initiated my lifelong admiration for birth. At that time, I was 19 years old waiting to enter medical university to become a physician, but I knew that my life would be determined by this event. My fascination and commitment to support childbirth were born and even more after the birth of my daughter. I realize now, it started even before this; my biological father died before I was born. Now, I understand that growing up in an environment that was mourning him impacted my fascination with birth too. This prologue is a brief review of my motives and journey to dedicate my work to bring more joy to childbirth.

After my midwifery study in Poland, I had the privilege to study midwifery in the Netherlands (at this time, known as 'the mecca' of natural childbirths in the world), and after my graduation, to start my own midwifery practice (1993). During my almost 25 years as an independent midwife in the Netherlands, I have supported more than twelve thousand pregnant women in their transition to motherhood. One in four of them gave birth under my supervision. During this time, I gradually witnessed decreasing joy and growing fear of childbirth among pregnant women and their partners. The first visible change of this was their unwillingness to cope with labour pain. Over the years, healthy pregnant women became more fearful of labour pain and the medicalization of the childbirth process started to grow (2009). Experiencing this shift taught me that unmedicated childbirth nowadays is not self-evident. More so, I had no tools to offer my clients who were afraid of labour pain and feared childbirth. I knew I had to look for these tools in physiological and more universal concepts such as neuroscience and other mind works. This insight came to me after seeing a documentary about the mirror visual feedback therapy of Ramachandran in patients experiencing limb phantom pain. In this therapy visual and psychological illusion of two intact limbs is used by putting the patient's affected limb into a "mirror box," with a mirror down the center (facing toward a patient's intact limb) to decrease pain experience in the phantom. I was fascinated about the power of the brain in interpretation of visual output and neuroscience.

I was so happy to meet and to work with dr. Ben van Cranenburgh, a neuroscientist who studied pain. His help to explore labour pain through a neuroscientific perspective initiated my first scientific research on pregnant women's expectations about labour pain and their ability to deal with pain during childbirth. This research was my master graduation project at the University of Amsterdam (UvA) on the faculty Evidence Based-Practice (2010). The results of this master thesis showed that pregnant women's expectations about labour pain were affecting their ability to deal with labour pain. To bring the results of my master thesis to a wider audience I contacted prof. Philip Spinhoven at the Leiden University with the request to help me to understand my study's

findings better. This collaboration resulted in a scientific publication on labour pain cognitions in pregnant women and their requests for pain relief during labour (*Chapter 2*). The insight about the influence of the mind on the body's functioning shaped the future direction of my research and solidified my general interest - resilience in natural childbirth. During this time, I became curious about two things: if there could be a simpler and more comprehensive way to detect fear of childbirth in pregnant women; and if there was a universal approach to fear of childbirth for use in midwifery care. Prof. Spinhoven collaborated with me on a cooperative research project between the UvA, led by prof. Susan Bögels, and the Free University Amsterdam (VU), led by prof. Anja Huizink, about the effects of mind interventions on pregnancy and childbirth outcomes (2012). One of the interventions was mindfulness. My personal experience with mindfulness encouraged me to commit myself to explore this method in childbirth. Numerous circumstances have ensured that I have been able to hold the PhD candidate position that originated from the joint project between Amsterdam's universities. Attempts for a financial grant for this project were eventually substantiated after two years when we succeeded to find financial support for our project partly thanks to Anna Kruger and her shared knowledge about grant conditions. The Dutch Healthcare Foundation Achmea awarded us with a grant, which was then doubled by the UvA with approval from prof. Frans Oort (2014). The research team, with among others prof. Susan Bögels, dr. Esther de Bruin and dr. Bonny van Steensel, was composed. The 'I've Changed My Mind' project, whose title evoked a wish that fearful pregnant women would change their perspective on childbirth, could begin.

This PhD thesis is conducted for all care givers in the psychosomatic midwife- and obstetrician-led care who are interested in improving guidance to pregnant women with fear of childbirth and facilitating a transition to joyful motherhood. But most of all, this PhD thesis is conducted for all new families who struggle with fears.

CHAPTER 1

General introduction

Midwifery in the Netherlands

Health system

The typical Dutch midwife-led healthcare system is based on the idea that pregnancy and childbirth are natural processes under the care of midwives, who are trained as independent medical practitioners (Hessing-Wagner, 1991). Pregnant women in midwife-led care at the onset of childbirth are considered to have low risk of complications thus they may choose between a homebirth or a planned hospital childbirth under the responsibility of independent midwives. In the event of complications (anticipated or otherwise) any time during pregnancy, childbirth or postpartum, women are referred to obstetric care in the hospital, known as obstetrician-led care (Crébas, 1990). If neonatal complications arise, new-borns will be referred to paediatric-led care (Crébas, 1990). If pregnant or labouring women need to be referred to obstetrician-led care due to obstetric or paediatric risk, then the responsibility of the independent midwife in the pregnant woman's care is ended. The risk selection and a clear division of tasks in midwife- and obstetrician-led care are based on the national List of Obstetric Indications (KNOV, 2003) to guarantee safe midwife-led care for women and the new-borns.

Homebirth

The most typical characteristic of the Dutch maternity healthcare system is a relatively high level of homebirths (13%; Perined, 2019). Recently, homebirth culture has even been added to the list of Dutch intangible heritage (KIEM, 2020); it is a woman's right to have a safe birth and it is a core value in determining women's autonomy. The Dutch national data showed that homebirths are relatively safe (de Jonge et al., 2009). A systematic review with meta-analysis based on the international data collected between 2000-2017 on the safety of homebirths in relation to births at hospitals showed benefits for homebirths: higher spontaneous delivery; less likely to undergo caesarean section, less likely to receive medical interventions, lower risk of foetal dystocia, lower risk of post-partum haemorrhage, while the two groups were similar with regard to neonatal morbidity and mortality (Rossi & Prefumo, 2018). Nevertheless, homebirths are decreasing in the Netherlands; in the post-war years 80% of women had a homebirth, in the 1990's homebirths accounted 35% of all births and nowadays only 13% of mothers give birth at home (Perined, 2019). According to the Dutch association of obstetricians the decrease in home births is related to an increase for medical pain relief during labour which cannot be administered at home.

Costs

Dutch healthcare operates to minimize medically 'unnecessary' interventions of any kind to protect health and decrease costs. The costs of midwifery care are financed through health insurance based on the Bismarck model. The financing of this system is

realised by social insurance and is managed by legally regulated private organizations (e.g., independent midwives' practices). Midwifery care is predominately free of charge for pregnant women, however, depending on the health care insurance some activities may only be partly reimbursed. If a normal pregnancy and childbirth are expected, the woman is obliged to attend the midwife-led care. The obstetrician-led care is the more expensive of the two. In the case of a normal pregnancy and childbirth, these costs are not reimbursed. Only if there is a referral for an intervention or consultation by the midwife, the insurer will reimburse the costs to the obstetrician.

Despite the system to protect the costs and physiological pregnancy and childbirth, 64% of pregnant women in the Netherlands starting labour in midwifery-led care are referred to obstetrician-led care for non-urgent obstetric interventions such as epidural analgesia and caesarean section, resulting from a failure to progress to childbirth (i.e., a medically set timeline) or an inability to cope with labour pain (Perined, 2019). Non-urgent obstetric interventions are interventions that do not require immediate investigation or treatment by obstetric care as they could be treated in midwifery care (Offerhaus et al., 2013). According to Dutch national data, 71% of all pregnant women in 2018 had childbirth within obstetrician-led care (Perined, 2019). Pregnant women's preferences and their right to choose the place and mode of labour are fundamental in the shared-decision-model of care (Härter et al., 2017). A problem with that is that pregnant women's preferences and finale use of non-urgent obstetric interventions during childbirth, such as epidural analgesia and caesarean section, occur more frequently in pregnant women with fear of childbirth (FOC), (Logtenberg et al., 2018; Ryding et al., 2015). Untreated FOC and pregnant women's requests, and use of non-urgent obstetric interventions during childbirth, contribute to increasing health care costs in the Netherlands and to increased international midwifery care costs (Gibbons et al., 2010). In Dutch midwifery care, no treatment or guidance for reducing FOC and reducing unneeded medical interventions during childbirth is available. The costs for birth care are still growing.

In this thesis we evaluated non-clinical assessment and treatment of FOC, in order to improve midwifery care by means of FOC reduction. Also, improvements in the childbirth outcomes for mother and child were taken in account. In our research, we addressed the values of the Dutch midwifery model as mentioned above: the midwife as the gatekeeper of midwife-led versus obstetrician-led care, pregnant women's freedom to choose the place of childbirth and the mode of childbirth, and to minimize, if possible, medically 'unnecessary' interventions in childbirth.

Theoretical framework on fear and anxiety

Fear of pain and fear of the unknown (i.e., anxiety), besides fear of death, are the fundamental fears in humans (Carleton, 2016). Fear and anxiety are vital emotions

with the aim to prepare for, avoid or escape life-threatening events (Craske et al., 2009). In accordance with Barlow's concept, these emotions, while similar, differ in their timing: fear is more an alarm response to current or imminent threat either real or perceived while anxiety is a future-oriented mood state preparing for possible, upcoming threatening events (Barlow, 2002). Both emotions are strongly related to each other. However, fear and anxiety differ in bodily symptoms (e.g., fear: heart racing, sweating; anxiety: abdominal tension), cognitive activity (e.g., fear: thoughts of imminent threat; anxiety: worries about the future) and behaviours (e.g., fear: escape; anxiety: avoidance), see Lang (1968). These bodily, cognitive, and behavioural symptoms are stress responses to imminent or perceived threat.

Stress responses can be lifesaving or harmful. In a situation of stress, the emotional axis of the nervous system (formation reticularis, hypothalamus, thalamus, amygdala, limbic system [home of emotion and attention] and basal nuclei) is (over)activated (Cranenburgh, 2021). In this way among others, the neuro-endocrine activation, and the narrowing of attention in stressful situations are generated. The neuro-endocrine activation produces stress hormones, such as adrenaline and cortisol, for bodily energy during *fight or flight* responses. The ability to narrow attention in stressful situations focuses attention on threat, in order to increase the chances for survival. In this way, fear and anxiety generated by a real threat are lifesaving. However, in a situation of a perceived threat - where only the thoughts about possible threat are present - the emotional axis activates the production of stress hormones as well and *flight or fight* responses are generated if one is experiencing an imaginary threat. Continuing experience of stress can ultimately be harmful to an individual in the longer term due to devastating effects of cortisol on the human body and mind system (Bao et al., 2008). In addition, the attention narrows in imaginary threat circumstances which blocks an individual's ability to reflect on the real situation (Eysenck et al., 2007).

Fear of childbirth

Characteristics

From an evolutionary perspective, some level of FOC might be functional (i.e., helpful) in guiding women to a safe environment to give birth. Most pregnant women can cope with fear and anxieties related to childbirth and/or anticipated motherhood. However, for many women a perspective of childbirth still leads to significant emotional distress.

FOC is a multidimensional concept incorporating different aspects of fear and anxiety within and external to the pregnancy itself (Huizink et al.; 2004; Rondung et al., 2016; Rouhe et al., 2011; Wijma et al., 1998). Complex causes of FOC can be viewed from a biopsychological perspective that includes biological factors of fear (e.g., fear of pain, fear of bodily harm, or fear of one's own or one's infant's death), psychological factors (e.g., personality traits, a history of traumatic life events or previous difficult

or traumatic obstetrical experience, loosing sense of control due to an unknown course of childbirth and motherhood) and social factors (e.g., lack of social support, dissatisfaction with the partner relationship, hearing "horror stories" about childbirth from the environment) (Veringa et al., 2016). Yet, there is no consensus on the exact definition and assessment of FOC as well as there is no description of the phenomena of FOC in the the Diagnostic and Statistical Manual of mental disorders (DSM-5; American Psychiatric Association, 2013). Additionally, there is no such thing as an international or national guideline for screening and treatment of fear of childbirth. This urges future research to examine these knowledge gaps. This thesis contributes to the research literature by conceptualizing and testing a multidimensional theory of FOC.

Multidimensional perspective

When framing FOC, two observations must be made: the actual definition as well as the time period of FOC appraisal (current or anticipated) within the child birthing process. Little is known about the psychological mechanisms underlying FOC (Rondung et al., 2016). In this thesis, FOC is examined from a perspective of cognitive theory (Beck, 1976). To do so, we conceptualized FOC by distinguishing emotional, cognitive, behavioural, and attentional dimensions. The emotional dimension is conceptualized as fearful and anxious feelings about childbirth. The cognitive dimension concerns biased cognitions about childbirth, such as catastrophic beliefs about what may happen around the childbirth. The behavioural dimension deals with maladaptive behaviour surrounding childbirth, such as avoidance of the challenges of childbirth. Lastly, the attentional dimension of FOC concerns a biased attention towards childbirth, such as a threat-focused attention. These four dimensions of FOC are interrelated. In this thesis, we assume that pregnant women are improving on FOC when all four dimensions are improved.

The multidimensionality of FOC in this thesis is also specified to include a broader timing of fear by combining birth and the postpartum period as one event. That is, FOC may for some women include the process of childbirth, while for others it is related to the postpartum period and the consequences of childbirth (Bayrampour et al.; 2016). In addition, these events are interrelated, and therefore we found it reasonable to include both FOC as well as fear for the postpartum period in the assessment of FOC.

Assessment

Detecting fear and anxiety in pregnant women has always been a challenge for clinicians and researchers, since the optimal methods to identify fear and anxiety in pregnancy in clinical settings have not yet been confirmed (Bayrampour et al.; 2016; Brunton et al., 2015). Several ways are used to diagnose FOC and are discussed next.

First, the most common way to assess FOC is to use the Wijma-Delivery Expectancy Questionnaire (W-DEQ-A; Wijma et al., 1998), a validated and popular questionnaire in clinical settings and most frequently used in midwifery research (Nilsson et al., 2018). W-DEQ-A assesses an anticipated emotional dimension of FOC through emotional appraisal towards childbirth. It covers six factors: general fear, negative appraisal, loneliness, lack of self-efficacy, lack of positive anticipation, and concerns about the child. Anticipated FOC according to W-DEQ-A can be distinguish by severity into three categories: *high* (W-DEQ-A≥ 66) when a pregnant woman worries about giving birth, yet she is capable of handling the problems; *severe* (W-DEQ-A≥5) where such a fear disables her life and ability to give birth; and *phobic* (W-DEQ-A≥100) FOC when the criteria of specific phobia according to DSM-5 is met - the pregnant woman's biopsychosocial functioning is paralyzed by her suffering from FOC (Nilsson & Lundgren, 2009). Although W-DEQ-A is a widely used screening tool for FOC, it has been criticized for assessing different constructs related to FOC and that it is not appropriate to calculate a total score (Pallant et al., 2016). Additional shortcomings of the questionnaire are limitations in the cultural transferability of some of the items; the length of the instrument (Pallant et al., 2016); and the difficulty to interpret it for the general population (Roosevelt and Low, 2016).

A second, but less common, way to assess FOC is to use a one-item scale based on the reliable and valid visual analogue scale (VAS; Ahearn, 1997) by asking pregnant women 'How much do you fear childbirth?' (Rouhe et al., 2009). This one-item VAS showed high sensitivity in screening for phobic FOC. To improve assessment of the internal consistency of the FOC -VAS question, a second question about worry was added. From this, the Fear of Birth Scale (FOBS) was developed (Haines et al., 2011). This scale, in comparison to other scales, addresses more explicitly the current, rather than the anticipated, FOC by adding "right now" to the question (i.e., "How do you feel right now about the approaching birth?"). FOBS had a high sensitivity for identifying a phobic FOC (W-DEQ-A≥100).

Third, the Pregnancy Related Anxiety Questionnaire – Revised (PRAQ-R; Huizink et al., 2004) can be used to assess FOC. It is a 10-item self-reported pregnancy-specific, anxiety measure for use in nulliparous women. FOC, alongside worries about bearing a physically or mentally handicapped child and concerns about their own appearance, is one of the three domains of PRAQ-R.

In addition to the assessment of FOC, fear of labour pain is commonly assessed. The rationale behind this is that fear of pain is a fundamental fear in humans. Cumulative research on pain showed that pain catastrophizing (an irrationally negative forecast of pain coupled with an inability to divert attention away from pain) was strongly related with fear and anxiety and played a crucial role in maintaining the pain (Quartana et al., 2009). However, the potential role of pain catastrophizing in FOC still needs to

be explored more extensively. Of the few studies that evaluated pain catastrophizing, findings demonstrate that pain catastrophizing is related to the anticipation of childbirth pain (Flink et al., 2009; Veringa et al., 2011), fear of being overwhelmed by pain (Van den Bussche et al., 2007), preferences for a caesarean section (Dehghani et al., 2014), poorer physical recovery in the postpartum period (Flink et al., 2009), and postpartum depression and social functioning adjustments (Ferber et al., 2005). To assess fear of labour pain in research settings, the 13-items Pain Catastrophizing Scale (PCS; Sullivan et al., 1995) is frequently used (Ferber et al., 2005; Flink et al., 2009; Van den Bussche et al., 2007). PCS covers three domains of pain catastrophizing: rumination, magnification, and helplessness about the experienced pain in general. Yet, a specific scale to assess catastrophic beliefs about the consequences of labour pain in pregnant women is lacking.

In this thesis, we chose three measures to evaluate FOC. First, the W-DEQ-A was used to assess FOC. Second, to acknowledge the time period stretching from pregnancy to childbirth to postpartum, the newly developed one-item VAS was used (*Chapter 3*). Third, to examine catastrophizing pain, the 12-items Catastrophizing Labour Pain, which is a subscale of the Labour Pain Cognitions and Coping List (LPCCL) based on the original Pain Coping and Cognition List (PCCL; Stomp-van den Berg et al., 2001), was used (*Chapter 2*).

Prevalence

FOC is highly prevalent among pregnant women in Western societies. The prevalence of anticipated FOC in Western societies is estimated at 25-31% for high, 7-15% for severe and 2-7% for phobic FOC based on W-DEQ-A (Nilsson et al., 2018). The prevalence of severe and phobic FOC in Dutch pregnant women is in line with the prevalence of FOC in other Western countries (respectively 10-12.4%, and 0.9-2.1%; Sluijs, 2020). Most studies on prevalence rates and consequences of FOC in pregnant women evaluated only severe (or phobic) FOC. However, a few studies showed that already high FOC is strongly related to mental health problems in pregnant women and their inability to adapt to childbirth (Hall et al., 2009; Rouhe et al., 2011; Toohill et al., 2015). However, the prevalence and risk factors related to high FOC in Dutch pregnant women are yet unknown. Therefore, in this thesis, we focused on the prevalence and related outcomes of high FOC.

Risk factors and consequences

Untreated FOC has negative somatic and mental health consequences for pregnant women/new mothers, and new-borns during the entire perinatal period (pregnancy, childbirth and postpartum). FOC can generate maternal psychological distress activating the maternal hypothalamic-pituitary-adrenal (HPA) axis and thus resulting in high levels of the (maternal) stress hormone cortisol (DiPietro, 2012). Negative

emotional states in pregnant women are related to maternal hypertension and preeclampsia (Thombre et al., 2015). The elevated activation of the HPA-axis in pregnancy can influence later vulnerability and health of an individual, as explained by the *foetal programming* hypothesis (Gluckman & Hanson, 2004). This hypothesis claims that foetal development is determined by maternal and placental physiology. Maternal high level of cortisol (maternal pathology) is teratogen (an agent that can generate deleterious perinatal and/or developmental outcomes) for new-borns (Dipietro, 2012). The most worrying consequence of high levels of cortisol in pregnancy is demetallation of the foetal DNA resulting in hindered and inversible expression of DNA in later life (Davis & Sandman, 2010; Dean et al., 2018; Palma-Gudiel et al., 2015). A hindered expression of DNA in new-borns can manifest into somatic and mental underdevelopment. Further, adverse bio-psychological responses of anxiety-related stress in pregnant women disadvantages the offspring in their cognitive-emotional development (Rice et al., 2010). There are indications that an elevated HPA-axis due to antenatal maternal anxiety is related to depressive symptoms in post-pubertal female adolescents (Van den Bergh et al., 2008). Children exposed to elevated prenatal, maternal cortisol and pregnancy-specific anxiety are at an increased risk for developing anxiety problems during the preadolescent period (Davis & Sandman, 2010). Stress caused by prenatal maternal anxiety and depression negatively influences the neuro- and emotional development of the new-born (Davis & Sandman, 2010; Dean et al., 2018). Besides, maternal high FOC is associated with an increased incidence of low birthweight (< 2500 g), small gestational age in new-borns, increased preterm birth rate, low Apgar scores at 1-minute, infant admission to intensive care, stillbirth, and early neonatal death (Räisänen et al., 2014). It can be stated that an untreated maternal FOC limits the child's life.

Further, FOC can also negatively influence the course of childbirth resulting in prolonged labours, failure to progress and need for augmentation of labour with oxytocin, a higher risk for an assisted delivery and an even more elevated risk for an emergency caesarean section (CS; Laursen et al., 2009; Nieminen et al., 2009; Rossignol et al., 2014; Ryding et al., 2015). Thereby, pregnant women experiencing FOC request more often non-urgent obstetric interventions such as demanding anaesthesia (Van den Bussche et al., 2007) and an elective caesarean section (Molgora et al., 2020) to avoid the challenges of childbirth (e.g., labour pain and uncertainty of the course of labour). Not only are these urgent and non-urgent obstetric interventions during childbirth associated with increased health care costs leading to financial consequences (Nieminen et al., 2017), but also these obstetric interventions during childbirth can further complicate the birth process. These interventions can cause unbearable labour pain, prolonged labour and increased risk of instrumental deliveries, as well as traumatic childbirth experiences (Adams et al., 2012; Kerkhof et al., 2013; Kjærgaard et al., 2008; Silverstein et al., 2019). Furthermore, FOC in pregnancy is strongly related to fear and anxiety postpartum (Sluijs et al., 2020). Postnatal maternal anxiety has negative effects on the mother-baby

relationship in the form of breast-feeding, bonding, and mother–infant interactions, and negatively impacts the infant's temperament, sleep, mental development, health and internalizing behaviour (Field, 2018). It was even associated with the presence of conduct disorder in adolescents (Field, 2018). Thus, FOC generates a vicious cycle by having detrimental impacts on the mother as well as downstream effects on the child.

In this thesis the relationship between high FOC in pregnant women in relation to non-urgent-obstetric interventions was evaluated (*Chapter 3*). Therein, we evaluated pregnant women's (mid-pregnancy) requests for epidural anaesthesia and elective caesarean section as well as requests to undergo epidural anaesthesia and caesarean section during labour.

Mental health

Several studies reported FOC being related to general mental health conditions in pregnant women, particularly anxiety and depression. Pregnant women with a history of general anxiety or trait and state anxiety were more than two times likely to develop FOC than pregnant women without these vulnerabilities (Rondung et al., 2016). Similarly, pregnant women with past depression were almost three times more likely to develop FOC than pregnant women without symptoms of depression. Consequences of untreated FOC extend to after the pregnancy and into the postpartum period. For example, new mothers are at risk for postpartum depression (Hymas & Girard, 2019; Iles et al., 2011). The strongest association was reported between FOC and the combination of both anxiety and depression symptoms, however strong relations between FOC and Post Traumatic Stress Disorder (PTSD) are also reported. A Swedish study reported that women with FOC have a six-fold risk of developing PTSD following childbirth (Söderquist et al., 2009) and a Dutch study (Hollander et al., 2017) showed that untreated FOC is strongly related to PTSD following childbirth. In the Dutch study, 2192 women who experienced childbirth as traumatic showed that 49.9% experienced fear for the baby's health and life, and 28.9% feared for their own health and life during childbirth (Hollander et al., 2017). Other mental health issues associated with FOC are history of trauma (non-childbirth related), sexual abuse, eating disorders, low self-esteem, and having less adaptive coping abilities (Hofberg & Ward, 2004; Rondung et al., 2016). In turn, mental problems, including FOC, in new mothers are related to mental problems in their offspring (Davis and Sandman, 2010; Dean et al., 2018)), biased responding to infant emotions (Webb & Ayers, 2014), and even avoiding contact with the newborn (Ferber et al., 2005). The interrelationship between FOC and mental problems before and/or after childbirth stresses the urgency of timely detection and treatment of FOC.

Fear of childbirth as a neglected problem

FOC, including other mental health problems in pregnant women, is frequently overlooked in a midwife and obstetrician-led practice and often remains unrecognized and untreated (Andersson et al., 2003; Howard et al., 2014; Kelly et al., 2001). Although the urgency of an early detection of FOC has been recommended by the National Institute for Health and Care Excellence Guideline (National Institute for Health and Care Excellence, 2014), barriers to an early detection also exist. For example, early detection is impeded by unfamiliarity with FOC symptoms and limited utilization of questionnaires to measure FOC in midwifery practice (Larsson et al., 2016). The limited utilization of screening for FOC can be explained by time constraints during midwifery consultations (Larsson et al., 2016) and the length of the 33-item W-DEQ-A (Wijma et al., 1998).

It can be said that FOC is a neglected problem in midwife-led care since guidelines to screen or treat high FOC have yet to be introduced, despite recognition of harmful effects of antenatal FOC. The safety for the mother and her new-born, within the Dutch midwifery care system, is mostly based on somatic-medical outcomes (e.g., blood pressure and birthweight, respectively), and not on psychological outcomes (e.g., childbirth and postpartum fear and anxiety). In the risk criterion detailed in the national List of Obstetric Indications (Verloskundige Indicatie Lijst; KNOV, 2003) to ensure safe somatic and mental health care in midwife- and obstetrician-led care, psychological outcomes are only outlined as psychiatric disorders (e.g., anxiety disorder, depression, psychosis, and PTSD due to childbirth) as a reason for a referral to obstetrician-led care. However, a Dutch study found that in obstetrician-led care, only one in five pregnant women with a psychiatric history of current depressive symptoms were detected (de Waal et al., 2010). Once referred to obstetrician-led care due to persisting or new mental health problems, pregnant women are further referred to the Psychiatric-Obstetric-Paediatric (POP) – outpatient clinics located in hospitals. In addition to an obstetrician, a psychiatrist and paediatrician as well as other health-care providers (e.g., social worker, psychiatric nurse, and infant mental health specialist) are involved in the care for pregnant women/new mothers. However, in case of high FOC pregnant women are not often referred for help because high FOC is not seen as a psychological/psychiatric problem. It can be suggested that the detection and even treating of high FOC belong to the care of midwives. However, for the time being, adequate knowledge and skills for detecting and treating FOC in a midwife-led acre are lacking.

Furthering this problem, barriers exist to disclosing and treating FOC. Pregnant women experiencing FOC in the Netherlands typically must disclose their fears to her midwife (or obstetrician). To expect her to do so, the relationship between her and the care provider has to be empathetic, personal and continuous, and preferably the same midwife is providing the care/supporting the women throughout the entire process. It

also requires that the midwife is able to detect and to communicate with the pregnant woman about her negative feelings of unsafety and ask relevant questions to reveal her fear and concerns about childbirth and the postpartum period. In an ideal situation, the midwife should be competent to take care of the pregnant women's FOC and help her to prepare for the known and unknown challenges of childbirth and motherhood. It is therefore essential that midwives first of all have the valid tools and know how to use them in order to correctly identify FOC in pregnant women.

In this thesis, a new approach to the assessment of FOC in midwife-led care is proposed. We evaluated a brief and easily accessible measurement tool, which can be administered in early pregnancy giving a possibility to start with early treatment of FOC (*Chapter 3*).

Non-clinical treatment options of fear of childbirth

In the past decades, the effects of non-clinical interventions (performed outside the mental health care system) to reduce FOC provided by midwives or/and obstetricians were evaluated in several Randomized Controlled Trials (Aguilera-Martín et al., 2021; Badaoui et al., 2019; Stoll et al., 2018; Striebich et al., 2018). Research on the effects of non-clinical interventions include various approaches: cognitive-behavioural therapy (CBT; Beck, 1976) antenatal education, individual antenatal psychoeducation, and individual counselling in pregnant women with FOC.

Saisto, Salmela-Aro, et al. (2001) were the first to introduce CBT (Beck, 1976) which is a clinical treatment, in routine obstetric consultations to reduce FOC in non-clinical settings. This new approach to FOC in which CBT is provided by an obstetrician-therapist, was evaluated in Finnish pregnant women (N = 176) with severe FOC (W-DEQ-A≥85), and CBT was compared to care as usual. No difference in FOC between groups and the use of obstetric interventions during childbirth was found (Saisto, Salmela-Aro, et al., 2001). However, in both the CBT and care as usual group, about 60% withdrew their initial request for an elective caesarean section as a mode of childbirth.

Rondung et al. (2019) and Toohill et al. (2015) evaluated eight modules of an internet-based cognitive-behavioural (ICBT) self-therapy. This study was conducted in Swedish pregnant women (N = 258) with severe (W-DEQ-A≥85) to clinical (W-DEQ-A≥100) FOC and compared ICBT to midwife-led fear of birth specific counselling sessions (i.e., Swedish care as usual). The ICBT intervention was focused on recognizing automatic thoughts and emotions, and how to cope with them. The postintervention levels of FOC did not differ between groups. Yet, FOC was found to be decreased over time in both groups, generally with medium within-group effect sizes during pregnancy and large effect sizes from mid pregnancy to one year postpartum (Rondung et al., 2019). The study reported a major limitation of only 10% of participants having followed five or

more modules, indicating low feasibility and acceptance of ICBT. The use of obstetric interventions during childbirth was not reported.

Toohill et al. (2015) evaluated the Birth Emotions and Looking to Improve Fear (BELIEF) method, which is based on CBT given by midwives. This study was conducted in a population of Australian pregnant women with high FOC (W-DEQ-A≥66) in two separate studies: by telephone with psychoeducation (*N* = 339; Toohill et al., 2015), and face to face in counselling sessions (*N* = 90; Andaroon et al., 2017). BELIEF, in the psychoeducation and the face-to-face study, was found to be effective in reducing FOC as compared to the Australian standard midwifery care. However, the effects with respect to the use of obstetric interventions were not significantly different between the BELIEF psychoeducation by telephone study and standard care. The effects of the BELIEF program in the face-to-face counselling on the use of obstetric interventions during childbirth were not reported.

Haapio et al. (2017) evaluated with Finish nulliparas women (*N* = 659) the effects of an extended antenatal education with elements of counselling given by midwives as compared to regular antenatal education classes. This extended antenatal education was based on constructivism theory (Whitman, 1993) in which the specific needs and previous knowledge of the participants were used to help them to understand antenatal education (Haapio et al., 2017). This method was found to be almost 40% more likely to reduce childbirth fear than regular antenatal education classes. However, no difference was observed between the groups in pregnant women's preferences to have an elective caesarean section as a mode of childbirth.

Larsson et al. (2015) evaluated a Swedish counselling method for FOC routinely offered by trained midwives to pregnant women (*N* = 936) in a national prospective cohort study. A comparison was made between women with (7.5%; *n* = 72) or without counselling (92.5%; *n* = 864). It was found that there was no difference between groups in FOC during pregnancy. However, pregnant women in the counselling group were more fearful after one year than women without counselling. Also, pregnant women who received counselling due to FOC more often underwent an elective caesarean section as a mode of birth (Larsson et al., 2015). Although the findings in this study did not support the counselling method in terms of a more reduced FOC, the pregnant women who received counselling did report high satisfaction with the given support.

Fontein-Kuipers et al. (2016) evaluated an internet-based program WazzUp *Mama* in Dutch midwifery settings on the reduction of maternal distress in pregnancy, including pregnancy-related anxiety. This program was developed for use by pregnant women and their midwives together, in order to prevent and to treat maternal distress in pregnancy. WazzUp *Mama* was evaluated in a non-randomized pre-post cohort study (*N* = 433) and findings demonstrated a reduction of maternal distress and pregnancy-related

anxiety (Fontein-Kuipers et al., 2016). However, again, the effect of this intervention on use of obstetric interventions during childbirth (e.g., analgesia, caesarean section, natural childbirth) was not reported.

Two studies (Afshar et al., 2018; Mirghafourvand et al., 2019) evaluated childbirth plans and its effects on women's childbirth satisfaction. A childbirth plan was composed by the woman and her provider and involves writing down and discussing details about the birthing process (e.g., if the women prefer medication or not). It is a common way of counselling pregnant women's preference for childbirth in the Netherlands (KNOV) and in other Western countries (Mirghafourvand et al., 2019). However, the effect of making a childbirth plan on FOC reduction is not yet evaluated. Nevertheless, there are a few studies reporting its effect on childbirth satisfaction (*N* = 3) and the use of obstetric interventions during childbirth (*N* = 1). The results of these studies indicate that there is not enough evidence to support that making a birth plan improves the childbirth experience (Mirghafourvand et al., 2019) or that it reduces the use of obstetric interventions during childbirth (Afshar et al., 2018).

Klabbers et al. (2019) evaluated the effects of haptotherapy (i.e., a non-clinical intervention focusing on body awareness and relaxation exercises) on the reduction of severe FOC in Dutch pregnant women (*N* = 134) coming from midwife- and obstetrician led care, however, delivered by a haptotherapist. The effects of haptotherapy on FOC were compared with two other study conditions: psychoeducation via the internet and care as usual. Findings demonstrate that haptotherapy is more effective in the reduction of FOC in pregnancy and postpartum than the two comparison groups (Klabbers et al., 2017). However, the effects of these interventions on childbirth outcome were not reported.

In this thesis, we have evaluated a new option for treatment FOC under the care of midwives (a mindfulness-program) with the potential to reduce FOC and to improve childbirth outcome (*Chapters 4, 5, 6* and *7*). In the light of the above-mentioned studies, we were the first to report the effects of this new intervention on the childbirth outcome (e.g., mode of childbirth, condition of the new-born).

Universal treatment of fear of childbirth

The multidimensionality, high prevalence, and time constraints of being pregnant (i.e., short window for intervention) make FOC a complex issue that needs more attention and requires a more universal and non-clinical (outside mental health care settings) approach. The universal approach to FOC is one in which more common (transdiagnostic) mechanisms across fear and anxiety, instead of symptom categorisation and formal diagnosis, are spotlighted as playing an important role in guiding and treating FOC in midwife-led care. A universal approach to psychological

suffering was first suggested by Harvey et al. (2004). Several common components to psychological suffering (e.g., fear and anxiety), such as biased attention, biased cognitive-emotional process, and avoidance behaviours, were suggested (Mansell et al., 2008). Additionally, intolerance of uncertainty (Carleton, 2016) and catastrophizing (Gellatly & Beck, 2016) have also been proposed as common mechanisms of mental health suffering. CBT was developed to target psychological suffering and to treat mental health problems (e.g., anxiety) by confronting and modifying the irrational thoughts and beliefs that are most likely at the root of the maladaptive behaviours (Beck, 1976). A large body of literature shows that CBT is the most researched, most used and the most effective treatment for anxiety and comorbid disorders utilizing a more universal approach (Craske, 2012). However, CBT can only be provided by trained psychotherapists, which means that this method is limited for use in midwife-led care. Promising, however, in the evidence-based treatment of the universal components of mental health suffering in clinical and non-clinical settings is mindfulness. Mindfulness training, similar to CBT, targets to reduce suffering and to improve mental health and daily functioning by improving biased attention, biased cognitive-emotional process, intolerance of uncertainty and catastrophizing. However, CBT and mindfulness differ in the method of dealing with cognitive-emotional and behavioural processes. The core of mindfulness is *decentering of* these processes while in CBT these processes are centralized. Besides, in mindfulness unpleasant experiences are as welcome as pleasant ones and these unpleasant experiences do not have to be actively changed. Further, in mindfulness the cognitive-emotional process is worked out through the body and thoughts are not treated as facts (Segal et al., 2002).

In this thesis, we explore mindfulness as a possible non-clinical approach to suffering in pregnant women with high FOC reporting its effects and working mechanisms (*Chapter 5* and *7*). In this way the thesis provides more insight to a universal approach to FOC.

Mindfulness

Mindfulness can be defined as "the awareness that arises from paying attention, on purpose, in the present moment, and non-judgmentally" or as "*awareness* and *relationality*" (Kabat-Zinn, 1990). Mindfulness can be practiced through mindfulness meditations. During mindfulness meditations, participants observe a variety of experiences, such as senses, thoughts, feelings, and bodily sensations that may arise, while cultivating an attitude of open interest to these experiences. This allows the experiences to exist without a willingness or reactivity to change or a desire to escape from them, even if they feel unpleasant. Mindfulness meditation helps the practitioner to realize that physical sensations, thoughts, and emotions are continuously changing, as they are arising and disappearing in the awareness. Mindfulness meditations are born from Eastern meditation traditions, which emphasize that the practice of mindfulness leads to less suffering and more wisdom, compassion, and equanimity (Shonin et al., 2016).

Traditional Buddhistic mindfulness meditations have been successfully adapted for use in Western mental health approaches through Mindfulness-Based Programmes (MBPs). The most well-known and investigated MBPs are Mindfulness-Based Stress Reduction (MBSR; Kabat-Zinn, 1990) and Mindfulness-Based Cognitive Therapy (MBCT; Segal et al., 2013). These two programs have become widely used in health care settings and with both clinical and non-clinical populations to reduce human suffering caused by psychological and physical vulnerabilities. MBSR was developed to improve mental health in people with chronic pain, distress, and other diseases (Baer, 2003; Grossman et al., 2004). This intervention also showed effectiveness in decreasing depression, anxiety, and avoidance symptoms, as well as improving quality of life in healthy populations (Khoury et al., 2015). MBCT was developed to reduce the risk of relapse in people with recurrent depression (Alsubaie et al., 2017)

With findings demonstrating a decrease in psychological suffering, MBPs might also be beneficial to reduce FOC and the use of non-urgent obstetric interventions (i.e., a childbirth outcome) during labour. Pooled results of uncontrolled studies on MBPs demonstrate reduced anxiety, depression, and perceived stress in pregnant women, however, pooled results of (underpowered) controlled studies do not (Dhillon et al., 2017).

Mindfulness-Based Childbirth and Parenting

The Mindfulness-Based Childbirth and Parenting (MBCP; Bardacke, 2012) programme was developed by Nancy Bardacke in 1998 as a formal adaptation of Mindfulness-Based Stress Reduction (MBSR; Kabat-Zinn, 1990, 2005). MBCP was designed for two reasons: "to reduce the perception of pregnancy, childbirth, and parenting-related stressors as threatening or harmful; and to promote awareness from which to select appropriate coping strategies, including the use of mindfulness skills". The first evaluation of MBCP in pregnant women (N = 27, uncontrolled study) showed large effect sizes in the reduction of pregnancy anxiety and the increase of mindfulness, and the increase of mindfulness (Duncan & Bardacke, 2010).

Swedish researchers evaluated the effects of MBCP in a randomized controlled trial (RCT) on pregnant women's perceived stress, depressive symptoms, positive states of mind, and mindfulness as compared to Lamaze childbirth classes (N = 193) at baseline, postintervention, and at 3, 9, and 12 months postpartum (Lönnberg et al., 2020). Post-intervention, MBCP was more effective than the active control since MBCP significantly reduced perceived stress and depressive symptoms and increased positive states of mind, and mindfulness. However, these effects were not sustained during the follow-up period (Lönnberg et al., 2020). In the same study's population, the participants' experiences (mothers n = 10; fathers n = 6) of the MBCP programme were explored through thematic analyses (Lönnberg et al., 2018). Participants with high motivation in MBCP experienced deeper self-knowledge and self-compassion;

and experienced the inter-personal benefits of being helpful in their relationships. Furthermore, what they had learned from MBCP was helpful for them during childbirth and early parenting.

Additional evidence from a pilot feasibility study on MBCP in pregnant women with a history of sexual trauma (*N* = 12) showed high satisfaction with the programme, an immediate reduction in prenatal anxiety, and an increase in interoceptive awareness skills over a longer period. MBCP seemed to be a feasible and acceptable approach for women with a history of sexual trauma (Price et al., 2019). MBCP was also evaluated in a qualitive interview study on the postpartum experience of mothers (*N* = 9). Perception of the present moment, breathing, acceptance, self-compassion and the perception of mindfulness as a safe space to process their experiences were themes which emerged from the descriptions of practicing mindfulness during the postpartum period (Roy Malis et al., 2017).

When examined across cultures, studies also demonstrate MBCP's effectiveness. Chinese researchers evaluated the effects of MBCP on mental health during pregnancy and early parenthood (*N* = 74) as compared to care as usual (Pan et al., 2019). A significant post-intervention between-group difference for stress reduction and depression was found in favour of the intervention group. Nonsignificant between-group results were found for mindfulness. More research on the effects of MBCP is expected from Spanish researchers, who's aim is to assess the efficacy of an adapted MBCP with elements of compassion training in primary care settings to decrease perinatal depression in pregnant women (*N* = 122) as compared to care as usual (Sacristan-Martin et al., 2019).

In this thesis, we are the first to explore the effects of MBCP on high FOC and to evaluate these effects in relation to childbirth outcome and cost-effectiveness. Thereby, we explored through which pathways of action MBCP may improve adaption to childbirth.

Aims

The overall aim of the thesis is to contribute to the knowledge of how to support women suffering from high FOC and to improve the childbirth outcomes in these women. To do so, four aims were formulated to be investigated in three separate Dutch cohorts. First, we investigated FOC assessments in relation to childbirth outcomes in community samples of pregnant women and evaluated a more easy and specific method for assessing FOC. Second, we evaluated the effects of the mindfulness-based childbirth and parenting (MBCP) programme in pregnant women with high FOC and the childbirth outcomes. Third, we examined the cost-effectiveness of MBCP as compared to enhanced care as usual (ECAU) for pregnant women with high FOC. Fourth, we evaluated the mechanisms of change contributing to natural childbirth.

Chapter 2 presents a prospective cohort study (data collected in 2009) investigating whether and which pain cognitions predict the request for pain relief during the first stage of labour. *Chapter 3* presents a prospective cohort study (data collected from 2016-2017) evaluating the predictive value of high FOC based on the W-DEQ-A and the one-item Fear of Childbirth-Postpartum-Visual Analogue Scale (FOCP-VAS) in identifying pregnant women who explicitly requested non-urgent obstetric interventions during pregnancy and/or received non-urgent obstetric interventions during labour. *Chapter 4* describes in detail the study protocol to compare the effectiveness, and cost-effectiveness of MBCP to enhanced care as usual in pregnant women with high FOC and their partners. Here we present the theoretical model on FOC and childbirth outcomes. Chapters 5 to 7 (data collected from 2014-2017) build on Chapter 4. *Chapter 5* presents the primary and childbirth outcomes of a randomized controlled trial evaluating the effects of MBCP in pregnant women with high FOC as compared to ECAU. *Chapter 6* describes the results of the cost-effectiveness of MBCP as compared to ECAU for pregnant women with high FOC from societal and healthcare perspectives. *Chapter 7* describes the outcomes of a mediation study evaluating the possible pathways of action of avoidance (e.g., having a self-requested caesarean section) versus approach (e.g., having a natural childbirth) to the challenges of childbirth in pregnant women with high FOC. Finally, *Chapter 8* provides an overall discussion of all previous chapters in which the results are integrated and interpreted. In this chapter, I addressed some recommendations for future investigations and applications on the MBCP programme in the Dutch midwife-led care.

CHAPTER 2

Pain cognitions as predictors of the request for pain relief during the first stage of labor: a prospective study.

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Abstract

Background: It is thought that pain cognitions determine coping behavior and success in adapting to labor. The aim of this study was to examine whether pain cognitions assessed by the labor pain coping and cognition list (LPCCL) predict the request for pain relief during the first stage of labor and which pain cognition is the strongest predictor of a request for pain relief over and above, and independent of, other pain cognitions.

Methods: Participants in this prospective study were 177 low-risk nulliparous pregnant women. Data were collected on two different occasions. The numerical pain intensity scale (NPS)-anticipated and the LPCCL were administered at 34–36 weeks' gestation followed by the NPS-during labor. Results: Catastrophizing and external pain control predicted the request for pain relief during labor after adjustment for relevant demographic and clinical characteristics, respectively (adjusted odds ratio [*OR*] 2.61 [95% CI 1.45–4.68] and adjusted *OR* 1.90 [95% CI 1.16–3.10]). Catastrophizing was found to be the strongest and independent predictor among the pain cognitions while controlling for significant background variables (adjusted *OR* 2.61 $p < 0.001$).

Conclusion: Catastrophizing seems to have a substantial impact on the request for pain relief in low-risk pregnant women.

Keywords: childbirth, coping, midwifery, pain, perinatal metal health.

Introduction

Labor pain is considered to be a complex phenomenon in which sensory, emotional and cognitive dimensions are involved (Lowe, 2002; Melzack, 1999). Given that birth is, principally, a physiological process, one would expect that all women should have the ability to adapt to labor pain in a normal labor (Russell et al., 2001). Labor is typically rated very highly when painful life experiences are ranked in order of severity (Dickinson et al., 2003; Melzack, 1984). However, remarkable differences in pain experience and coping behavior in response to labor have been reported among women (Lally et al., 2008; Smith et al., 2006). It has been suggested that the cognitive dimension of labor, that is the meaning that individual women attach to their pain and their expectations regarding pain, plays a crucial role in the experience of labor (Flink et al., 2009; Wuitchik et al., 1989). Moreover, it is thought that the particular meaning and expectations -pain cognitions- determine the individual's coping behavior and success in adapting to labor (Escott et al., 2009). Studies suggest that mainly negative cognitions, such as fearing the worst or catastrophizing, and lacking a belief in internal pain control are associated with poor adaptation to labor pain (Escott et al., 2009; Flink et al., 2009; Van den Bussche et al., 2007; Wuitchik et al., 1989). Labor pain research reports that poor adaptation to this otherwise physiological process contributes not only to an increase in medical interventions (Saisto, Kaaja, et al., 2001; Van den Bussche et al., 2007), but may also influence the mental and physical health of new mothers (Alcorn et al., 2010; Vermelis et al., 2010) and possibly their offspring (Ferber et al., 2005; Ferber & Feldman, 2005).

In the Netherlands, as in most Western cultures an indication for the use of pharmacological pain intervention during labor is either a woman's preference or their belief in their inability to adapt to labor pain (American Society of Anesthesiologists Task Force on Obstetric Anesthesia, 2007; Nederlandse Vereniging voor Anesthesiologie en Nederlandse Vereniging voor Obstetrie en Gynaecologie, 2008). It seems reasonable to expect that women who do not believe they are able to adapt to pain will request pain treatment during labor.

Knowledge about pain cognitions among pregnant women may create an opportunity for caregivers to tailor the way in which they help women to identify their own behavior in coping with pain in response to prospective labor pain. It could also lead to an appropriate guide for women in choosing coping strategies immediately before and during labor (Escott et al., 2009).

The first aim of the present study is to examine whether pain cognitions, as assessed in late pregnancy in nulliparous women, predict the request for pain relief during the first stage of labor. Secondly, we analyze which pain cognitions predicted the request for pain relief during labor over and above, and independent of, other pain cognitions while controlling for significant background variables.

Methods

Participants

From April to August 2009, a total of 270 pregnant women in 12 primary care midwifery practices were asked to participate in the study according to the sequence of their visit. Nineteen women (7%) refused to participate. The two main reasons for refusal were the wish not to be disturbed during labor and their perceived inability to grade the intensity of pain with a number. Written informed consent was obtained at 34–36 weeks' gestation from 251 low-risk nulliparous pregnant women. Women with premature labor (< 37 weeks) or post-term pregnancy (≥42 weeks), or who were referred to an obstetrician during pregnancy or labor due to medical reasons other than pain relief, were excluded from the study. Mastery of the Dutch language was required to complete the questionnaires. This study was exempted from formal ethical approval by the Dutch Central Ethical Committee (CCMO, The Hague). After written informed consent, the women completed the numerical pain intensity scale (NPS-anticipated) and the labor pain coping and cognitions list (LPCCL) (first measurements). Sixty women (24%) were excluded because of a referral to an obstetrician during pregnancy. Finally, 191 out of 251 women (76%) completed all measurements (LPCCL, NPS-anticipated and NPS-during labor, general questionnaire). Eleven women (4%) were excluded because they completed the questionnaires using more than one answering category. Three more women were excluded: two of them because of obstetrical pathology (Caesarean section indicated), and one woman was excluded because of the use of high doses of antidepressants. An analysis was performed on 177 out of 251 (71%) of the women with complete data.

Design

In this prospective cohort study, data were collected on two different occasions. The NPS-anticipated and the LPCCL were administered at 34–36 weeks' gestation followed by the NPS-during labor.

Measures

LPCCL

The original pain coping and cognition list (PCCL) is a valid, reliable and compact list that has been used in a clinical setting for years in the assessment of chronic pain (Stomp-van den Berg et al., 2001). The PCCL aims to measure pain cognitions in a comprehensive way and covers the meaning and expectations of pain, and cognitive coping strategies. This list was modified in close consultation with the designers of the PCCL, for use regarding labor pain. In the adapted version, every item represents a thought or strategy about labor pain. The modified list was called the LPCCL. The LPCCL consists of 42 items to be scored on a six-point Likert scale ranging from one:

= completely disagree to six: = completely agree. The sum of the items belonging to a particular subscale was divided by the number of subscale items in the subscale. Four subscales can be distinguished: (i) Catastrophizing, or having negative thoughts about the possible catastrophic consequences of labor pain (e.g., 'I think that labor pain will dominate everything during my labor'); (ii) Internal pain control, that is having positive expectations about personal control over labor pain (e.g., 'It depends on me how much influence the pain will have on me during labor'); (iii) External pain control, having positive expectations about control over labor pain by medical specialists or others (e.g., 'Only a midwife or a gynecologist can help me with my labor pain'); and (iv) Coping with labor pain, using primarily cognitive strategies to cope with labor pain such as diverting attention, ignoring pain or using self-statements (e.g., 'When I am in labor pain, I will ignore the pain').

NPS

Two NPS, anticipated and during labor, were used to measure a woman's labor pain intensity measured on a range from one to ten, (one = minimal intense pain to ten = most intense pain) (Jensen et al., 1986). The NPS-anticipated measures a woman's most intense imaginable prospective labor pain and the NPS-during labor measures experienced labor pain.

Data collection

At the intake, the NPS-anticipated and the LPCCL were filled out by the women. During actual labor, the self-report NPS during labor was obtained. The midwife asked the women to grade their pain intensity with a number. On average, this last measurement took place six weeks (*SD* = 1.07) after the intake. This assessment was carried out either at the moment when women in labor made a spontaneous request for pain relief or when women in labor had an established need for pain relief, or when women in labor had attained full cervical dilatation without a request or need for pain relief. The time of request and the cervical dilatation rate were recorded. The importance of a spontaneous request that is without being influenced by the midwife was emphasized. The request for pain relief was relevant during the whole dilatation period including the moment of full cervical dilatation until the delivery phase began. If pain relief was requested, the obstetrician made the final decision regarding pain intervention. The midwife, who had coached the woman through the labor, completed a general questionnaire to assess demographic and clinical variables. The onset of the first stage of labor was defined as regular and painful contractions with continuous progression.

Analysis

Data analysis was performed using the Statistical Package for Social Sciences (SPSS 15.0, Chicago, IL). Missing answers were estimated by calculating the mean of the

subscale when less than 10% of the answers were missing on a subscale. To evaluate the data, descriptive statistics were calculated, and distributions checked. First, univariate logistic regression analyses were performed to identify subscales of the LPCCL, which significantly predicted the request for pain relief during labor. The odds ratios (*OR*), 95% confidence intervals (CI) and *p*-values are presented.

In addition, demographic and clinical variables which could also be related to the request for pain relief were analyzed using univariate logistic regression, see Table 1 and Table 2. These variables included: education level (Schytt & Waldenström, 2010); ethnicity (Sheiner et al., 2000); psychological problems, such as stress, anxiety, or sexual abuse (Sieber et al., 2006; van der Hulst et al., 2006); attendance at an antenatal class (Bergström et al., 2009); anticipated (Lally et al., 2008) and experienced labor pain intensity (Melzack, 1984); continued support from the midwife or the doula during labor (Hodnett et al., 2007); intended place of labor (van Der Hulst et al., 2004); and the duration of the first stage of labor (Wuitchik et al., 1989). Using multivariate logistic regression, it was subsequently investigated whether individual LPCCL subscales still predicted the request for pain relief during labor after controlling for relevant demographic and clinical predictors of the request for pain relief, which were significantly related to the request for pain relief with a *p*-value ≤ 5%.

Finally, in order to investigate which pain cognitions predicted the request for pain relief during labor over and above, and independent of, other pain cognitions while controlling for significant background variables, a hierarchical multivariate logistic prediction model was constructed, based on the predictive factors significantly related to the request for pain relief as identified in the univariate analyses (*p*-value in = 0.05 and *p*-value out = 0.10). First, demographic and clinical variables, significantly related to the request for pain relief, were added into the model in the first step, subsequently the relevant pain cognitions were added to the model with a stepwise forward selection procedure for exploratory model building.

Table 1. *Antenatal data of nulliparous women who did and did not request pain relief during labor, using univariate logistic regression analyses, N =177*

Characteristics	Respondents	Nulliparous women requested pain relief	Nulliparous women did not request pain relief	Crude *OR* & 95%CI	*p*-value
	***N* = 177(100)**	***N* = 48/177 (27%)**	***N* = 129/177 (73%)**		
Age Mean (SD)	29.2 (4.7)	28.9 (4.9)	29.3 (4.6)	0.98 [0.92-1.06]	0.63
Dutch versus non-Dutch	160 (90.4%)	49 (83.3%)	120 (93%)	0.38 [0.14-1.04]	0.06
	17 (9.6%)	8 (16.7%)	9 (7%)		
Education level					
Lower	77 (44.1%)	27 (56.3%)	51 (39.5%)	1.97[1.006-3.85]	0.048
Higher	99 (55.9%)	21 (43.7%)	78 (60.5%)		
Antenatal Classes *yes*	127 (71.8%)	28 (58.3%)	99 (76.7%)	0.42 [0.21-0.86]	0.02
no	50 (28.2%)	20 (41.7%)	30 (23.3%)		
Psych. Problem in the past	18 (10.2%)	4 (8.3%)	14 (10.9%)	0.75 [0.23-2.39]	0.62
Continuous support from partner	162 (91.5%)	45 (93.8%)	117 (90.7%)	1.54 [0.42-5.71]	0.52
Continuous support from midwife/doula	69 (39%)	18 (37.5%)	51 (39.5%)	0.92 [0.49-1.70]	0.78
Duration of dilatation period in hours	7 (1&25)	10 (2&24)	6 (1&25)	1.13 [1.06-1.21]	< 0.001
Intended place of labor					
Home	105 (59%)	26 (54%)	64 (50%)	0.75 [0.38-1.46]	0.40
Hospital	72 (41%)	22 (46%)	65 (50%)		

Table 2. *Means (M), standards deviations (SD), crude ORs and 95% CI and p-values of the scores on the labor pain coping and cognition list (LPCCL), the numerical pain intensity scale (NPS)-anticipated and the NPS-during labor in women requesting and not requesting pain relief during labor, using univariate logistic regression analyses, N = 177*

Subscales of LPCCL& NPS score	Nulliparous women requested pain relief	Nulliparous women did not request pain relief	Crude *OR* and 95%CI	*p-value*
	N* = 48/177 (27%) *M(SD)	***N* = 129/177 (73%) *M(SD)***		
Internal pain control	3.86 (0.61)	4.05 (0.51)	0.53 (0.29 – 0.99)	0.045
External pain control	3.57 (0.83)	3.02 (0.75)	2.36 (1.52 – 3.67)	< 0.001
Catastrophizing	3.05 (0.80)	2.47 (0.61)	3.48 (2.01 – 6.03)	< 0.001
Coping with pain	4.00 (0.46)	3.84 (0.52)	1.89 (0.96 – 3.70)	0.08
NPS-anticipated	7.66 (1.35)	8.05 (1.20)	0.79 (0.61 – 1.02)	0.07
NPS-during labor	9.03 (0.87)	8.59 (1.01)	1.64 (1.13 – 2.38)	0.008

Results

Data

Numerical data collected for pain cognitions (LPCCL) were normally distributed, except the scores for catastrophizing. To analyze the subscale catastrophizing as a continuous variable we performed a logarithmic (ln) transformation of this variable. The missing values were estimated two times for the subscale coping with pain and once for the subscale external pain control. The Cronbach's α for each subscale of the LPCCL was calculated. These were catastrophizing 0.84, internal pain control 0.64, external pain control 0.72 and coping with pain 0.62.

Differences in characteristics in women requesting and not requesting pain relief

A cohort of 177 women (100%) started labor spontaneously, of whom 48 (27%) requested pain relief. Of these, 35 (73%) did so during the latent phase of labor defined as up to 4 cm cervical dilatation and 13 (27%) did so during the active phase of labor before 8 cm cervical dilatation (Figure 1). The entire group of women who requested pain relief during the latent stage of labor received pharmacological pain relief. At least 10 out of 13 (77%) of the women who had requested pain relief during the active phase of labor had received pharmacological pain relief. Midwives established need for pain relief in 6 (3%) women. These women were included in the group of women not requesting pain relief, although they received pain relief. Table 1 describes the antenatal data of the final sample of nulliparous women. The basic characteristics of

our sample were compared with the characteristics of Dutch women (data not given). The mean age, ethnicity and education level of the study participants were comparable to the data from the Dutch Perinatal Registry (Perined, 2009). The prevalence of previous psychological problems, such as stress, anxiety, or sexual abuse, among the women responding was comparable to national data (RIVM Bilthoven, 2010). There are no national data available concerning the frequencies of attendance of antenatal classes and the continuous support of a partner, midwife or doula. Characteristics such as the age of a woman, previous psychological problems and continuous support during labor from a partner, midwife or doula did not differ significantly between women who did and did not request pain relief during labor. A significant difference between groups was found in the education level and attendance at antenatal class. Compared to women who did not request pain relief, women who did request pain relief during the first stage of labor had a lower educational level, respectively 56.3 versus 39.5% (*p*-value 0.048), and had not attended antenatal class, respectively 23.3 versus 41.7%, (*p*-value 0.02) and had a longer dilatation period, respectively 10 versus 6 hours (p-value < 0.001).

Figure 1. *Flowchart of participants who did and did not request pain relief during labor*

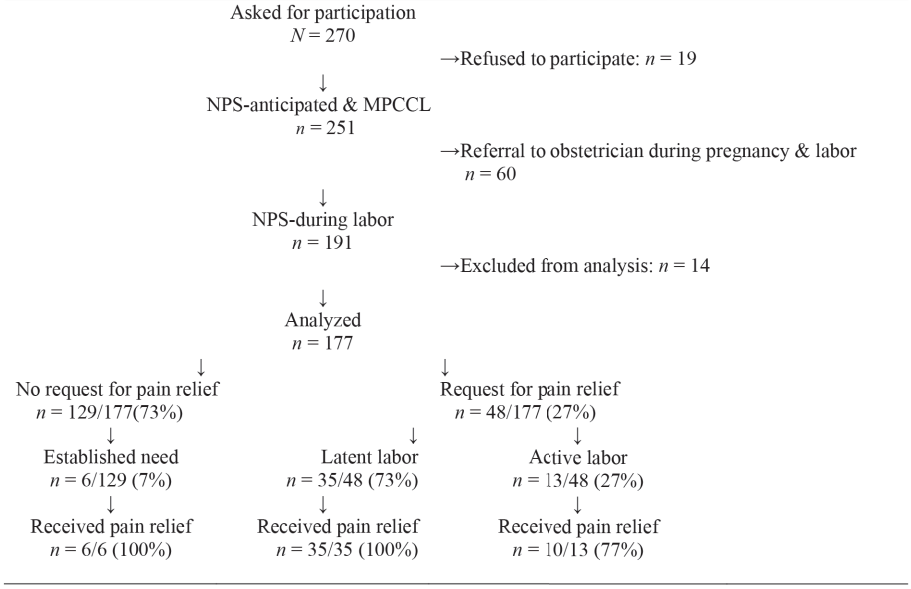

Table 3. *Results of multivariate logistic regression analyses predicting the request for pain relief during labor by the individual LPCCL subscales, adjusted to relevant background factors (lower education level, attendance at antenatal class, higher scores on the NPS-during labor, the duration of the first stage of labor), n = 177.*

Subscales of MPCCL	β	S.E	Adjusted exp.(β)	95% CI	*p*-value
Internal pain control	−0.49	0.34	0.61	0.32–1.19	0.15
External pain control	0.64	0.25	1.90	1.16–3.10	0.01
Catastrophizing	0.96	0.30	2.61	1.45–4.68	< 0.001
Coping with pain	0.64	0.40	1.91	0.87–4.20	0.11

Univariate predictors of request for pain relief

Table 2 shows the scores for the pain cognitions as measured on the LPCCL and crude ORs that were associated with the request for pain relief during labor in the two groups of participants, requesting and not requesting pain relief during labor.

Women who did not request pain relief scored statistically, significantly higher on the subscale internal pain control (*p*-value 0.045). Women who requested pain relief during the first stage of labor scored significantly higher on the LPCCLs' subscales: external pain control and catastrophizing (*p*-value < 0.001 and < 0.001, respectively) and on the NPS-during labor (*p*-value 0.008). There were no significant differences in scores on the subscale coping with pain and scores on the NPS-anticipated between women, who did and did not request pain relief during the first stage of labor.

Multivariate predictors of request for pain relief

Table 3 summarizes the results of multivariate logistic regression analyses of the predictive value of individual LPCCL subscales after statistical adjustment for relevant background variables significantly related to the request for pain relief (i.e., low education levels, attendance at antenatal class, high scores on NPS-during labor, and the duration of the first stage of labor). Women who scored high on external pain control were almost twice as likely to request pain relief during labor as those who scored lower (adjusted *OR* 1.90 [95% CI 1.16-3.10]). Women with high scores for catastrophizing were more than two and a half times as likely to request pain relief during labor as women with lower scores (adjusted *OR* 2.61 [95% CI 1.45-4.68]). High scores on internal pain control no longer predicted the request for pain relief after controlling for relevant background variables.

We then performed a stepwise forward hierarchical multiple regression analysis as shown in Table 4 in order to analyze which pain cognitions predicted the request for pain relief during labor over and above, and independent of, other pain cognitions while controlling for significant background variables. Catastrophizing was found to be the most powerful predictor of the request for pain relief during the first stage of labor

(adjusted *OR* 2.61 *p*-value < 0.001). Coping with pain, internal pain control and external pain control were not entered into the model as they did not predict the request for pain relief over and above catastrophizing.

Table 4. *Results of a stepwise forward hierarchical multiple regression model of the unique predictive power of the LPCCL subscales in predicting the request for pain relief during labor adjusted to relevant background factors (lower education level, attendance at antenatal class, higher scores on the NPS-during labor, the duration of dilatation period), n = 177*

	(β)	**SE**	***Exp.* (β)**	***p*-value**	**95% CI**
Step 1					
Constant	−6.96	1.95			
Lower education level	0.10	0.41	1.11	0.80	(0.50–2.45)
Attendance at antenatal class	−0.80	0.42	0.45	0.055	0.20–1.01)
NPS-during labor	0.33	0.20	1.40	0.10	(0.94–2.08)
Dilatation period in hours	0.09	0.03	1.10	0.006	(1.03–1.17)
Catastrophizing	0.96	0.30	2.61	< 0.001	(1.45–4.67

Note. R2 = 0.28 for Step 1

Discussion

We performed a concomitant evaluation of different pain cognitions such as catastrophizing, external and internal pain control and coping with pain before labor using a multidimensional pain cognitive framework (Lazarus & Folkman, 1984). The aim of this study was to examine whether pain cognitions as assessed by the LPCCL may predict poor pain coping behavior in the first stage of labor, defined as a request for pain relief, in low-risk nulliparous pregnant women. We found that catastrophizing and external pain control predict the request for pain relief during labor after adjustment for relevant demographic and clinical characteristics such as, education level, attendance at an antenatal class, actual labor pain intensity, and the duration of the first stage of labor.

However, it can be argued that the time factor in the self-appraisal of a woman's ability to cope with labor played a crucial role in our study, as 73% of all requests for pain treatment were made in the latent phase of labor. Finally, we found that women who requested pain relief had a longer dilatation period and more medical interventions during labor.

Above all, catastrophizing was found to be the strongest predictor of the request for pain relief among other pain cognitions and will therefore be discussed more extensively.

Our finding that catastrophizing is associated with an increase of medical treatment is not only consistent with an extensive chronic pain research (Keefe et al., 1997; McCracken, 1997; Sullivan et al., 2001, 2004; Turk & Okifuji, 1999) but also with a very

little research on labor pain in this area (Ferber et al., 2005; Flink et al., 2009; Van den Bussche et al., 2007). According to some chronic pain studies, catastrophizing has been found to be a potential predictor of an increase of pain perception in general (Keefe et al., 2004; Vlaeyen & Linton, 2000). One would expect that women in labor, endorsing this pain cognition would experience high levels of pain. In our study, catastrophizing, assessed in late pregnancy, turned out to be the strongest predictor for the request for pain treatment even when adjusted for the actual severity of labor pain. In our analysis, due to the condition that the request for pain treatment was relevant through the whole dilatation period up until the delivery phase, we have considered pain severity to be an independent factor related to the request for pain relief. Apparently, catastrophizing pain was still predictive for requesting medical pain treatment after adjustment for the level of subjective pain experience in our study population. Consistent with this finding, we suggest that pain coping behavior, such as a request for pain treatment while still in the latent phase of labor (73%) and not the actual perception of pain in the women in labor could be a deciding factor in requesting pain treatment. This suggestion may be supported by the research of van den Bussche where catastrophizing was found to be an independent factor positively associated with the avoidance of prospective labor pain by choosing a priori an epidural anesthesia (Van den Bussche et al., 2007). Furthermore, the study of Flink reported that women who catastrophized about labor pain showed a tendency to avoid physical activity after labor, resulting in slower adaptation to daily activities (Flink et al., 2009). Besides these findings, the studies of Ferber demonstrated that labor pain catastrophizing rather than labor pain intensity predicted avoidance of social contacts and diminished interactions between new mothers and their offspring (Ferber et al., 2005; Ferber & Feldman, 2005).

The fear-avoidance model of pain may help clarify our study results (Vlaeyen & Linton, 2000). According to this model negative emotions and cognitions regarding pain play a crucial role not only in the experience of pain, but also in coping behavior such as avoidance of threatening pain stimuli. Originally, this model is proposed to explain the development of acute in chronic pain. However, there is some evidence that persons catastrophize future pain as a coping behavior in order to reduce prospective distress (Escott et al., 2009; Sullivan et al., 2001) consistent with the present study results and those of Ferber, van den Bussche and Flink (Ferber et al., 2005; Flink et al., 2009; Van den Bussche et al., 2007). Furthermore, given that catastrophizing as a variant of defeatism covers anxiety, depression and weak self-perception (Keefe et al., 1997; McCracken, 1997; Sullivan et al., 2001, 2004), it seems reasonable to suggest that women endorsing this pain cognition exempt themselves from any effort to cope with labor pain because the magnitude of the threat of painful stimuli is perceived as overwhelming (Manning & Wright, 1983). So, it is conceivable that the fear-avoidance model is also applicable to labor pain, future research on this phenomenon may validate the suggestion that the similar pain mechanisms may operate in anticipated acute pain as in the chronification of pain (Escott et al., 2009).

We observed that the educational level or attendance at an antenatal class did not contribute to any beneficial adjustment to labor pain, which is in line with the results of the Bergstrom study (Bergström et al., 2009). Even continued support from the midwife or the doula during labor had no relationship to the beneficial adaptation to labor pain. This was unexpected and contrasted with the reports of the Hodnett's review (Hodnett et al., 2007). These findings might support the suggestion that catastrophizing is an inherent pain cognition (Ferber et al., 2005; Flink et al., 2009; Keefe et al., 2004; Van den Bussche et al., 2007) and requires intense and individual guidance as recommended in a recent review on psychological pain management during childbirth (Escott et al., 2009).

We attempted to provide more insight into the role of pain cognitions in the adaptation to labor. However, we should address some limitations of the study. A substantial number of women (28%) were excluded because of a referral to an obstetrician due to medical reasons other than pain relief. Secondly, the required ability in the Dutch language may have resulted in the exclusion of an interesting group, which may have influenced our results. Thirdly, the results of our study may not be generally applied to other pregnant populations since the Dutch health system with its physiological primary care and home birth culture is critically different from other health systems. Fourthly, we have to consider whether our adapted questionnaire was able to measure pain cognitions in pregnant women adequately: since the LPCCL is not validated yet for a population of pregnant women and a qualitative study on the original PCCL has identified some ambiguous items for a sub-acute neck pain population. However, also in this study the psychometric properties of the subscale catastrophizing proved to be satisfactory (Pool et al., 2010). Finally, because the pain intensity measurements as collected by the midwives took place at unexpected and sometimes inconvenient hours, we were unable to monitor or confirm that midwives did not inadvertently influence pain intensity ratings.

Reports on this topic are scarce and the present study is just a first step in providing systematically collected empirical data on this clinically relevant topic. Moreover, this study touches upon a central area in midwifery care which has enough potential for the clinical setting to improve labor pain management (Escott et al., 2009; Lally et al., 2008; Rijnders et al., 2008). Our study results may be viewed in relation to other labor pain research reporting that poor adaptation to this otherwise physiological process may contribute to an increase in medical interventions (Saisto, Kaaja, et al., 2001; Van den Bussche et al., 2007). However, it might also influence the process after childbirth given that catastrophizing overlaps with depression and anxiety (Alcorn et al., 2010; Ferber et al., 2005; Ferber & Feldman, 2005; Vermelis et al., 2010).

In conclusion, catastrophizing appears to have substantial impact on cognitive pain coping behavior even in low-risk pregnant women. It may be beneficial for the labor process to identify women who catastrophize and offer them tailored antenatal training

and guiding of labor. Midwives should be aware of the powerful effects of cognitive processes in adapting to labor pain.

We recommend, in particular, exploring the role of catastrophizing, besides other pain cognitions, in adapting to labor pain. It will be a challenge to identify what factors may contribute to catastrophic thoughts about this physiological process. Finally, an adequate intervention in order to decrease or eliminate negative pain cognitions should be created. In order to achieve this, the first step should be the development and validation of the LPCCL and a larger and more heterogeneous population of low and high-risk pregnant women should be included in the future studies.

CHAPTER 3

Can a simple assessment of fear of childbirth in pregnant women predict requests and use of non-urgent obstetric interventions during labour?

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Abstract

Objective: To examine whether the Wijma Delivery Expectation Questionnaire (W-DEQ-A) and the one-item Fear of Childbirth-Postpartum-Visual Analogue Scale (FOCP-VAS) - measuring high FOC - are useful tools in predicting requested and received non-urgent obstetric interventions in pregnant women.

Methods: A prospective cohort study. Self-selected pregnant women from midwifery care settings (N = 401). W-DEQ-A and FOCP-VAS were assessed at two timepoints in pregnancy. Measures of non-urgent obstetric interventions which were derived from medical files were: induction of labour, epidural analgesia, augmentation with oxytocin due to failure to progress and self-requested caesarean section. Hierarchical logistics regression models were used.

Main outcome measures: The change in the Nagelkerke $R^2$was examined for three models predicting two outcome measures: (1) explicitly requested non-urgent obstetric interventions during pregnancy and (2) received non-urgent obstetric interventions during labour. The first model only included participants' characteristics, the second model also included FOCP-VAS≥5, and in the third model the W-DEQ-A≥66 was added.

Results: High FOC measured with FOCP-VAS≥5 predicted requested (pseudo-R^2 = 0.33, X^2 = 59.82, p < 0.001) and received non-urgent obstetric interventions (pseudo-R^2 = 0.19, X^2 = 32.81, p < 0.001) better than high FOC measured with W-DEQ-A≥66.

Conclusion: This study is the first evaluating self-reported FOC and postpartum based on VAS (subjective outcome) in relation to actual pregnancy and childbirth outcomes derived from medical files (objective outcome). Non-urgent obstetric interventions could already be predicted in the first half of pregnancy by means of a simple FOC assessment with the one-item FOCP-VAS. Implementing this easy to use one-item screening tool in midwifery care is suggested.

Keywords: Fear of childbirth, Visual Analogue Scale, Wijma Delivery Expectation Questionnaire, screening, obstetric interventions.

Introduction

Fear of childbirth (FOC) is a complex concept covering different aspects of fear, anxiety and depression within, and external to the pregnancy itself (Rondung et al., 2016; Rouhe et al., 2011). FOC seems to be overlooked in clinical practice and often remains unrecognized and untreated (de Vries et al., 2020; de Waal et al., 2010; Howard et al., 2014; Saisto & Halmesmäki, 2003). However, one out of four pregnant women in Western societies experiences high FOC (Richens et al., 2018) as measured with the Wijma-Delivery Expectancy Questionnaire (W-DEQ-A≥66; Wijma et al., 1998). A large Australian study (*N* = 1386) showed that high (W-DEQ-A≥66-84) and severe FOC (W-DEQ-A≥85) is strongly related to mental health problems in pregnant women and their inability to adapt to childbirth (Toohill et al., 2015). In addition, a Canadian study (*N* = 650) reported a significant relationship between high FOC and anxiety, and between high FOC and fatigue in pregnant women (Hall et al., 2009).

The inability to adapt to childbirth is evident in the number of pregnant women's request and use of non-urgent obstetric interventions during labour such as epidural analgesia (EA) or self-requested caesarean section (sCS) in order to avoid stress related to childbirth (Hildingsson, 2014; Räisänen et al., 2014). However, these obstetric interventions are associated with serious downsides. For example, EA is associated with assisted vaginal births and a lower Apgar score in new-borns (Ravelli et al., 2020; Törnell et al., 2015). The risk of severe acute morbidity is five times higher with CS than with vaginal births (Zwart et al., 2008), and having had a previous CS increases the risk for morbidity in an ongoing pregnancy by three times (van Dillen et al., 2010). In turn, obstetric interventions can generate a cascade of instrumental and operative deliveries (Rossignol et al., 2014), as well as traumatic experiences for labouring women (Hollander et al., 2017) In face of growing obstetric interventions in childbirth the World Health Organization (WHO) asks for actions to promote spontaneous childbirth which includes interventions for FOC (WHO, 2018) as unrecognized and untreated FOC also has negative consequences. That is, it may lead to trauma (Hollander et al., 2017) and postpartum depression in new mothers (Hymas & Girard, 2019), to disturbed mother-newborn bonding (Dubber et al., 2015), and to the neuro- and emotional maldevelopment of the newborn (Davis & Sandman, 2010; Dean et al., 2018).

Despite recognition of harmful consequences of FOC and recommendations of the National Institute for Health and Care Excellence Guideline (National Institute for Health and Care Excellence, 2014), early detection of FOC seems to be impeded by limited utilization of questionnaires in midwifery practice (Larsson et al., 2016). The limited utilization of screening for FOC can be explained by time constraints during midwifery consultations (Larsson et al., 2016) and the length of the 33-item W-DEQ-A (Wijma et al., 1998). An approach to solve this problem would be the availability of a brief and easily accessible measurement tool, which can be administered preferably in early pregnancy.

The one-item FOC measure is based on the reliable and valid visual analogue scale (VAS; Ahearn, 1997) and could be such an instrument. Rouhe et al. (2009) have first used such a measure (e.g., 'How much do you fear childbirth?') showing high sensitivity in screening for clinical FOC (W-DEQ-A≥100) with a VAS threshold of 5.0. However, it is unknown whether the one-item VAS could predict actual non-urgent obstetric interventions in pregnant women. Furthermore, the recent reviews suggested measuring FOC from a broader timeline perspective including not only childbirth but also the postpartum period in order to increase the dimensionality of FOC (Bayrampour et al., 2016; Rondung et al., 2016). By combining childbirth and the postpartum period as one event, a broader interpretation of threat related to childbirth and its consequences over time for the transforming body and mind of pregnant women could be captured. That is, FOC may for some women include the process of childbirth while for others it is related to the consequences of childbirth (postpartum). From a psychological perspective fear and anxiety are always about the events in the future (Craske & Stein, 2016), and therefore including both fear of childbirth as well as fear for the postpartum period in FOC seems valid.

The aim of this study was to examine the predictive value of high FOC based on the W-DEQ-A and the one-item Fear of Childbirth-Postpartum-Visual Analogue Scale (FOCP-VAS) in identifying pregnant women who explicitly requested non-urgent obstetric interventions during pregnancy and/or received non-urgent obstetric interventions during labour.

Methods

Participants and procedure

A self-selected cohort of pregnant women (*N* = 401) was recruited between April 2016 and December 2017 (see Figure 1). Twelve primary midwife-led care practices participated which were evenly distributed over urban (*n* = 6) and rural areas (*n* = 6). Midwives invited all pregnant women who visited the midwifery practices during a three months-period (*N* = 526) to participate in a study on emotions about childbirth. In addition, 23 pregnant women applied via an advertisement on Facebook and completed the measurements. Of those women, 485 (88.3%) agreed to be approached by the research team and 401 (73%) completed the first measurement.

After digital informed consent was acquired, participants filled out the online questionnaires, using the Lotus program with a forced response. Being able to read Dutch sufficiently and being between the 16th and the 26th weeks of pregnancy at the first wave of data collection (T1; *N* = 401) were inclusion criteria. The second wave of data collection (T2; *n* = 356) took place ten weeks later, and data were collected from the medical records after birth at T3 (*n* = 370; 92.3% of the T1 sample).

Measurements

Participants' characteristics – which are found to be related to non-urgent obstetric interventions – such as parity, age and educational level (Christiaens et al., 2010), born outside the Netherlands, attendance to antenatal classes (Veringa et al., 2011), the size of attended midwifery practices (Yvonne Fontein, 2010), and received treatment for FOC or related emotions in the current pregnancy, were collected from medical files.

The one-item FOCP-VAS ('Please rate your current degree of fear of childbirth and the postpartum period?') was completed first. It was used to make a brief overall assessment of FOC and ranged from zero (not fearful at all) to ten (very much fearful). Cronbach's α was not applicable as the measure consists of one item.

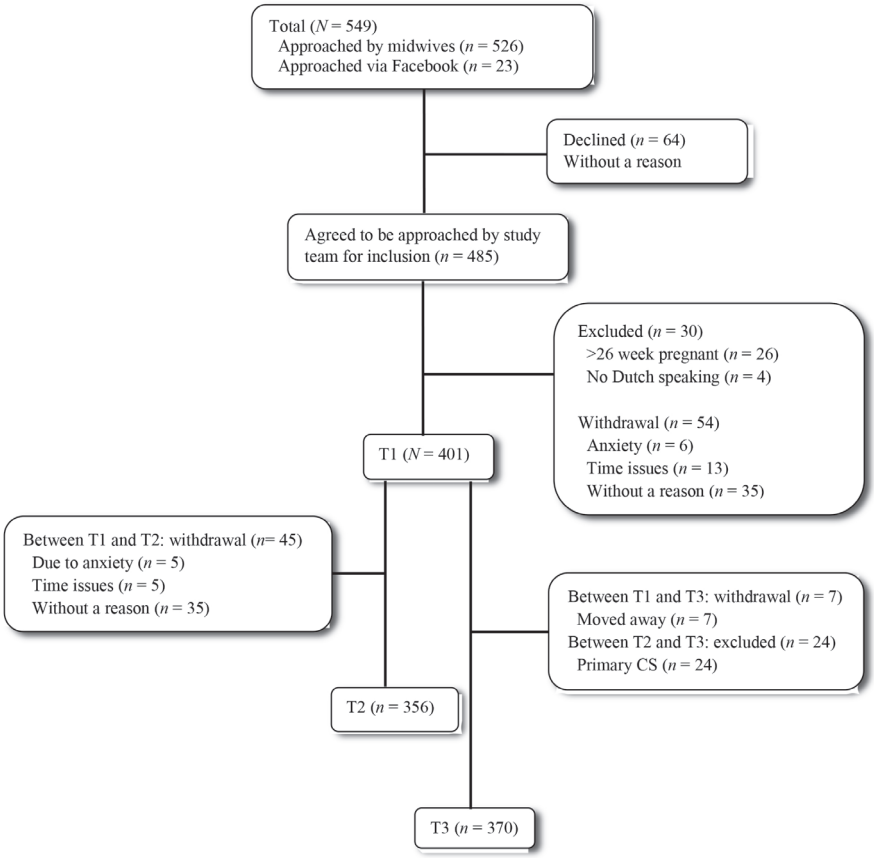
Next, the W-DEQ-A was completed. The W-DEQ-A is a 33-item scale assessing an anticipated emotional appraisal towards childbirth (e.g., 'How do you think you will feel in general during the labour and delivery'; Wijma et al., 1998). Answers are rated on a 6-point scale with the total scores ranging from 0-165 and cut-offs indicating high (≥66), severe (≥85), and clinical (≥100) FOC. In the present study Cronbach's α at T1 and T2 was 0.94.

In line with Offerhaus et al. (2013), non-urgent obstetric interventions were defined as interventions that did not require immediate investigation or treatment by obstetric care as they could be treated in midwifery care. However, these interventions were provided to support pregnant women to cope with the challenges of childbirth. The decision to use non-urgent obstetric intervention was made by a pregnant/labouring woman and her midwife. Non-urgent obstetric interventions were divided in: (I) *explicitly requested during pregnancy*: induction of labour, EA or intravenous analgesia (IA; such as a Remifentanil intravenous pump) for anticipated labour, and sCS (as documented in the medical files by care providers), and (II) *received during labour*: augmentation with oxytocin (due to failure to progress), EA or IA, and sCS (as derived from the delivery reports in the medical files). The choice for these outcomes was based on a Dutch national data study evaluating the increasing numbers of referrals for non-urgent obstetric interventions during childbirth (Offerhaus et al., 2013).

Power analysis

A priori power analysis, with G*Power (3.9.1.2) indicated that a sample size of 378 would be sufficient to detect a significant small effect (Odds Ratio [*OR*] 1.4) of FOC predicting non-urgent obstetric interventions given the percentage of women (28%) requesting EA during labour (Veringa et al., 2011), assuming a power of 0.80 and an alpha of 0.05.

Figure 1.
Flowchart of participants



Note. CS = Caesarean Section; T1 = first measurement at circa 20 weeks of pregnancy; T2 = second measurement, ten weeks after T1; T3 = third measurement (information from medical records of childbirth), within two weeks after birth. Measurements of T1 and T2 were used for determining prevalence of FOC over time. Measurements of T3 were used for hierarchical logistic models' analyses.

Statistical analyses

Statistical analyses were carried out using SPSS 25.0 (Statistical Package for Social Science for Windows, Chicago, IL, USA). Frequencies, Cronbach Alpha's, paired and one-sample *t*-test were used for continuous data and Chi-square was used for dichotomous data. Cohen's Kappa was used to assess the agreement between W-DEQ-A and FOCP-VAS. Skewness and kurtosis values of the dimensional W-DEQ-A and FOCP-VAS scores at T1 and T2 were within the boundary of -1.96 and 1.96.

In order to investigate which FOC measure (W-DEQ-A or FOCP-VAS) predicts non-urgent obstetric interventions best, two dichotomous dependent outcomes variables

were computed: requested non-urgent obstetric interventions during pregnancy (*yes/no*) and received obstetric interventions during labour (*yes/no*). Hierarchical multiple logistic prediction models using *entry* method were used. For the two outcomes, three models per outcome were compared: the first model consisted of the participants' characteristics only; the second model consisted of the first model with the addition of the FOCP-VAS; the third model consisted of the second model with the addition of the W-DEQ-A. The third model examined whether the W-DEQ-A had additional significant value next to the FOCP-VAS in predicting non-urgent obstetric interventions. We have chosen the FOCP-VAS (entered in the second step) over the W-DEQ-A (entered in the third step) due to practicality: i.e., the FOCP-VAS is a one-item measure and more easy to administer and implement in midwifery practices than the W-DEQ-A. The change in the Nagelkerke $R^2$was interpreted and p-values < 0.05 were considered significant. Nagelkerke R^2 (pseudo-R^2) does not summarize the proportion of variance in the dependent variable associated with the predictor (independent) as R^2 does in linear models, and therefore we do not report or interpret the proportion of variance explained. Nagelkerke R^2 is used to compare competing models for the same data, independent of the sample size. It is a good compromise to evaluate the goodness of fit of the logistic regression model and to provide a gauge of the substantive significance of the model (Nagelkerke, 1991).

Results

Descriptives

The sample at T1 (N = 401) consisted of 193 (48.1%) nulliparous and 208 (51.9%) multiparous women. Mean gestational age was 20 weeks (M 19.9 ±3.01) at T1 and 32 weeks (M 31.8 ±3.14) at T2. Their age varied between 20 and 43 years (M 30.9 ±4.27). The majority of women were born in the Netherlands (93.5%; n = 375). Their educational level was distributed as follows: low level - primary education and lower vocational education (9.5%; n = 38), middle level - secondary and middle vocational education (25.4 %; n = 102), and high level - high vocational and university education (63.1 %; n = 253). About half of the participants attended antenatal classes (50.1 %; n = 201). The majority (73 %; n = 270) came from small to middle practices (1 to 4 midwives), and 27% (n = 100) from large sized midwifery practices (≥ 5 midwives).
At T1, 33.9% (n = 136) of women reported high FOC (W-DEQ-A≥66), 11.5% (n = 46) severe FOC (W-DEQ-A≥85), and 2.7% (n = 11) reported clinical FOC (W-DEQ-A≥100). Additionally, mean W-DEQ-A scores at T1 and T2 were not different, and showed high correlation (r = 0.72, $P < 0.001$), indicating stability of FOC over time. There were also no differences in mean scores between nulli- and multiparous participants (see Table 1). Notably, only 3% (n = 12) of pregnant women received some kind of treatment specific for FOC and related emotions.

About 19% (*n* = 73/382) of pregnant women explicitly requested non-urgent obstetric interventions during pregnancy: induction of labour (*n* = 11), EA or IA for anticipated labour (*n* = 36), induction of labour and EA or IA for anticipated labour (*n* = 14), and sCS as a way of delivery (*n* = 12). Almost 30% (*n* = 114/382) received non-urgent obstetric interventions during labour: augmentation with oxytocin due to failure to progress (*n* = 14), EA or IA (*n* = 40), augmentation with oxytocin due to failure to progress and EA or IA (*n* = 48), and sCS (*n* = 12).

W-DEQ-A and FOCP-VAS agreement

The correlation between the W-DEQ-A and the FOCP-VAS dimensional scores was $r = 0.51$, $p < 0.001$. Pregnant women ($N = 401$) who scored W-DEQ-A≥66, scored an average score of 5 ($M = 4.84 \pm 2.52$) on the FOCP-VAS. Based on this result and in accordance with a previous study conducted by (Rouhe et al., 2009), the FOCP-VAS cut-off score of five was used as the threshold for high FOCP. At T1 24.2% (*n* = 97/401) of the pregnant women scored FOCP-VAS≥5. Cohen's Kappa between the two FOC measures (W-DEQ-A≥66 and FOCP-VAS≥5) was 0.30, demonstrating a fair correspondence (Landis & Koch, 1977).

Correlations between predictors and outcome measures

Table 2 summarizes the percentage of women with high versus low FOC on having requested/received non-urgent obstetric interventions. Being nulliparous, born outside the Netherlands, having a low educational level, and receiving care from midwifery practices of ≥5 midwives were entered as the participants' characteristics, as these variables were found to be significantly related with one or two of the non-urgent obstetric intervention outcomes (see Table 3). The analyses also showed that high FOC based on W-DEQ-A≥66 ($p < 0.05$) and FOCP-VAS≥5 ($p < 0.01$) was significantly related to the two outcomes of non-urgent obstetric interventions. In addition, Table 2 summarizes the percentage of women with high versus low FOC on having requested/received non-urgent obstetric interventions.

Table 1.
Dimensional W-DEQ-A and FOCP-VAS scores at T1 and T2, and parity

	Total			**Nullipara**			**Multipara**		
	T1	**T2**		**T1**	**T2**		**T1**	**T2**	
	M (SD)	*M (SD)*	*p**	*M (SD)*	*M (SD)*	*p**	*M (SD)*	*M (SD)*	*p**
FOCP-VAS	3.26 (2.61)	3.33 (2.48)	0.23	3.36 (2.71)	3.44 (2.66)	0.65	3.01 (2.44)	3.21 (2.29)	0.22
W-DEQ-A	56.39 (23.37)	55.95 (23.52)	0.70	53.71 (24.93)	53.18 (24.68)	0.94	58.94 (22.44)	58.10 (22.51)	0.54

Note. FOCP-VAS: Fear of Childbirth-Postpartum-Visual Analogue Scale; W-DEQ-A: Wijma-Delivery Expectancy Questionnaire

* Result of a paired *t*-test

Table 2.

Percentage of women with high and low levels of FOC on requested and received non-urgent obstetric interventions during labour

	W-DEQ-A			FOCP-VAS		
	≥66 (*n* = 126)	**< 66 (*n* = 256)**	***p*-value**	**≥ 5 (*n* = 91)**	**< 5 (*n* = 291)**	***p*-value**
Non-urgent obstetric interventions requested[1] (yes)	(*n* = 37) 29.4 %	(*n* = 36) 14.1 %	0.002	(*n* = 46) 50.5%	(*n* = 27) 9.3 %	< 0.0001
Non-urgent obstetric interventions received[2] (yes)	(*n* = 49) 38.9 %	(*n* = 65) 25.4 %	0.007	(*n* = 52) 57.1 %	(*n* = 62) 21.3 %	< 0.0001

Note. FOCP-VAS: Fear of Childbirth-Postpartum-Visual Analogue Scale; W-DEQ-A: Wijma-Delivery Expectancy Questionnaire.

[1] Induction of labour, epidural analgesia or intravenous analgesia for anticipated labour, induction of labour and epidural analgesia or intravenous analgesia for anticipated labour, and self-requested caesarian section.

[2] Augmentation with oxytocin due to failure to progress, epidural analgesia or intravenous analgesia, augmentation with oxytocin due to failure to progress and epidural analgesia or intravenous analgesia, and self-requested caesarian section.

Predicting non-urgent obstetric interventions

The results of the model fit parameters for both outcomes, as compared to the baseline model, are presented in Tables 4 and 5. Results of the hierarchical logistic models for explicitly requested non-urgent obstetric interventions in pregnancy showed that the first model including the participant's characteristics was significant (pseudo-R^2 = 0.09, X^2 = 20.24, $p < 0.001$). The second model (adding FOCP-VAS≥5) was significantly better in predicting non-urgent obstetric interventions requested during pregnancy (pseudo-R^2 = 0.33, X^2 = 59.82, $p < 0.001$). The third model (adding W-DEQ-A≥66) did not increase the predictive value any further (pseudo-R^2 = 0.33, X^2 = 0.93, p = 0.34), indicating that W-DEQ-A≥66 does not contribute to the prediction of this outcome variable over and above FOCP-VAS≥5.

Non-urgent obstetric interventions received during labour was significantly explained by the participants' characteristics which were included in model 1 (pseudo-R^2 = 0.07, X^2 = 19.04, p = 0.001). The second model (adding FOCP-VAS≥5) was significantly better in predicting received non-urgent obstetric interventions during labour (pseudo-R^2 = 0.19, X^2 = 32.81, $p < 0.001$). The third model (adding W-DEQ-A≥66) was not significantly better in predicting non-urgent obstetric interventions received during labour than the second model (pseudo-R^2 = 0.19, X^2 = 0.02, p = 0.89). This result (again) indicates that W-DEQ-A≥66 does not contribute to the prediction of non-urgent obstetric interventions received during labour over and above FOCP-VAS≥5.

Table 3

Chi-Square coefficients of dichotomized participants 'characteristics and high FOC in relation with non-urgent obstetric interventions during labour

	Non-urgent obstetric interventions					
Participants' Characteristics	**Requested Total**	**Received Total**	**Requested induction of labour**	**Requested EA or IA**	**Received augmentation with oxytocin**	**Received EA or IA**
Nullipara (*yes*)	1.42	3.80	0.23	0.12	0.63	7.47**
Age > 35 years (*yes*)	1.20	1.44	0.05	0.68	1.12	2.05
Born outside the Netherlands (*yes*)	4.70*	3.04	0.38	7.59**	0.38	5.29*
Low educational level (*yes*)	4.16*	2.99	6.62*	0.55	3.87	3.81
No antenatal classes (*yes*)	0.05	0.03	0.14	0.01	2.66	0.16
Practice ≥ 5 midwives (*yes*)	20.41***	11.11**	1.32	22.10***	2.45	11.81**
FOCP-VAS≥ 5(*yes*)	83.29***	34.69***	32.00***	73.38***	36.45***	25.53***
W-DEQ-A ≥ 66 (*yes*)	11.80**	4.47*	0.81	14.72***	3.46	5.48*

Note. EA: epidural analgesia; FOCP-VAS: Fear of Childbirth-Postpartum-Visual Analogue Scale; IA: intravenous analgesia (Remifentanil pump); W-DEQ-A: Wijma-Delivery Expectancy Questionnaire

* $p < 0.05$ (2-tailed), ** $p < 0.01$ (2-tailed), *** $p < 0.001$ (2-tailed)

Table 4.
Result of hierarchical logistic models for non-urgent obstetric interventions requested during pregnancy

	OR	95% CI	*p*	X2	*p*	-2 Log likelihood	Cox & Snell *R2*	Nagelkerke *R2*
Model 1				20.24	< 0.001	311.02	0.05	0.09
Constant	0.17	-	< 0.001	-	-	-	-	-
Nullipara	1.14	0.64 - 2.02	0.66	-	-	-	-	-
Born outside the Netherlands	1.07	0.40 - 2.90	0.89	-	-	-	-	
Low educational level	0.55	0.24 - 1.25	0.15	-	-	-	-	-
Practice ≥ 5 midwives	3.20	1.78 - 5.74	< 0.001	-	-	-	-	-
Model 2				80.06	< 0.001	251.20	0.20	0.33
Constant	0.05	-	< 0.001	-	-	-	-	-
Nullipara	1.11	0.58 - 2.12	0.75	-	-	-	-	-
Born outside the Netherlands	0.66	0.21 - 2.15	0.49	-	-	-	-	-
Low educational level	0.71	0.28 - 1.80	0.47	-	-	-	-	-
Practice ≥5 midwives	4.81	2.41 - 9.61	< 0.001	-	-	-	-	-
FOCP-VAS≥5	12.35	6.26 - 24.36	< 0.001	-	-	-	-	-
Model *3*				80.99	< 0.001	250.27	0.20	0.33
Constant	0.04	-	< 0.001	-	-	-	-	-
Nullipara	1.16	0.61 - 2.24	0.65	-	-	-	-	-
Born outside the Netherlands	0.64	0.20 - 2.10	0.47	-	-	-	-	-
Low educational level	0.69	0.28 - 1.75	0.44	-	-	-	-	-
Practice ≥ 5 midwives	4.87	2.43 - 9.78	< 0.001	-	-	-	-	-
FOCP-VAS≥5	11.34	5.64 - 22.79	< 0.001	-	-	-	-	-
W-DEQ-A≥66	1.39	0.71 – 2.73	0.33					

Table 5.
Results of hierarchical logistic models for non-urgent obstetric interventions received during labour

	OR	95% CI	*p*	X^2	*p*	-2 Log likelihood	Cox & Snell R^2	Nagelkerke R^2
Model 1				19.04	0.001	416.69	0.05	0.07
Constant	0.57	-	0.18	-	-	-	-	-
Nullipara	0.58	0.36 - 0.94	0.03	-	-	-	-	-
Born outside the Netherlands	1.60	0.68 - 3.75	0.28	-	-	-	-	-
Low educational level	0.56	0.27 - 1.18	0.13	-	-	-	-	-
Practice ≥5 midwives	2.09	1.30 - 3.37	0.01	-	-	-	-	-
Model 2				51.85	< 0.001	383.88	0.13	0.19
Constant	0.32	-	0.09	-	-	-	-	-
Nullipara	0.52	0.38 - 0.99	0.01	-	-	-	-	-
Born outside the Netherlands	1.37	0.66 - 3.66	0.50	-	-	-	-	-
Low educational level	0.68	0.27 - 1.19	0.33	-	-	-	-	-
Practice ≥5 midwives	2.35	1.29 - 3.35	< 0.01	-	-	-	-	-
FOCP-VAS≥5	4.87	2.81 - 8.44	< 0.001	-	-	-	-	-
Model 3				51.87	< 0.001	383.86	0.13	0.19
Constant	0.31	-	0.01	-	-	-	-	-
Nullipara	0.53	0.32 - 0.87	0.01	-	-	-	-	-
Born outside the Netherlands	1.37	0.55 - 3.42	0.50	-	-	-	-	-
Low educational level	0.68	0.31 - 1.49	0.33	-	-	-	-	-
Practice ≥5 midwives	2.35	1.42 - 3.90	< 0.01	-	-	-	-	-
FOCP-VAS≥5	4.82	2.72 - 8.54	< 0.001	-	-	-	-	-
W-DEQ-A≥66	1.04	0.61 - 1.78	0.89	-	-	-	-	-

Notably, when models were reversed (adding first W-DEQ-A≥66 and then FOCP-VAS≥5), FOCP-VAS≥5 still significantly contributed to the prediction of requested and received non-urgent obstetric interventions in pregnant women over and above W-DEQ-A≥66. Moreover, in the reversed models, W-DEQ-A≥66 only significantly predicted requested (but not received) non-urgent obstetric interventions during pregnancy and only did so in the absence of FOCP-VAS≥5 (see Table 6 and 7).

Women receiving (s)CS: exploratory analyses

We compared FOC scores of the 12 (50%) women who received sCS (while a vaginal birth would have been possible) to the 12 (50%) women for whom CS was medically indicated. The first group had significantly higher scores on the FOCP-VAS (*M* 6.42 ± 2.61; *t* [22] = -3.03, *p* = 0.006) and the W-DEQ-A (*M* 73.33 ± 15.10; *t* [22] = -2.82, *p* = 0.01) as compared to the second group (FOCP-VAS: *M* 3.52 ± 2.04; and W-DEQ-A: *M* 49.75 ± 24.77). Due to the small sample sizes, nonparametric tests were also conducted, which yielded similar results.

Discussion

Main findings

The aim of this study was to examine the predictive value of high FOC based on the W-DEQ-A next to the one-item FOCP-VAS in identifying pregnant women who explicitly requested non-urgent obstetric interventions during pregnancy and/or underwent non-urgent obstretic interventions during pregnancy and/or underwent non-urgent obstetric interventions during labour. We found that FOCP-VAS≥5 was the strongest predictor for requested and received non-urgent obstetric interventions. We found that W-DEQ-A≥66 did not contribute over and above FOCP-VAS≥5 to the prediction of non-urgent obstetric interventions.

Contrary, when reversing the sequence of analysis, FOCP-VA≥5 was still significantly predictive of non-urgent obstetric interventions during pregnancy and labour, over and above W-DEQ-A≥66.

Table 6.

Results of hierarchical logistic models for non-urgent obstetric interventions requested during pregnancy

	OR	95% CI	*p*	X^2	*p*	-2 Log likelihood	Cox & Snell R^2	Nagelkerke R^2
Model 1				20.24	< 0.001	311.02	0.05	0.09
Constant	0.17	-	< 0.001	-	-	-	-	-
Nullipara	1.14	0.64 - 2.02	0.66	-	-	-	-	-
Born outside the Netherlands	1.07	0.40 - 2.90	0.89	-	-	-	-	-
Low educational level	0.55	0.24 - 1.25	0.15	-	-	-	-	-
Practice ≥ 5 midwives	3.20	1.78 - 5.74	< 0.001	-	-	-	-	-
Model 2				28.59	< 0.001	302.67	0.07	0.13
Constant	0.12	-	< 0.001	-	-	-	-	-
Nullipara	1.30	0.72 - 2.34	0.38	-	-	-	-	-
Born outside the Netherlands	0.98	0.35 - 2.72	0.97	-	-	-	-	-
Low educational level	0.53	0.23 - 1.23	0.14	-	-	-	-	-
Practice ≥5 midwives	3.27	1.80 - 5.92	< 0.001	-	-	-	-	-
W-DEQ-A≥66	2.39	1.33 - 4.32	< 0.001	-	-	-	-	-
Model 3				80.99	< 0.001	250.27	0.20	0.33
Constant	0.04	-	< 0.001	-	-	-	-	-
Nullipara	1.16	0.61 - 2.24	0.65	-	-	-	-	-
Born outside the Netherlands	0.64	0.20 - 2.10	0.47	-	-	-	-	-
Low educational level	0.69	0.28 - 1.75	0.44	-	-	-	-	-
Practice ≥ 5 midwives	4.87	2.43 - 9.78	< 0.001	-	-	-	-	-
W-DEQ-A≥66	1.39	5.64 - 22.79	0.33	-	-	-	-	-
FOCP-VAS≥5	11.34	0.71 - 2.73	< 0.001	-	-	-	-	-

Note. The block-changes (i.e., additional value of the new model over the previous model) for model 2 ($X^2 = 8.34$, $P < 0.01$) and for model 3 ($X^2 = 52.40$, $p < 0.001$

Table 7.
Results of hierarchical logistic models for non-urgent obstetric interventions received during labour

	OR	95% CI	*p*	X^2	*p*	-2 Log likelihood	Cox & Snell R^2	Nagelkerke R^2
Model 1				19.04	0.001	416.69	0.05	0.07
Constant	0.57	-	0.18	-	-	-	-	-
Nullipara	0.58	0.36 - 0.94	0.03	-	-	-	-	-
Born outside the Netherlands	1.60	0.68 - 3.75	0.28	-	-	-	-	-
Low educational level	0.56	0.27 - 1.18	0.13	-	-	-	-	-
Practice ≥ 5 midwives	2.09	1.30 - 3.37	0.01	-	-	-	-	-
Model 2				21.94	0.001	413.78	0.06	0.08
Constant	0.48	-	0.09	-	-	-	-	-
Nullipara	0.61	0.38 -0.99	0.05	-	-	-	-	-
Born outside the Netherlands	1.55	0.66 - 3.66	0.31	-	-	-	-	-
Low educational level	0.57	0.27 - 1.19	0.13	-	-	-	-	-
Practice ≥ 5 midwives	2.08	1.29 - 3.35	< 0.01	-	-	-	-	-
W-DEQ-A ≥ 66	1.54	0.94 - 2.52	0.86	-	-	-	-	-
Model 3				51.87	< 0.001	383.86	0.13	0.19
Constant	0.31	-	0.01	-	-	-	-	-
Nullipara	0.53	0.32 - 0.87	0.01	-	-	-	-	-
Born outside the Netherlands	1.37	0.55 - 3.42	0.50	-	-	-	-	-
Low educational level	0.68	0.31 - 1.49	0.33	-	-	-	-	-
Practice ≥ 5 midwives	2.35	1.42 - 3.90	< 0.01	-	-	-	-	-
W-DEQ-A ≥ 66	1.04	0.61 - 1.78	0.89	-	-	-	-	-
FOCP-VAS ≥ 5	4.82	2.72 - 8.54	< 0.001	-	-	-	-	-

Note. The block-changes (i.e., additional value of the new model over the previous model) for model 2 ($X^2 = 2.90$, $p = 0.09$) and for model 3 ($X^2 = 29.92$, $p < 0.001$)

Strengths and limitations

This study is the first evaluating self-reported FOCP-VAS (subjective outcome) in relation to actual pregnancy and childbirth outcomes derived from medical files (objective outcome). Thereby, this study showed that requests and use of non-urgent obstetric interventions could already be predicted in the first half of pregnancy by means of a simple FOC assessment with the one-item FOCP-VAS. Another strength of this study is the order in which the FOC measures were collected; the one-item FOCP-VAS was completed first and before the W-DEQ-A, insuring an assessment of FOC without any bias of previous assessments.

However, the following limitations of this study have to be considered. Firstly, the sample mostly consisted of highly educated Caucasian women. Such a sample limits the evaluation of cultural influences on childbirth and possibly limits the generalisation of these findings to non-western populations. Second, the study sample was self-selected, which means that only women who were willing to report on their emotions concerning childbirth and were willing to share their childbirth outcomes participated in the study. This self-selection limits generalization of the study's results. Additionally, despite the high response rate (88%), we do not have data about 12% of the potential subject pool who did not provide informed consent. A third limitation is the relatively low occurrence of received non-urgent obstetric interventions during labour (30.8%) which is much lower compared to the Dutch national data (60%; Offerhaus et al., 2013; Perined, 2019). This discrepancy could be explained by selection bias since midwives participating in the study both recruited and took care of the pregnant women during childbirth. That is, the decision for use of non-urgent obstetric interventions was made by the pregnant woman together with the midwife. It is possible that the midwives have given the women more support during childbirth and/or advised them not to have non-urgent interventions due to their participation in the study. In addition, (Offerhaus et al., 2015) suggested that - next to maternal characteristics – the characteristics of midwifery practices are related to referral rates, and evidence for this was also found in our study (women who came from small to middle sized practices received/requested less non-urgent interventions). As the vast majority of the women who participated in this study came from small to middle sized practices, this might have resulted in the lower number of non-urgent obstetric interventions in our study.

Interpretation

In our study, W-DEQ-A≥66 significantly predicted only explicitly requested non-urgent obstetric interventions during pregnancy, but only in the absence of FOCP-VAS≥5. The limited value of W-DEQ-A≥66 in predicting non-urgent obstetric interventions during labour is in accordance with the results of a smaller Dutch study (n = 105), in which no relationship between the W-DEQ-A scores and actual obstetric interventions during childbirth was found (Sluijs et al., 2012). In contrast, two previous studies did report

a strong relationship between W-DEQ-A≥66 and depression, and low self-efficacy (Toohill et al., 2015) as well as anxiety, fatigue, preferences for use of EA and elective CS for the anticipated labour, or women's preferences for obstetric interventions in future pregnancies. In addition, other research using W-DEQ-A≥85 showed a significant relationship with obstetric interventions in different populations of pregnant women (Richens et al., 2018; Størksen et al., 2015). Interestingly, the participants in this study who requested CS scored lower on the W-DEQ-A (>73) and FOCP-VAS (*M* 6.4) than in the study of Rouhe et al. (W-DEQ-A>87; VAS [*M* 7.0]; 2009). The significant value of FOCP-VAS≥5 in predicting other requested non-urgent obstetric interventions during pregnancy in our study is in accordance with the results of a study by (Rouhe et al., 2009).

The results indicate that the individual's idiosyncratic fear simply expressed in one number (FOCP-VAS) seems to be the most effective evaluation of fear in terms of anticipated maladaptation to childbirth and the postpartum period. The open question 'Please rate your current degree of fear of childbirth and the postpartum period?' may create space to integrate the unique appraisal of specific and unspecific components of FOC. In addition, the uncomplicated manner of assessment of FOC with the FOCP-VAS (by using one, easily formulated, question with a scale ranging from 0 to 10) may be more appealing and more easy to answer for pregnant women with lower oral- or reading capacities, or with a lower education level than for example the W-DEQ-A (consisting of 33 questions about anticipated emotions of FOC with inverted answer opportunities). This conclusion could be confirmed by the strong predictive value of the FOCP-VAS (as opposed to the W-DEQ-A scores) in identifying pregnant women with explicit request for induction of labour; especially considering that the request for induction of labour was significantly correlated with low education level. This finding increases the practicality of this measure in midwifery practice.

The limited predictive value of the W-DEQ-A for non-urgent obstetric interventions in our study could be explained by explicit differences between the W-DEQ-A and the FOCP-VAS. First is the current (FOCP-VAS) versus the anticipated (W-DEQ-A) appraisal of FOC. Addressing the current appraisal of FOC might be the most efficient measurement as it could be difficult to appraise what emotions pregnant women might be having during future childbirth, and thus not assessing FOC in the moment. This possible limitation was already addressed by Wijma, the developer of the W-DEQ-A (Wijma et al., 1998). Second, as compared to the W-DEQ-A - which assesses the period before and during labour – the FOCP-VAS examines FOC from a broader scope by also including the postpartum period, as a continuum of childbirth. It may have elicited more reflection on childbirth in the pregnant women's appraisal about fear and may capture pregnant women who were more fearful about the postpartum period (recovering from childbirth or becoming mother) than about childbirth itself. Third, the cut-offs of FOCP-VAS in our study and the VAS proposed by (Rouhe et al., 2009) were the same and both studies found this cut-off to be effective in predicting preferences

for non-urgent obstetric interventions during labour. This is in contrast to the studies using the W-DEQ-A showing inconsistent results for cut-offs of the W-DEQ-A in relation to preferences and use of obstetric interventions during labour (Toohill et al., 2015). And thus, it is still unclear which cut-off of the W-DEQ-A should be used to identify pregnant women at risk for non-urgent obstetric interventions.

In light of psychological studies, pregnant women's requests for obstetric interventions can be seen as an avoidant coping strategy for FOC. Avoidant coping strategies may reduce distress in the short term, but unfortunately can maintain and even strengthen fear and anxiety in the next pregnancy and childbirth. Importantly, in accordance with psychological theories such as Cognitive Behavioural Theory (Beck, 1976) and Experiential Avoidance Theory (S. C. Hayes et al., 1996, 1999), it is not the actual distressful negative beliefs, emotions, and unpleasant sensations, but how one responds to them that is linked to a wide range of mental health issues. Therefore, early screening of FOC, identifying pregnant women with avoidant coping strategies and offering them adequate care for FOC, could not only improve the childbirth process but also reduce FOC in the future. This also brings us to an important additional finding of the current study, namely that high FOC was quite prevalent among the pregnant women in our study (33.9%), while only 3% of these women received some treatment for their fears and related emotions. Based on this finding, it seems that FOC is still a largely unrecognised and untreated phenomena in Dutch midwifery care. This deserves attention, especially given the results of this study that high FOC strongly predicts (requested) non-urgent obstetric intervening, and that measuring FOC can be easily implemented when using the one item FOCP-VAS.

Preferences of pregnant women regarding perinatal care receive more attention of health-care policy makers nowadays and current healthcare models seem to prioritize requests for medical interventions as an important factor in the shared-decision-model (SDM; Härter et al., 2017). Given that preferences of pregnant women are fundamental in SDM, the detection of FOC - which seems to be related to requesting and receiving non-urgent or medically not needed interventions - should be taken into account much more prominently. For instance, an international Delphi study examined SDM in maternity care in which 45 quality criteria for SDM were defined (Nieuwenhuijze et al., 2014), but FOC was unfortunately not addressed. Measuring FOC by means of the FOCP-VAS in SDM could clarify the real needs of pregnant women and bring about more adequate participation in SDM and care for FOC. Open communication about difficult emotions may contribute to a trustful partnership (DeBaets, 2017). The systematic use of the FOCP-VAS could contribute to this open communication in SDM, as it may help to understand the impact of FOC on requests for and use of non-urgent obstetric interventions during childbirth.

Finally, the significant relationship between the number of midwives working in a midwifery practice and the use of requested and received non-urgent obstetric interventions is noteworthy. This finding is in line with previous Dutch research showing that a large number of midwives taking care of pregnant women is related to more non-urgent referrals during childbirth (Offerhaus et al., 2015; Yvonne Fontein, 2010). This result may suggest that among pregnant women who already have difficulties coping with uncertainty of childbirth, the uncertainty caused by being cared for by many different midwives could be a compiling factor. In support, research has shown that the continuity of perinatal care is associated with more spontaneous childbirth (Sandall et al., 2016) and less FOC in pregnant women (Hildingsson et al., 2019). Midwifery-care systems are trying to identify pregnant women who could benefit the most from a continuity of perinatal care (i.e., care received from small midwifery practices) and the identification has largely been based on medical or socio-economic risk factors. However, FOC might be a 'hidden' psychological factor that deserves attention as well and the finding that small to middle sized practices are related to less non-urgent obstetric interventions might suggest that women suffering from FOC benefit from continuity of care.

Conclusion

This study demonstrated that highly prevalent FOC remains unrecognized and untreated in midwife-led practices. Our findings showed that the one-item assessment of current appraisal of fear related to childbirth and the postpartum period was the strongest identifier of non-urgent obstetric intervening in pregnant women. In addition, requests and use of non-urgent obstetric interventions were found to be related to large sized midwifery practices. We recommend a replication study using the same FOC measures and corresponding cut-offs to confirm the predictive value of the one-item FOCP-VAS in other populations of pregnant women. Besides, we strongly recommend an implementation study on the FOCP-VAS as a first step in screening for FOC in midwife- and obstetrician-led practices and to study the relation between FOC, size of midwifery practice, and non-urgent obstetric interventions in pregnant women.

CHAPTER 4

‘I’ve Changed My Mind’, Mindfulness-Based Childbirth and Parenting (MBCP) for pregnant women with a high level of fear of childbirth and their partners: a study protocol of the quasi-experimental controlled trial.

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Abstract

Background: Approximately 25 % of pregnant women suffer from a high level of Fear of Childbirth (FOC), as assessed by the Wijma Delivery Expectancy Questionnaire (W-DEQ-A, score ≥66). FOC negatively affects pregnant women's mental health and adaptation to the perinatal period. Mindfulness-Based Childbirth and Parenting (MBCP) seems to be potentially effective in decreasing pregnancy-related anxiety and stress. We propose a theoretical model of Avoidance and Participation in Pregnancy, Birth and the Postpartum Period in order to explore FOC and to evaluate the underlying mechanisms of change of MBCP.

Methods: The 'I've Changed My Mind' study is a quasi-experimental controlled trial among 128 pregnant women (week 16–26) with a high level of FOC, and their partners. Women will be allocated to MBCP (intervention group) or to Fear of Childbirth Consultation (FOCC; comparison group). Primary outcomes are FOC, labour pain, and willingness to accept obstetrical interventions. Secondary outcomes are anxiety, depression, general stress, parental stress, quality of life, sleep quality, fatigue, satisfaction with childbirth, birth outcome, breastfeeding self-efficacy and cost-effectiveness. The total study duration for women is six months with four assessment waves: pre- and post-intervention, following the birth and closing the maternity leave period.

Discussion: Given the high prevalence and severe negative impact of FOC this study can be of major importance if statistically and clinically meaningful benefits are found. Among the strengths of this study are the clinical-based experimental design, the extensive cognitive-emotional and behavioural measurements in pregnant women and their partners during the entire perinatal period, and the representativeness of study sample as well as generalizability of the study's results. The complex and innovative measurements of FOC in this study are an important strength in clinical research on FOC not only in pregnant women but also in their partners.

Keywords: Fear of childbirth, Labour pain, Mindfulness, Obstetrical interventions, Cost-effectivene

Background

Fear of childbirth (FOC) is a highly prevalent negative emotion among pregnant women characterized by high levels of stress and emotional maladaptation to the normal physiological and psychological processes of being pregnant and giving birth (Hofberg & Ward, 2004; Saisto & Halmesmäki, 2003). Reports demonstrate that approximately 25 % of pregnant women suffer from a high level of FOC, as assessed by the Wijma Delivery Expectancy/Experience Questionnaire (W-DEQ-A and B), defined as a W-DEQ-A score ≥66 (Wijma et al., 2002). Besides, approximately 10 % of pregnant women have been found to suffer from severe FOC (W-DEQ-A score ≥85; Kjærgaard et al., 2008). The complex causes of FOC can be examined from a biopsychosocial perspective (Engel, 1977) that includes biologically-oriented dimensions of fear (e.g., fear of pain, fear of bodily harm, or fear of one's own or one's infant's death), psychological factors (e.g., personality traits, a history of traumatic life events or previous difficult or traumatic obstetrical experiences, feelings of helplessness, or anxiety about motherhood), and social factors (e.g., dissatisfaction with the partner relationship, lack of social support, low socioeconomic status, hearing 'horror stories' about labour from family, friends, acquaintances, and media sources (Hofberg & Ward, 2004; Saisto, Salmela-Aro, et al., 2001; Zar et al., 2001). FOC can be categorized as 'primary FOC' occurring in nulliparous women (first-time mothers) and 'secondary FOC' following a previous difficult or traumatic childbirth experience. Differences in severity of FOC between nulliparous and parous women are still being investigated (Alehagen et al., 2001; Ryding et al., 1998). FOC seems to be a specific domain of anxiety associated with, yet distinct from, general anxiety or depression (Zar et al., 2002). Only a small number of studies have evaluated the content and interrelationship of pregnant women's FOC and their partners' FOC (Eriksson et al., 2006; Hildingsson, 2014); the role of fathers' perinatal distress as a contributing factor to FOC among pregnant women is still unknown.

Consequences of FOC

Studies have shown that FOC negatively affects women in a number of ways, including sleep disturbance and depression in pregnancy (Hall et al., 2009), increased health care use during the perinatal period (Andersson et al., 2004), requests for medical interventions such as an elective caesarean section, *a priori* request of epidural analgesia without pain experience (Alehagen et al., 2005; Nieminen et al., 2009; Van den Bussche et al., 2007; Waldenström et al., 2006), negative experience of childbirth, postpartum depression, post-birth trauma (Alder et al., 2011; Robertson et al., 2004; Söderquist et al., 2009), and low rates of breastfeeding (Ferber & Feldman, 2005; O'Keane & Marsh, 2007). Negative effects of FOC are also associated with increased incidence of small gestational age (15 %), increased preterm birth rate (12 %), infant admission to intensive care (Class et al., 2011; Loomans et al., 2013) as well as poor quality of infant's sleep (Tikotzky & Sadeh, 2009).

Increasing FOC in labouring women in the Netherlands?

The prevalence of FOC in the Dutch population of pregnant women as assessed by the W-DEQ-A is unknown. However, 47 % of first time Dutch mothers do report fear of childbirth (Deliver, 2011). Maladaptation during childbirth in Dutch women can be seen in the increasing numbers of non-urgent medical referrals during labour (Offerhaus et al., 2013). The Dutch midwifery-led model of care assumes that pregnancy, birth and the postnatal period are healthy life events for a mother and her baby. This care is offered in independent midwifery practices in the community and in hospitals. If or when complications arise, women are referred to obstetrician-led care and new-borns are referred to paediatric care.

The most recent data, collected in 2000 - 2008, evaluating the Dutch midwifery-led care system showed that while almost 84 % of all pregnant women started prenatal care in primary midwifery-led care, only 29 % of them actually gave birth under the supervision of a midwife. This means that 71 % of all births took place in secondary obstetrician-led care settings. In 2014 this trend remained stable (Perined, 2014). Overall, almost 60 % of the medical referrals were for non-urgent conditions, such as the need for pain relief, augmentation of labour with oxytocin, or instrumental deliveries due to prolonged labour. However, these referrals did not lead to better child outcomes (such as fewer new-borns with a five-minute Apgar score below seven or a lower rate of natal or neonatal mortality) when compared with births in primary care (Offerhaus et al., 2013).

Management of FOC in midwifery-led care in the Netherlands

Currently, the most commonly applied strategy to prevent and guide FOC in the perinatal period in midwifery practice in The Netherlands is for pregnant women to attend antenatal classes and to write a birth plan. However, studies of individuals and groups in antenatal education have questioned the efficacy of these programmes in preparing expectant couples for the challenges of childbirth and early parenting. A large body of research on structured educational programmes provided during pregnancy and offered in midwifery care reported no consistent results of the effects on knowledge acquisition, antenatal anxiety, maternal sense of control, labour pain, use of medication, psychological adjustment to parenthood and obstetrical interventions (Bergström et al., 2009; Gagnon & Sandall, 2007). Birth plans take into account the preferences of the pregnant woman and her partner regarding medical management of the childbirth experience (Inch, 1988). One of the main purposes of these birth plans, which were developed in the 1980's in many other Western countries, was to increase a woman's feelings of control over her birthing situation, as well as to reduce the medicalization of childbirth. Studies assessing the effects of using birth plans showed a small improvement in dealing with fear, pain and the overall childbirth experience (Berg et al., 2003; Lundgren et al., 2003).

These findings may suggest that the management of FOC should include more specific cognitive strategies to identify and shift patterns of cognition that may be potentially distressing to women in labour (Escott et al., 2009).

Studies evaluating psychological strategies in the management of FOC

Randomized controlled trials (RCT's) and prospective cohort's studies reporting positive effects of interventions including psychological strategies such as psychoeducation, cognitive-behavioural therapy or mindfulness-based programmes (MBP's) in pregnant women with FOC are limited. In Table 1 a summary of the currently available studies is provided. As can be seen, two large randomized trials with an active control group (Rouhe et al., 2015; Toohill et al., 2014) and one non-randomized trial (Fontein-Kuipers et al., 2016) demonstrated small to moderate effects of psychoeducational based programmes on the reduction of FOC, while one small pre- and post-study evaluating cognitive behavioural therapy on FOC reduction in pregnant women with sever FOC showed a large effect size (Nieminen et al., 2016). Another four studies reported large effects of MBP's on the reduction of FOC or pregnancy related anxiety in different populations of pregnant women (Duncan & Bardacke, 2010; Goodman et al., 2014; Guardino et al., 2014; Vieten & Astin, 2008). However, the sample sizes of these studies were small and only two of them were randomized controlled trials (Guardino et al., 2014; Vieten & Astin, 2008).

Given the limited amount of evidence-based effective psychological interventions for reduction of FOC in pregnant women, and the relatively unknown effects of the existent interventions on the birth-related outcomes more large randomized controlled trials in this field should be recommended. Further, as the effect sizes of the MBP's appear to be higher than those of other psychological interventions (see Table 1), high quality RCT's comparing MBP's to control treatments are in need.

Table 1.
Overview of studies on psychological interventions for reduction of FOC and pregnancy-related anxiety

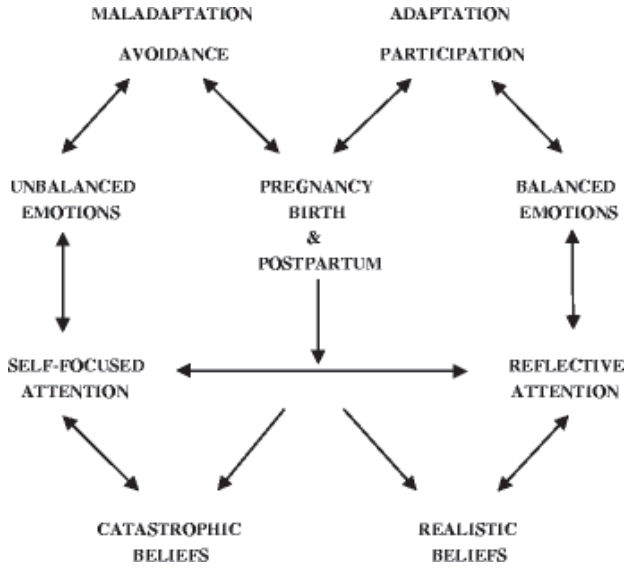
Research group	Research design, (*N*), population	Type of experimental intervention	Primary outcome post intervention
Duncan & Bardacke (2010) United States of America.	Uncontrolled pre- and post-study. (*N* = 27). Community sample of pregnant women.	Nine 3-hours group sessions of MBCP led by a midwife -mindfulness instructor.	Reduced anxiety (PAS) with a large effect *within* the EI group: Cohen's $d = 0.81$, $p < 0.0001$
Fontein et al. (2016) The Netherlands.	Non-randomized trial. (*N* = 433). Pregnant women with maternal distress.	*WazzUp Mama*?! internet-delivered programme supported by midwives vs. CAU.	EI > CAU reduced anxiety (PRAQ) with a moderate effect *between* the groups: Cohen's $d = 0.64$, $p < 0.001$
Goodman et al. (2014) United States of America.	Uncontrolled pre- and post-study. (*N* = 23). Pregnant women with anxiety symptoms.	Eight 2-hours group sessions of CALM led by a mindfulness instructor.	Reduced anxiety (BAI) with a large effect *within* the EI group: Cohen's $d = 0.83$, $p < 0.001$
Guardino et al. (2014) United States of America.	Randomized controlled trial. (*N* = 47). Pregnant women with stress.	Six 2-hours group sessions of MAPS led by a mindfulness instructor vs. CAU.	EI > CAU reduced anxiety (PSA) with a large effect *between* the groups: Cohen's $d = 0.77$, $p < 0.05$
Nieminen et al. (2016) Sweden.	Prospective cohort study. (*N* = 28). Nulliparous pregnant women with sever FOC.	Eight weeks ICBT programme supported by a therapist.	Reduced FOC (W-DEQ-A) with a large effect *within* the EI group: Cohen's $d = 0.95$, $p < 0.0005$
Rouhe et al. (2012) Sweden.	Randomized controlled trial. (*N* = 371). Pregnant women with a sever FOC.	Six 2-hours session of psychoeducational group therapy led by psychologists vs. CAU.	EI > CAU reduced FOC (W-DEQ-B) with a small effect *between* the groups: Cohen's $d = 0.35$, $p = 0.02$
Thoohill et al. (2014) Australie.	Randomized controlled trial. (*N* = 198). Pregnant women reporting FOC.	Two psychoeducational telephone sessions led by trained midwives vs. CAU.	EI > CAU reduced FOC (W-DEQ-A) with a moderate effect *between* the groups: Cohen's $d = 0.59$, $p < 0.001$
Vieten & Astin (2008) United States of America.	Randomized controlled waitlist trial. (*N* = 31). Pregnant women with mood concerns.	Eight 2-hours group sessions of Mindful Motherhood led by a psychologist-mindfulness instructor vs. CAU.	EI > CAU reduced anxiety (STAI) with a large effect *between* the groups: Cohen's $d = 0.85$, $p < 0.04$

Note. BAI Back Anxiety Inventory, *CALM* Coping with Anxiety through Living Mindfully, *CAU* care-as-usual, *EI* experimental intervention, *ICBT* Internet-delivered Cognitive Behavioral Therapy, *MAPS* Mindful Awareness Practice Sessions, *MBCP* Mindfulness-Based Childbirth and Parenting, *PAS* Pregnancy Anxiety Scale, *PRAQ* Pregnancy Related Anxiety Questionnaire, *PSA* Pregnancy Specific Anxiety, *STAI* State-Trait Anxiety Inventory, *W-DEQ-A* Wijma Delivery Expectancy Questionnaire-version A, *W-DEQ-B* Wijma Delivery Expectancy Questionnaire-version B

A theoretical model of avoidance and participation in pregnancy, birth and the postpartum period

Figure 1 shows a theoretical model of Avoidance and Participation in Pregnancy, Birth and the Postpartum Period. This model can serve as a heuristic in which current psychological knowledge and research on the effects of beliefs and emotions on women's behaviour in pregnancy, birth and the postpartum period is integrated. We adapted elements of Vlaeyen's Fear-Avoidance Model of Pain (Vlaeyen & Linton, 2000), Beck's Cognitive Theory (Beck, 1976), and Lazarus and Folkman's Stress and Coping Theory (Lazarus & Folkman, 1984) in this model. Two opposite behavioural responses to pregnancy, birth and the postpartum period are postulated, namely avoidance and participation. Attention is the point of engagement for change in the presented cognitive-emotional pathways and behaviours.

Figure 1.
A theoretical Model of Avoidance and Participation in Pregnancy, Birth and the Postpartum Period



In accordance with Cognitive Theory, a belief is a state of mind in which a person thinks something to be true with or without empirical evidence. An individual's beliefs are the result of cognitive-emotional information processing starting at an early age of perception. Beliefs guide individuals' behavioural (i.e., approach or avoidance) and psychophysiological responses (i.e., arousal). Cognitive-emotional information processing can be biased by self-focused attention to a certain event, which may lead to biased core beliefs about the event (Beck, 1976). Biased core beliefs such as catastrophic

beliefs (irrational worst-case outcomes) lead to maladaptation. Maladaptation is a trait that is or has become more harmful than helpful. Its source can be related to a personal experience (i.e., trauma, environment), education (i.e., lack of knowledge), and biological predisposition (i.e., genetics). Clinical studies have shown a potentially causal role of catastrophic beliefs in developing unbalanced emotions, such as anxiety, fear and depression (Alloy et al., 2006). However, the relation between beliefs, attention, emotions, and behaviour is likely to be bidirectional. In accordance with Stress and Coping Theory (Lazarus & Folkman, 1984) a person with unbalanced emotions will avoid the stressful event and appraise the event as too overwhelming to adapt to. Adaptation is a process of change by which a person becomes better suited to an event. Avoidance, a maladaptive type of behaviour, may reduce distress in the short term, but will maintain and strengthen the unbalanced emotions, since by avoiding the event, the catastrophic beliefs are not disconfirmed and realistic beliefs are not generated.

How can these theories be applied to the perinatal situation? Pregnant women with catastrophic beliefs view the perinatal period in terms of danger and harm that may occur in the future: during pregnancy (e.g., *'My baby will die'),* birth (e.g., '*Labour pain will predominate everything'*) and the postpartum period (e.g., '*My recovery will take too long'*). They have a hyper focus on danger (self-focused attention) rather than appraising these perinatal events in terms of relevance and reality. Perinatal catastrophic beliefs can contribute to pregnant women's behavioural (e.g., avoidance or participation), emotional (e.g., fear, stress, depressed mood) and psychophysiological (e.g., higher levels of stress hormones) maladaptation to the natural process of being pregnant, birthing, postpartum recovery and mothering (Alehagen et al., 2005; Ferber & Feldman, 2005; Ryding et al., 1998; Van den Bussche et al., 2007). It can therefore be expected that pregnant women with catastrophic beliefs and unbalanced emotions will attempt to exempt themselves from any effort to approach to distressful perinatal events (e.g., by requesting *a priori* epidural anaesthesia or an elective caesarean section). A negative spiral may be the result; avoidance may further strengthen unbalanced emotions, leading to postpartum depression or posttraumatic stress syndrome and future maladaptive behaviours, such as avoidance of pregnancy, natural birth, contact with the baby and social contacts (Flink et al., 2009; Hofberg & Ward, 2004).

The opposite of catastrophic beliefs are realistic beliefs about pregnancy, birth and the postpartum period, the counter half of the model. Realistic beliefs are characterized by a reflective attention for causes and conditions of the perinatal events due to unbiased cognitive-emotional information processing. In this half of the model, relationships between appraisals, attention, and emotions can also be considered bidirectional. Therefore, it can be expected that pregnant women with realistic perinatal beliefs and balanced emotions will participate (approach), instead of avoiding, an event (e.g., giving birth) due to positive appraisal of the reality and their ability to adapt to the perinatal events.

Since the quality of attention can influence the cognitive-emotional- information processing and behaviours in pregnant women, interventions targeting the quality of attention and developing adaptive behaviours towards perinatal events are in need of more psychological midwifery research.

Mindfulness-based programmes and their mechanisms of action

MBP's such as Mindfulness-Based Stress Reduction (MBSR; Kabat-Zinn, 2005) and MBCT (Khoury et al., 2013) have become widely used in health care settings and have shown to be effective for a variety of psychological and physical conditions including depression, anxiety, stress (Khoury et al., 2013), and chronic pain (Reiner et al., 2013) in both clinical and non-clinical populations. A more recent application of mindfulness is mindful parenting. Recent data suggest that mindful parenting effectively reduces parental stress, parental psychopathology, child psychopathology, and improves parenting and co-parenting (Bögels et al., 2014; Singh et al., 2014).

These MBP's are based on Buddhist meditation practices. Mindfulness can be defined as "the awareness that arises from paying attention, on purpose, in the present moment, and non-judgmentally" (Kabat-Zinn, 2005). The non-judgmental quality of the attention during meditation practice allows individuals to observe physical sensations, thoughts, and emotions, to work at accepting them as they are, and thereby reduce automatic reactions to them (Baer, 2003). Mindfulness practice helps the practitioner realize that physical sensations, thoughts and emotions are continuously changing. In addition, with on-going practice of mindfulness meditation, feelings of caring and kindness toward oneself and others, and compassion for the common human experience may arise (Keng et al., 2012). The above-mentioned skills seem to be key processes of change underlying the MBP's positive outcome.

Whether MBP's also improve the well-being of parents-to-be is, as of yet, largely unknown. There are early indications that MBP's reduce perinatal anxiety, depression and the severity of labour pain in various populations of pregnant women (Duncan et al., 2014; Duncan & Bardacke, 2010; Goodman et al., 2014; Guardino et al., 2014; Vieten & Astin, 2008). A good example is the well-developed Mindfulness-Based Childbirth and Parenting (MBCP) programme. MBCP, as evaluated in a pilot study ($n = 27$), seems to be potentially effective considering the significant large effect size in the decrease in pregnancy-related anxiety (Cohen's $d = 0.81$), the increase in non-reactivity (Cohen's $d = 0.85$), and increase in positive affect (Cohen's $d = 0.40$) found among pregnant women who participated in MBCP (Duncan & Bardacke, 2010). MBCP is a childbirth education programme that integrates mindfulness meditation with current knowledge of the neurobiological processes of the perinatal period.

We hypothesize three underlying mechanisms of action of the effectiveness of MBCP. First, an increase in mindful awareness, which is defined as the ability to observe moment to moment internal and external experiences in body and mind, to describe these experiences, to respond rather than react towards inner experiences or events, and to be more accepting. Second, an increase in self-compassion, meaning being moved by one's own suffering, experiencing kindness towards inherent shortcomings, and acknowledging one's own experience being a part of the common human experience. And third, a decrease in catastrophic beliefs, such as worries about anticipated events and experiences.

Given the promising impact of MBP's on fear and stress, and the promising application for women experiencing pregnancy-related anxiety, in this study we will evaluate the effectiveness of MBCP on FOC in a population of pregnant women with a high level of FOC during the perinatal period. We will use a quasi-experimental design to compare MBCP with a structured version of care- as-usual: Fear of Childbirth Consultations (FOCC).

Aims

The 'I've Changed My Mind study' is designed with four primary aims: 1) to assess the effects of MBCP, as compared to FOCC, on the primary outcome measures of a) FOC, b) labour pain, and c) willingness to accept obstetrical interventions without medical indications in pregnant women with a high level of FOC; 2) to assess the effects of MBCP, as compared to FOCC, on the secondary outcome measures of a) anxiety, b) depression, c) general stress, d) pre- and postnatal stress, e) quality of life, f) sleep quality of women, her partner and infant, g) pre- and postnatal fatigue, h) satisfaction with childbirth, i) birth outcome for mother and child, and j) breastfeeding self-efficacy in pregnant women with a high level of FOC and their partners; 3) to examine overall mindful awareness, self-compassion, and catastrophic beliefs as possible mediating mechanisms underlying the effectiveness of MBCP; 4) to assess the costs of health care use due to FOC and cost-effectiveness of MBCP as compared to FOCC. These four aims will be examined in three time periods: a) during pregnancy, b) after labour, and c) during the maternity leave period following the birth.

It is hypothesized that participants in the MBCP group, as compared to those in the FOCC group will a) show larger and longer lasting effects on all primary and secondary outcome measures, b) demonstrate increased overall mindful awareness and self-compassion, and decreased catastrophic beliefs, and c) have lower FOC related health care costs, indicating that MBCP is more cost-effective than FOCC.

Methods

Design

The study design is a quasi-experimental controlled trial with two arms (intervention and active comparison group) involving four assessment time points. Participants will be allocated by the order of inclusion in the study (alternation). Inclusion will take place at baseline 16–26 weeks gestational age. Subsequently, questionnaires will be filled in one-two weeks pre-intervention (T1) and post-intervention (T2), and two-four weeks (T3) and 16–20 weeks (T4) following the birth. Participating couples will receive a fee of €50 upon completion of data collection (T4).

Participants from an urban area in The Netherlands will be quasi-randomized to the intervention (MBCP) or comparison group (FOCC) using an Excel program of created codes with the intent of producing equivalent training group cohorts of approximately six participants each. The flowchart of the study design and participants is depicted in Fig. 2.

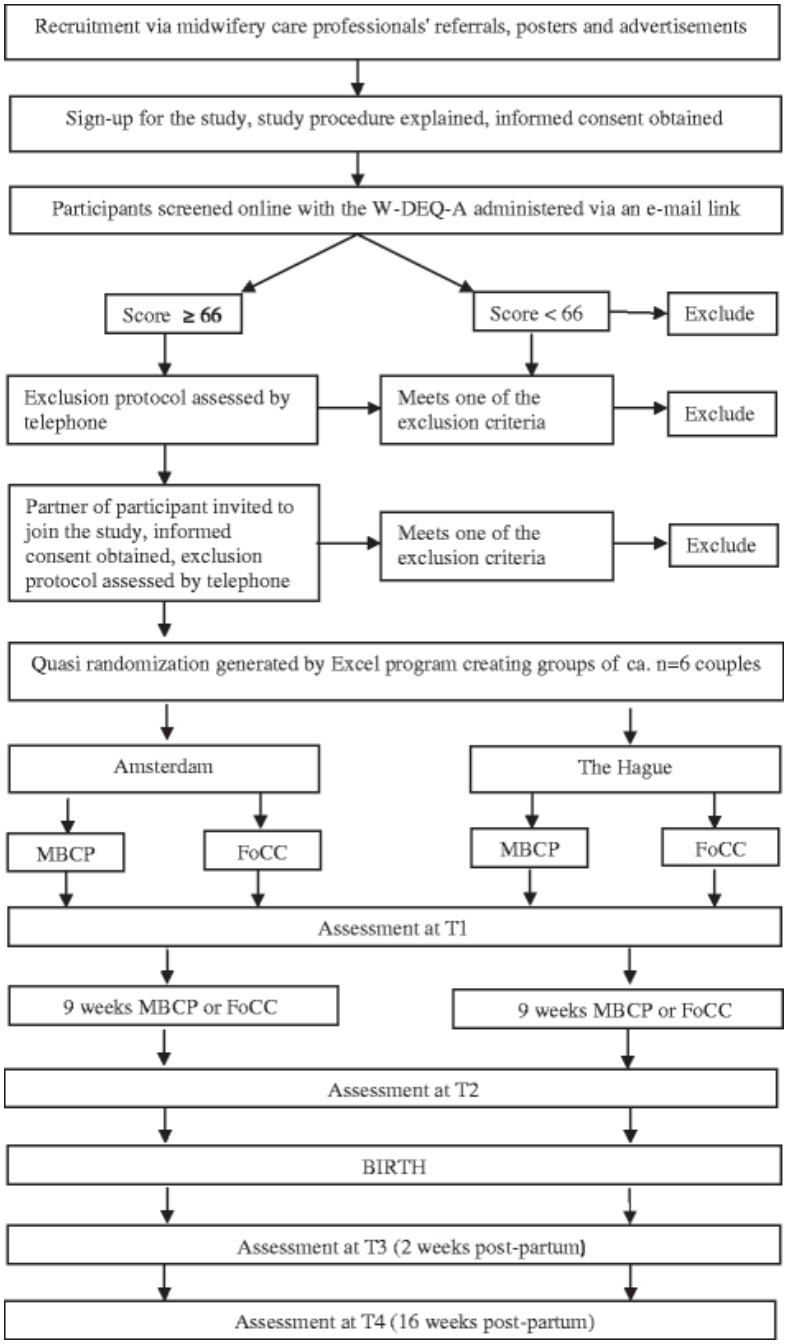
Sample size

Assuming a medium effect size of MBCP compared to the comparison condition and referrals of 30 % from primary to secondary midwifery care due to maladaptation to childbirth (Offerhaus et al., 2013) we aim to include n =128 pregnant women with a high level of FOC and their partners (64 couples in each arm) to achieve a power of 80 % to find a significant effect (test of between-within interaction, 5 % alpha, 0.5 correlation). We based our power calculations on a medium effect size versus the large effect size found in a single-group trial of MBCP for decreasing pregnancy anxiety (d = 0.81, p < 0.0001) in the study of Duncan & Bardacke (2010) and the overall medium mean effect size of MBP's (d = 0.59; Baer, 2003), in part due to the unknown effect size of the FOCC comparison condition.

Participants

This trial will be conducted in primary and secondary midwifery care settings in Amsterdam and The Hague, The Netherlands. All study procedures and informed consent forms received approval from the Ethics Review Board of the Faculty of Social and Behavioural Sciences at the University of Amsterdam (certificate number 2013-CDE-3064). This trial is registered in the Dutch Trial Register (NTR) under number 4302. Participation is entirely voluntary and pregnant women and/or their partners can stop participating at any time without having to sign anything or provide a reason for stopping.

Figure 2.
Flow-chart of inclusion of the 'I've Change My Mind Study'



Inclusion criteria

Participants are nulliparous and multiparous women, aged ≥18, fluent in the Dutch or English language who are more than 16 weeks and less than 26 weeks pregnant at baseline and are experiencing a high level of FOC (W-DEQ-A≥66; Ryding et al., 1998). If an eligible woman agrees to participate, her partner will be asked to take part in the study as well. As 'partner' we refer to the father or co-parent of the expected baby, or a significant other person related to the pregnant woman who will be present at the birth. Pregnant women may enter the study without a partner or a significant other.

Exclusion criteria

Exclusion criteria for this study are: (a) previous acute psychotic episode or diagnosed psychotic disorder; (b) current suicidal risk; (c) current substance use and dependency; (d) borderline personality disorder in the pregnant woman or her partner; (e) current trauma unrelated to childbirth traumatic stress disorder; or (f) participation in a MBP within the past year. The use of antidepressant medication, as long as the prescribed dose remains stable during the study, participation in an on-going psychological intervention or a prenatal education course, or a childbirth trauma as assessed by the Traumatic Event Scale (TES-B; Wijma et al., 1997) are not exclusion criteria. Women with a multiple gestation, HIV infection, or at high risk for premature labour will be excluded. Please see Procedure section below for a description of a two-stage exclusion protocol that will be employed.

Intervention: The Mindfulness-Based Childbirth and Parenting (MBCP) programme

The MBCP programme (Duncan & Bardacke, 2010), developed in the United States by midwife, anthropologist and mindfulness teacher Nancy Bardacke, CNM, MA, is a formal adaptation of MBSR specifically adjusted to the needs of expectant parent population. The teachings of mindfulness through formal and informal meditations are fully integrated with the knowledge of the psychobiological processes in pregnancy, birth, breastfeeding, postpartum adjustment and the psychobiological needs of the infant. MBCP as developed by Bardacke includes nine weekly three-hour classes, a 7-hour day of silent meditation practice and a 3.5-hour reunion gathering after all the babies have been born. For purposes of this study, the standard MBCP was adapted (with permission by Bardacke). Two first classes were combined as Class 1 and the 7-hour day of silent meditation practice was reduced to one 3-hour class (see Table 2). Expectant parents are asked to commit to practicing the formal meditations at home for 30 min a day, six days a week with the instructional MP3 files that are given as part of the course materials. Adherence to the intervention is assessed by reporting the number of classes attended and weekly diaries of the amount of time spent between sessions in formal daily meditation practice and being mindful of the activities of

daily living (informal practices). The importance of keeping a meditation diary will be emphasized. Each MBCP course will be taught by an experienced midwife, who, in accordance with the MBCP protocol, has been trained as an MBCP teacher by Nancy Bardacke. All MBCP sessions will be video recorded to assure fidelity to the MBCP model. Ratings of fidelity to the MBCP model will be carried out by two independent raters. The MBCP sessions will be free of charge and take place at a Mindfulness Centre in Amsterdam and The Hague.

Table 2.
Outline of the Dutch adaptation of the Mindfulness-Based Childbirth and Parenting programme

Week 1	Background of mindfulness, the MBCP programme, introduction to mindfulness meditation through an eating meditation, awareness of breathing meditation.
Week 2	Body scan meditation, attitudinal foundations of mindfulness, community building.
Week 3	Awareness of breathing meditation, body scan meditation, psycho-education: physiology of childbirth from a body-mind perspective.
Week 4-6	Yoga, sitting meditation, pain meditations using ice and a variety of pain-coping strategies, expanding the capacity to "be with" unpleasant/challenging sensations in the body and unpleasant or stressful thoughts and emotions, 3-Minute Breathing Space meditation, exploration of the notion of "being in control" during childbirth, psycho-education: baby's journey through the pelvis.
Week 7	Session of silence, body scan, yoga, sitting meditation, mindful eating, walking meditation, mindful speaking and listening inquiry practice regarding fears and joys around childbirth and the life change the couple is living.
Week 8	Loving-kindness meditation, psychoeducation: biological, emotional and social needs of the newborn and mindfulness practice for moment to moment caretaking, the needs of the postpartum family.
Week 9	Psychoeducation: physiology of breastfeeding, mindfulness as a skill for coping with breastfeeding challenges and postpartum adjustment, closing ceremony.

Active Comparison Condition: Fear of Childbirth Consultation (FOCC)

The target sample of pregnant women included in this study suffer from intense FOC. In order to acknowledge the fears of these women we have upgraded care as usual into structured consultations on FOC (FOCC). FOCC consists of an adaptation of the Biopsychosocial Model (Engel, 1977) and the Childbirth Plan of the Royal Dutch Organization of Midwives (KNOV Geboorteplan, n.d.).

This individualized programme for expectant couples includes two consultation sessions with a trained midwife of one-hour each over a nine-week period (see Table 3). The aim of FOCC is to gain insight into the variety of specific factors playing a role in the origin and presence of fear and stress around pregnancy, birth and the postpartum period as well as designing a suitable coping plan based on the particular fears and stresses, and includes some components of psychoeducation about fear. A structured form is used to collect information about FOC related factors and for the coping

plan. The coping plan may include referral to a psychologist or other mental health care services. All FOCC sessions will be audio recorded in order to assure treatment fidelity. Two recordings per consultation will be randomly selected and evaluated by an independent midwife. The free of charge FOCC sessions will take place at the participant's midwifery practice or place of residence.

Table 3.
Outline of the two sessions of the fear of childbirth consultations

FOCC First Consultation
Mapping of the bodily, mental and social factors underlying FOC and the postpartum period. Interview about the pregnant woman's overall state of physical health and current pregnancy, her mental health and emotional state, her ideas and values regarding being pregnant, the process of giving birth and being a parent, incidence of psychopathology in her family of origin, her most severe fears about childbirth and the postpartum period, her relationship with her partner, family, presence of social support, workplace experiences, important life events and potential vulnerabilities. A written psychoeducation about FOC and matching behavior from a body and mind perspective is provided.
FOCC Second Consultation
Designing an Individual Childbirth Plan based on the findings from the first consultation and the pregnant woman's wishes, including the care provider's, partner's and family's attitudes towards her upcoming childbirth, the woman's intrinsic coping strategies regarding childbirth including her approach to labour pain and 2nd stage pushing, potential requests for care and guidance from her care provider and family, her ability to adapt to possible medical interventions, and guidance regarding first contact with her newborn.

Outcome measures

In this study several assessment tools will be used. Some measures were translated specifically for this study. Translations were made in accordance with the scientific standards for translating questionnaires (Beaton et al., 2000) and permission to translate has been given by the original authors. Table 4 presents an overview of the primary and secondary outcome measures and the time points of study assessments.

Table 4.
Overview of measures, outcomes, and corresponding measurement occasions for the (pregnant) women and their partners

Measure	Outcome domain	Measurement occasion			
		T1	T2	T3	T4
W-DEQ-A	Anticipated fear of childbirth	X	X		
W-DEQ-B	Experienced fear of childbirth			X	X
PDSS[a]	Perinatal disaster scenarios	X	X	X	X
PAFS	Responses to anxiety and fear	X	X	X	X
CLP	Catastrophizing of labour pain	X	X		
LPAQ	Acceptance of labour pain	X	X		
VAS	Labour pain intensity	X	X	X	
WAOI[a]	Willingness to accept interventions	X	X		
DASS-21[a]	Depression, anxiety and stress	X	X	X	X
PSS[a]	Stress	X	X	X	X
EPDS	Prenatal/postnatal depression	X	X	X	X
PES-US	Uplifting experience of pregnancy	X	X		
NPSI-SF[a]	Parenting stress			X	X
EQ-5D[a]	Quality of life	X	X	X	X
PSQI[a]	Sleep quality	X	X	X	X
HSDQ-I[a]	Insomnia	X	X	X	X
ISVIS[a]	Interpretation of infant sleep	X	X	X	X
BISQ	Infant sleep			X	X
MAF[a]	Fatigue	X	X	X	X
SIL[a]	Satisfaction with birth			X	X
MR	Medical report about perinatal period				X
BSES-SF	Breastfeeding self-efficacy			X	X
FFMQ[a]	Mindful awareness	X	X	X	X
IM-P[a]	Mindful parenting skills			X	X
SCS-SF[a]	Self-compassion	X	X	X	X
PHCQ	Costs in and outside the healthcare sector	X	X	X	X

Note[a] instruments are filled in by (pregnant) woman and partner, others are filled in by (pregnant) women only. T1 = pre-intervention; T2 = post-intervention; T3 = two -four weeks after birth; T4 = 16–20 weeks after birth. MBCP or FOCC takes place between T1 and T2. BISQ Brief Infant Sleep Questionnaire, BSES-SF Breastfeeding Self-Efficacy Scale-Short Form, CLP Catastrophizing Labour Pain, DASS-21 Depression Anxiety Stress Scale, EPDS Edinburgh Prenatal/Postnatal Depression Scale, EQ-5D Five-Dimensional EuroQol, FFMQ Five Facets Mindfulness Questionnaire, HSDQ-I Holland Sleep Disorders Questionnaire-Insomnia subscale, IM-P Interpersonal Mindfulness in Parenting scale, ISVIS Infant Sleep Vignettes Interpretation Scale, LPAQ Labour Pain Acceptance Questionnaire, MAF Multidimensional Assessment of Fatigue, MR Medical Report, NPSI-SF Nijmeegse Parental Stress Index-Short Form, PAFS Perinatal Anxiety/Fear Scale, PES-US Pregnancy Experience Scale-Uplifts Subscale, PDSS Perinatal Disaster Scenarios Scale, PHCQ Perinatal Healthcare Costs Questionnaire, PSQI Pittsburgh Sleep Quality Index, PSS Perceived Stress Scale, SCS-SF Self Compassion Scale Short-Form, SIL Salomon's Item List, WAOI Willingness to Accept Obstetrical Interventions, W-DEQ-A Wijma Delivery Expectancy Questionnaire-version A, W-DEQ-B Wijma Delivery Expectancy Questionnaire-version B.

Primary outcome measures

Primary outcome measures are (a) FOC, (b) labour pain, and (c) willingness to accept obstetrical interventions without medical indications.

The complexity of FOC will be measured by three instruments, namely the W-DEQ-A and B (Wijma et al., 2002), the newly developed Perinatal Disaster Scenarios Scale (PDSS; Veringa, van Berge, Wouters, de Bruin: PDSS, unpublished), and the experimental Perinatal Anxiety/Fear Scale (PAFS; Veringa, de Bruin, Bögels: PAFS, unpublished). First, anticipated and experienced levels of FOC will be assessed with the 33 items self-report W-DEQ- A and B covering several domains of FOC: (a) general fear, (b) negative appraisal, (c) loneliness, (d) lack of self-efficacy, (e) lack of positive anticipation, and (f) concerns about the child (Garthus-Niegel et al., 2011). Second, the individual perinatal fear-eliciting beliefs, in pregnant women and their partners, will be assessed by the PDSS. We developed the PDSS, which is based on the Social Phobia Belief Scale (SPBS; Voncken & Bögels, 2006), for this study in order to describe catastrophic beliefs about childbirth and future-related events that are eliciting fear (maximum of 3 beliefs). The PDSS assesses the probability of actual occurrence of those catastrophic events, the severity, and the ability to cope with them in the future on the Visual Analogue Scale (VAS; McCormack et al., 1988; 0–100 %). And third, to assess responses to anxiety and fear in pregnant women we will administer the experimental PAFS based on the Dimensional Anxiety Self-report of Social Phobia level 3 DSM-IV (First et al., 1996).

Subsequently, three instruments will be included to assess labour pain. First, anticipated and experienced cognitive and emotional components of labour pain will be assessed by the 13 item self-report Catastrophizing Labour Pain (CLP) subscale derived from the Labour Pain Cognitions and Coping List (LPCCL; Veringa et al., 2011), the 20 item self-report Labour Pain Acceptance Questionnaire (LPAQ; Veringa, Wouters, Lowe, Langedijk, de Bruin: LPAQ, unpublished), an adaptation of the Chronic Pain Acceptance Questionnaire (CPAQ; McCracken et al., 2004), and the expected and experienced severity of labour pain will be assessed by the VAS (McCormack et al., 1988; 0–10).

Last, the willingness to accept obstetrical interventions without medical indications will be assessed by the Dutch version of the Willingness to Accept Obstetrical Interventions measure (WAIO; Green & Baston, 2007; Veringa, Wouters, Lowe, de Bruin: Dutch version of WAIO, unpublished).

Secondary outcome measures

Secondary outcome measures are a) anxiety, b) depression, c) general stress, d) stress, e) quality of life, f) sleep quality, g) fatigue, h) satisfaction with childbirth, i) birth outcome for mother and infant, and j) breastfeeding self-efficacy.

Anxiety, depression, and general stress will be assessed by the Depression, Anxiety and Stress Scale (DASS-21; Lovibond et al., 1995). Psychological stress, the degree to which individuals appraise events in their lives as stressful, will be assessed by the Perceived Stress Scale (PSS; S. Cohen, 1988). In addition, current perinatal depression symptoms will be assessed by using the Edinburgh Prenatal/Postnatal Depression Scale (EPDS; Cox et al., 1987). Pregnancy stress will be assessed by the Dutch version of the Pregnancy Experience Scale (van der Zwan, de Vente, Koot, Huizink: Validation of the Dutch version of the Pregnancy Experience Scale for pregnant women and partners of pregnant women, under review) using the uplifts subscale (PES-US) derived from the Pregnancy Experience Scale (PES; DiPietro et al., 2008). Subsequently, parental stress after birth will be assessed by the Nijmeegse Parental Stress Index-Short Form (NPSI-SF; Brock et al., 1992). Quality of life will be assessed by the Five-Dimensional EuroQol instrument (EQ-5D; EuroQol Group, 1990), which assesses mobility, self-care, usual activities, pain/discomfort and anxiety/depression.

Sleep quality will be assessed by the Pittsburgh Sleep Quality Index (PSQI; Buysse et al., 1989) with additional sleep efficiency questions, and the Insomnia scale derived from the Holland Sleep Disorders Questionnaire (HSDQ-I; Kerkhof et al., 2013). Sleep quality of the infant will be measured by the Dutch version of the Infant Sleep Vignettes Interpretation Scale (ISVIS; Sadeh et al., 2007; van Berge, Veringa, Wouters, de Bruin: Dutch version of ISVIS, unpublished), and by the Brief Infant Sleep Questionnaire (BISQ; Sadeh, 1994). Furthermore, fatigue will be assessed by the Multidimensional Assessment of Fatigue (MAF; Belza, 1995). Satisfaction with childbirth will be assessed by the Dutch version of the Salomon's Item List (SIL; Salmon & Drew, 1992; Veringa, Wouters, Lowe, de Bruin: Dutch version of SIL, unpublished). Birth outcome for mother (e.g., modus partus) and infant (e.g., birth weight and APGAR score) will be derived from the medical report (MR). And last, breastfeeding self-efficacy of the mother will be assessed by the Dutch version of the Breastfeeding Self-Efficacy Scale-Short Form (BSES-SF; Dennis et al., 2011; Veringa, Wouters, Lowe, de Bruin: Dutch version of BSES-SF, unpublished).

Mechanisms of action and process evaluation

Changes in overall mindful awareness, self-compassion, and catastrophic beliefs are hypothesised to be potential underlying working mechanisms of MBCP leading to positive changes in mental health and behaviour during the perinatal period. Overall mindful awareness including qualities such as observing, describing, acting with awareness, non-judging and non-reactivity to inner experience, will be assessed by the Five Facet Mindfulness Questionnaire (FFMQ; Baer et al., 2006; de Bruin et al., 2012). In addition, mindful awareness specifically related to one's role as a (new) parent will be assessed with the Interpersonal Mindfulness in Parenting Scale (IM-P; de Bruin et al., 2014). Self-compassion will be assessed by the Self-Compassion Scale-Short Form (SCS- SF; Neff, 2003), and catastrophic beliefs will be assessed by the Perinatal Disaster Scenarios Scale (PDSS).

Expectancy effects in women and partners will be assessed by the question: "If you had a choice, which one of the study's programmes would you prefer to participate in?". Adherence to MBCP will be assessed by number of classes attended and weekly diaries of the number of minutes spent in formal meditation practice each week between sessions. Data regarding the number of attended sessions of FOCC will also be collected.

Cost-effectiveness evaluation

The evaluation of cost-effectiveness will be carried out from a societal and health care perspective including direct and indirect costs, with an average time frame of six months following study inclusion. Participants will fill out a standardized Perinatal Health Care-costs Questionnaire (PHCQ) in which they are retrospectively asked how often they had contact with the health care system, including type, duration, medications used, number of days absent from work, production losses, and professional and family support. At T1participants are asked to report any contacts with the healthcare system from the time of first knowledge of pregnancy to the start of MBCP or FOCC - which contains information about the past three to five months; from T1 till T4 participants report about the past three months. Costs of both programmes will be calculated separately based on the duration and frequency of sessions and group size. Costs will be derived by multiplying the resources used by the unit price of each resource. Unit prices will be based on Dutch standard prices from the Dutch Guideline of Cost Research (Tan et al., 2012) or other published unit prices. The costs of the interventions will be based on the standardized hourly pay of midwives and the invested intervention related educational costs. The EQ-5D (EuroQol Group, 1990) is administrated to provide utilities and to calculate quality adjusted life years (QALY's).

Recruitment

Figure 2 provides an overview of the recruitment and study procedures. Recruitment for this study started in April 2014. Midwives and obstetricians were briefed on the study at workshops and fraternity meetings. Pregnant women are invited to join the study in two ways: via advertisement posters and brochures in midwifery waiting rooms inviting them to visit the study's website http://www.mbcpmidwife.nl/ or by midwives and obstetricians who find they are caring for a highly anxious and/or stressed pregnant woman and offer them information about the study. After a potentially eligible pregnant woman or her care provider contacts the research team, informed consent is obtained. Subsequently, the pregnant woman completes an online screening questionnaire (W-DEQ-A; Wijma et al., 2002). Questionnaire responses are scored within 48 h. Women who score ≥66 on the W-DEQ-A are contacted by telephone and the study's two-stage exclusion protocol is administered. After this procedure, the eligible participant's partner is invited to join the study, informed consent is obtained and the two-step exclusion interview is administered.

The first step of the exclusion protocol is carried out by the research midwife by telephone in order to identify a current risk for a psychosis/psychotic disorder, potential suicidal risk, substance abuse and dependency, or borderline personality disorder in the woman and/or her partner. In cases where any of the above risks or disorders are suspected, an extensive personal psychological interview is conducted by a trained psychologist using the Structured Clinical Interview for DSM-IV disorders Axis I and Axis II (SCID-I and SCID-II; First et al., 1996). Subsequently the general physician of the participant is informed of the existing or risk for a particular mental disorder.

Recruitment will continue until at least 64 participants with a W-DEQ-A≥66 have completed the study's programme in each of two study arms.

Quasi-experimental allocation to the two study conditions

The allocation to the two study groups will be done on the sequence of entry into the study using an Excel program of created codes. This procedure ensures that the referral midwives and obstetricians are not able to predict the group to which the participant will be assigned. The choice for quasi-experimental allocation is based on a steadily increasing gestational age, dependence on recruitment speed and efficiency, and the required minimum group size of six participants in the MBCP intervention group.

Statistical analyses

Primary analyses

Dichotomous outcome data will be analysed using Chi-square tests or logistic regression using the method of 'last observation carried forward' (i.e., assuming no change) to handle dichotomous incomplete data. Continuous outcome data will be analysed with Multi-level analyses. Multi-level analyses with full information maximum likelihood (FIML) estimation use all available data and allow intention-to-treat analyses including all participants with incomplete data and participants who dropped out during the study. Continuous variables will be transformed into *Z*-scores. In this way, the parameter estimates can be interpreted as a measure of effect: i.e., as Cohen's *d* for dichotomous predictors and as *r* for continuous predictors. Outliers will be identified. Analyses will be run twice: once in which all original scores will be included and once in which outliers will be changed to *Z*-scores (-) 3.29. Dependent variables will be level of FOC, labour pain and willingness to accept obstetrical interventions without medical indications. Predictors will be the different time measurements (T2, T3, and T4 against T1) and condition (MBCP versus FOCC). Interaction effects of time X condition will be added to the model to examine which programme is more effective over time.

Secondary analyses

Multilevel mediation analyses will be conducted to evaluate the possible underlying mechanisms of action in MBCP. In these analyses only participants considered to be "treated" i.e., those who have received at least five out of nine MBCP sessions will be included. We will examine the mediating effect of general mindful awareness, self-compassion, and catastrophic beliefs.

Cost-effectiveness

Incremental costs effectiveness ratio (ICER) will be calculated and expressed as (a) the cost per woman that displays a significantly reduced level of FOC, and (b) the cost per QALY. Standard sensitivity analyses will be performed to test for the robustness of the cost-effectiveness result. Non-parametric bootstrapping method will be used, performing 1000 replications of the original costs data, to produce confidence intervals around the costs estimates and quantify uncertainty around the calculated ICERs (Briggs et al., 1997). Cost-effectiveness planes will be used to represent the bootstrapped ICERs: the horizontal line reflects the difference in effect and the vertical line reflects the difference in costs. Cost-effectiveness acceptability curves will be used to inform decision-makers on the probability that the studied intervention is cost-effective at a range of ceiling ratios.

Dissemination recommendation

In order to inform future dissemination of MBCP into midwifery care we will evaluate the value of MBCP for midwifery care taking into account clinical relevance. Two pillars will provide perspective on clinical relevance: (I) the clinical significance of the effects and (II) acceptability and feasibility of MBCP for the participants. To assess the clinical significance of MBCP, we will compare the pre- and post-treatment raw scores of primary and secondary measures with current established norms relevant for a population of pregnant women. To assess acceptability and feasibility of MBCP, participants will be asked to complete an evaluation form about the personal value they found from participating in the programme, along with our assessment of the number of sessions attended and adherence to home practice.

Discussion

This will be the first RCT comparing the effects of MBCP to FOCC on an array of childbirth and early parenting outcomes in pregnant women with a high level of FOC and their partners. This study will provide greater insight into the psychological processes underlying the occurrence, development and responses to FOC. Given the high prevalence and severe negative impact of FOC for pregnant women and their infants, this study can be of major importance if statistically and clinically meaningful

benefits are found. Addressing the problem of FOC is critical and the proposed study evaluates an innovative MBCP that holds the potential of being an effective, non-invasive, and non-medical intervention for pregnant women with FOC, whit the potential for widespread dissemination that builds on the popularity of MBP's. Further, we expect a potentially stronger effect of MBCP than FOCC on adaptation to the perinatal period, and a decrease in not-urgent medical interventions during childbirth. A reduction in unnecessary medical interventions has the potential to reduce or redirect the costs of midwifery care towards a more preventive approach for women and their partners in the perinatal period.

Some limitations to this study design need to be considered. First, the quasi-experimental study design creates less homogeneous groups then with full randomization (RCT) and permits a greater risk of bias due to potential alternation and allocation problems. To work with this, we adopted the recommendations for designing the Q-RCT studies from the Cochrane Handbook for Systematic Reviews of Interventions (Higgins & Green, 2011). Due to the steadily increasing gestational age, dependency on recruitment speed and efficiency, and the required size of approximately six participants in the intervention group, we are obliged to use the quasi-randomization procedure in order to be able to conduct this study efficiently. A second limitation is the uncertainty of the power of this study due to the unknown effect size of the comparison group. To cover this limitation, we have chosen to downsize the expected large effect size of MBCP as shown in Duncan & Bardacke's study (2010) to a medium effect size in order to not under-power our study. An additional limitation is the potentially sizable dropout of participants due to their possibly strong preferences for one of the study's interventions, the nine weeks duration of the programmes, and the relatively long and direct follow up after the birth. As a retention strategy we provide the participants with a financial incentive (€50) for completing the measurements following the birth.

Among the strengths of this study are the clinical-based experimental design, the extensive cognitive-emotional and behavioural measurements in pregnant women and their partners during the entire perinatal period, and the representativeness of the study sample as well as the generalizability of the study's results. The complex and innovative measurements of FOC in this study are an important strength in research on FOC not only in pregnant women but also in their partners.

In the future, it would be interesting to evaluate the effects of MBCP on the physiological pathways of the stress response, such as the hypothalamic–pituitary–adrenal (HPA) axis, and maternal and foetal levels of corticosteroids in relation to perinatal outcomes for mother and baby. A study of the implementation and dissemination of MBCP into midwifery practice in the Netherlands would be the next logical step in MBCP research. Future research on the effects of mindful parenting on the mother-infant relationship, assessments of infant emotional expression and regulation, and stress due to fear,

anxiety or depression in new mothers will allow for continuity between research and treatment for women at risk.

With this study we also aim to increase awareness among maternity caregivers of the important effects of maternal psychological wellbeing during the processes of adaptation to pregnancy, childbirth and parenting. Findings from this study would help midwives in their role of signaling, referring, cooperating with psychologists and preparing expectant women and their partners who are experiencing consequences of FOC in pregnancy, during childbirth and in parenting. Midwives are an ideal group of professionals to incorporate MBCP into their midwifery practices in the Netherlands for prevention and co- treatment purposes, because of the frequent and intimate contact with pregnant women and new families.

CHAPTER 5

Fear of childbirth, non-urgent obstetric interventions, and newborn outcomes: a randomized controlled trial (I've Changed My Mind) comparing Mindfulness-Based Childbirth and Parenting with enhanced care as usual

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Abstract

Objective: To investigate whether Mindfulness-Based Childbirth and Parenting (MBCP) or enhanced care as usual (ECAU) for expectant couples decreases fear of childbirth (FOC) and non-urgent obstetric interventions during labor and improves newborn outcomes.

Design: Randomized controlled trial.

Setting: Midwifery settings, the Netherlands, April 2014-July 2017.

Population: Pregnant women with high FOC (N = 141) and partners.

Methods: Allocation to MBCP or ECAU. Hierarchical multilevel and intention-to-treat (ITT) and per-protocol (PP) analyses.

Main outcome measures: Primary: pre-/postintervention FOC, labor anxiety disorder, labor pain (catastrophizing and acceptance), and preferences for non-urgent obstetric interventions. Secondary: rates of epidural analgesia (EA), self-requested cesarean birth (sCB), unmedicated childbirth, and 1- and 5-minute newborn's Apgar scores.

Results: MBCP was significantly superior to ECAU in decreasing FOC, catastrophizing of labor pain, preference for non-urgent obstetric interventions, and increasing acceptance of labor pain. MBCP participants were 36% less likely to undergo EA (RR 0.64, 95% CI [0.43-0.96]), 51% less likely to undergo sCB (RR 0.49, 95% CI [0.36-0.67]), and twice as likely to have unmedicated childbirth relative to ECAU (RR 2.00, 95% CI [1.23-3.20]). Newborn's 1-minute Apgar scores were higher in MBCP (DM −0.39, 95% CI [−0.74 to −0.03]). After correction for multiple testing, results remained significant in ITT and PP analyses, except EA in ITT analyses and 1-minute Apgar.

Conclusions: MBCP for pregnant couples reduces mothers' fear of childbirth, non-urgent obstetric interventions during childbirth and may improve childbirth outcomes. MBCP adapted for pregnant women with high FOC and their partners appears an acceptable and effective intervention for midwifery care.

Keywords: cesarean birth, fear of childbirth, mindfulness

Introduction

The World Health Organization (WHO) has asked for a reduction in the use of non-urgent obstetric interventions during childbirth, such as the use of unnecessary cesarean birth (CB; WHO, 2018). Non-clinical interventions supporting this call are required (WHO, 2018) to improve the health of mothers and new-borns (Sandall et al., 2018) and to reduce health care costs (Nieminen et al., 2017). Common, non-urgent obstetric interventions include epidural analgesia (EA) and CB (Anim-Somuah et al., 2018; Domingues et al., 2014; Størksen et al., 2015; Wang, 2017; WHO, 2018). Proportions of childbirths incorporating EA are 77% in France, (Kpéa et al., 2015) 73% in USA (Butwick et al., 2018), and 44% in Sweden (Törnell et al., 2015). CB is requested by 28% of pregnant women in China (Wang, 2017) and Brazil (Domingues et al., 2014) and 10% in Norway (Størksen et al., 2015). Half of all births in China and Brazil (Wang, 2017), and a third of all births in the United States (Boerma et al., 2018) result in CB, whereas in the Netherlands, only 15% of all births are by CB (Perined, 2018). Nevertheless, in the Netherlands, 60% of pregnant women starting labor in midwifery-led care are referred to obstetricians for non-urgent obstetric interventions, resulting from a failure to progress or an inability to cope with labor pain (Offerhaus et al., 2013; Perined, 2018).

Although EA and CB are valued obstetric achievements, they are not risk-free. For example, EA is associated with assisted vaginal births and a lower Apgar score in new-borns (Ravelli et al., 2020). The risk of severe acute maternal morbidity is five times higher with CB than with vaginal births (Zwart et al., 2008). Furthermore, having had a previous CB increases the risk for morbidity in ongoing pregnancy by three times (van Dillen et al., 2010). Children born by CB have an increased risk of allergo-immunological problems, asthma, and obesity (Sandall et al., 2018).

Worldwide, self-requested CB (sCB) and EA are strongly associated with a fear of childbirth (FOC) (Garthus-Niegel et al., 2014; Olieman et al., 2017; WHO, 2018), and a fear of pain (Domingues et al., 2014; Wang, 2017). FOC is a complex concept incorporating different aspects of fear and anxiety within and external to the pregnancy itself (Rondung et al., 2016; Rouhe et al., 2011). Untreated FOC is a risk factor for traumatic childbirth (Garthus-Niegel et al., 2014; Hollander et al., 2017) and pregnancy specific anxiety - including fear of birth - is associated with impaired neuro-emotional development in new-borns caused by high levels of maternal cortisol (Erickson et al., 2017; Van den Bergh et al., 2005). Reducing FOC may reduce sCB and EA; however, scarce research on the use of non-clinical interventions to reduce CB rates currently exists (Chen et al., 2018). Psychoeducation is a non-clinical intervention associated with less FOC (Toohill et al., 2014), and a birth plan is associated with better childbirth outcomes (Afshar et al., 2018). Mindfulness-based interventions (MBIs) are non-clinical interventions aimed at reducing symptoms like anxiety (Goyal et al., 2014) and

chronic pain (Reiner et al., 2013). Therefore, MBI might also be beneficial to reduce FOC. Pooled results of uncontrolled studies and (underpowered) RCT's evaluating anxiety, depression, and perceived stress have demonstrated a significant benefit for different MBIs when compared with a control group (Dhillon et al., 2017). We conducted an adequately powered controlled study to investigate whether mindfulness-based childbirth and parenting (MBCP) for pregnant women with high FOC, and their partners, would decrease FOC, as well as the use of EA and sCB, and improve childbirth outcomes, when compared with an active comparison group.

Methods

Study design

We conducted a block randomized controlled trial (RCT) with two conditions: MBCP and enhanced care as usual (ECAU). The study involved screening with the Wijma-Delivery Expectation Questionnaire30 (W-DEQ-A) before allocation (T0) and at three assessment time-points: (1) 1 to 2 weeks pre-intervention (T1 = 16-26 weeks' pregnancy), (2) postintervention (T2 = 26-36 weeks' pregnancy), and (3) medical data from childbirth reports (T3 = 2-4 weeks' postpartum). Recruitment took place between April 2014 and July 2017, facilitated by caregivers.

Participants

We included low-risk, nulli-, and multi-parous pregnant women aged ≥18 years without a priori restriction on having an unmedicated childbirth (spontaneous, without any obstetric intervention), experiencing a high FOC (W-DEQ-A≥66 and self-confirmed FOC). Participants were recruited from midwifery care settings in Amsterdam and The Hague, the Netherlands. Exclusion criteria were unwillingness to be randomized, current severe psychological problems, participation in another MBP, or hypno-birthing training in the past year. The use of stable-dose antidepressant medication, participation in an ongoing psychological intervention, or a prenatal educational course were not exclusion criteria. Details about the recruitment procedure and inclusion and exclusion criteria can be found in the trial's protocol (Veringa et al., 2016).

Randomization and masking

Both conditions were presented to the referrers and pregnant women. The first author checked for randomization eligibility and screened participants at T0. An independent assistant communicated the allocation and sent the link per e-mail for the precondition measurements at T1. Allocation was done according to the order of entry, using blocks of codes created using Microsoft Excel (Microsoft Corporation, Redmond, WA, USA). The blocks of codes started with MBCP, alternating between four to six participants, depending on recruitment speed, followed by ECAU. Although

conducting T1 assessments before randomization is typical in RCTs, the decision for a priori allocation was based on a steadily increasing gestational age, dependence on recruitment speed and efficiency, required minimum group size, and adherence to an equal length of time (maximum 2 weeks) between T1 assessment and the start of MBCP/ECAU. In addition, the participants' preferences for MBCP or ECAU were collected. The allocation process was concealed from the referrers and from the independent outcome assessor. Once allocated, conditions could not be concealed from the participants or referrers any longer. Data collection was carried out online, using required responses via the Qualtrics software (Qualtrics, Provo, UT, USA).

Experimental intervention

The experimental condition comprised the secular, face-to- face, group-based MBCP programme for expectant couples published as "Mindful Birthing" (Bardacke, 2012). We adapted the programme for pregnant women with FOC, focusing on management techniques for anxiety and fear, guided meditations, and enquiry. The nine weekly sessions lasted three hours each and were delivered by experienced midwives certified in MBCP. Sessions included mindfulness meditation practice and enquiry (eg, participants sharing about meditation experiences to improve meditation practice), and teachings about psychobiological processes in the perinatal period for women, new-borns, and the family.

Mindfulness meditation aims to cultivate the deliberate, immediate, and nonjudgmental quality of attention to current experiences. This quality of attention allows individuals to observe experiences (such as physical sensations, thoughts, and emotions) through a gentle lens, resulting in increased tolerance and acceptance, and reduced reactivity to these experiences (Baer, 2003). Participants were asked to commit to meditation practices at home for 30 minutes each day.

Enhanced care as usual

ECAU (Freedland et al., 2011) consisted of two individual 90-minute sessions for the expectant couple. Both sessions were spread over a ten-week period (like MBCP) and were delivered by trained midwives. ECAU was designed to reduce FOC by gaining insight into the factors causing and maintaining fear and stress in the perinatal period, including psychoeducation about fear, and making a coping plan. The first session was based on the biopsychosocial model (Engel, 1977), and the second session consisted of writing the Childbirth Plan of the Royal Dutch Organization of Midwives (KNOV Geboorteplan, n.d.). The content of the original MBCP and ECAU is described in more detail in the study protocol (Veringa et al., 2016).

Primary outcomes

The primary outcomes were FOC, labor anxiety disorder, labor pain (catastrophizing and acceptance), and preferences for non-urgent obstetric interventions in childbirth. FOC was measured using the 33-item W-DEQ-A covering general fear, negative appraisal, loneliness, lack of self-efficacy, lack of positive anticipation, and concerns about the child (Wijma et al., 1998). Higher scores indicate increased FOC: high (W-DEQ-A≥66), severe (W-DEQ-A≥85), and phobic (W-DEQ-A≥100; O'Connell et al., 2017). Labor anxiety disorder was assessed by the 10-item subscale of the newly developed DSM-5 Perinatal Anxiety Disorder-Labor (DSM-5 PAD-L; Veringa, de Bruin, et al., 2013). Catastrophizing and acceptance of labor pain were assessed using the 12-item Catastrophizing Labor Pain (CLP; Veringa et al., 2011) and the 20-item Labor Pain Acceptance Questionnaire (LPAQ; Veringa, Wouters, et al., 2013). Pregnant women's preferences for non-urgent obstetric interventions were assessed using the 7-item Willingness to Accept Obstetric Interventions (WAOI; Green & Baston, 2007); scores >28 indicate preference for non-urgent obstetric interventions such as EA and CS. The Perinatal Disaster Scenario Scale (PDSS) was excluded from our analysis due to low responses (*n* = 53; 37.6%).

Secondary outcomes

The secondary outcomes in the pregnant women (rates of EA, sCB, and unmedicated childbirth [birth without obstetric intervention]) and the new-borns (1-and 5-minute Apgar score) were derived from medical files.

Sample size calculation

A priori power calculations showed that under the assumption of a medium effect size of MBCP compared with ECAU, at least 128 participants were required to achieve a power of 80% to find a significant effect (test of between-within interaction, 5% alpha and 0.5 correlation).

Quality control

MBCP sessions were recorded and supervised by SB. ECAU sessions were audiotaped, and the birth plan was documented. Treatment acceptability in MBCP was assessed by registering session attendance and minutes spent practicing meditation exercises. In both groups, attendance at additional prenatal educational courses was registered.

Statistical analyses

The primary analysis was performed using intention-to- treat (ITT). Little's Missing Completely at Random (MCAR) were used to identify missing data. We used hierarchical linear model (HLM) analyses for continuous outcomes; pre-and post-

assessments (level 1) were nested in individuals (level 2). We used fixed parameters and entered T2 (time 2; postintervention compared with pre-intervention), condition (MBCP compared with ECAU, a main effect), and the interaction (T2*condition, a difference between effects) as predictors. T2 as a significant predictor indicated a main effect of time (ie, scores changed between pre-and postintervention). Condition as a significant predictor indicated a main effect of condition (a significant difference in scores between MBCP and ECAU). A significant interaction term indicated a difference between effects of MBCP and ECAU. All outcome measures were standardized. As such, parameter estimates could be interpreted as an effect size (Cohen's *d*: 0.2 = small, 0.5 = moderate, and 0.8 = large; J. Cohen, 1992). Chi-square analyses with Fisher's exact test were used for binary outcomes. Relative risk (*RR*) and relative risk reduction (*RRR*) with a 95% confidence interval (CI) were examined. Number needed to treat (*NNT*) with a 95% CI was calculated using MedCalc statistical software (MedCalc Software Ltd, Ostend, Belgium). Independent *t*-tests were used for continuous outcomes that were assessed postintervention only (newborn outcomes). Analyses were also conducted per-protocol using the same statistical rules (PP; Figure 1). All analyses were performed two-sided, α-level of 0.05, using SPSS (version 24; IBM Corp., Armonk, NY, USA). Since multiple tests were conducted, a Holm-Bonferroni correction (Holm, 1979) was applied to the obtained *p*-values of primary and secondary outcomes to prevent type I errors. Standardized values > (–)3.29 were considered as outliers. With respect to HML analyses, no outliers were identified. Outliers in childbirth outcomes were not removed; two outliers for low Apgar at 1 minute, four outliers for low Apgar at 5 minutes, and two outliers for gestational age were found. Skewness and kurtosis values were within the boundary of –1.96 and 1.96, except for the Apgar 1-and 5-minute scores and gestational age. Therefore, nonparametric tests were also run on these variables, which yielded similar results.

Results

Recruitment and attrition

The rates of recruitment, reasons for refusal, exclusion, withdrawal, and attritions are summarized in the trial's flowchart (Figure 1). We randomly assigned 141 pregnant women to MCBP (*n* = 75) or ECAU (*n* = 66). To create equal numbers of participants who received a minimum intervention dose (as stated in the protocol; Veringa et al., 2016), we needed to recruit additional participants for MBCP to protect power. W-DEQ-A scores at T0 were similar between conditions ($p = 0.45$), as well as baseline characteristics (Table 1), and no differences were found between the participants who did (*n* = 113) and did not (*n* = 28) complete T2 measurements ($p > 0.10$). Missing data at T2 was random (MCAR test $\chi 2 = 12.70$, $df = 13$, $p = 0.47$). No reporting bias was found because no difference in mean scores at T1 was revealed for the participants who were allocated to their preferred (*n* = 63) or nonpreferred (*n* = 50) condition

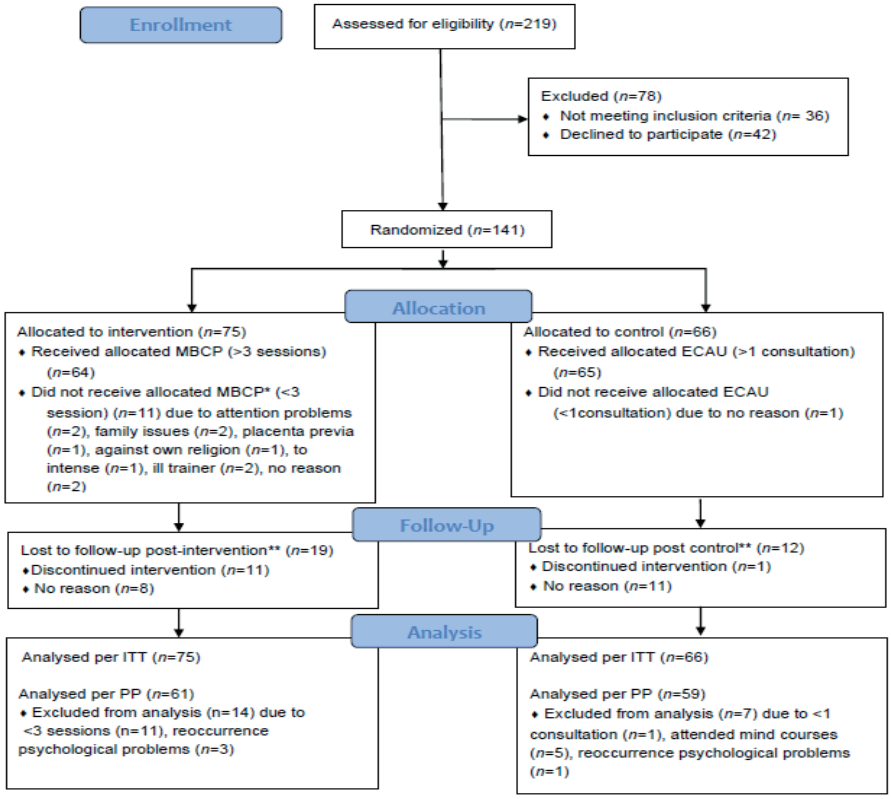
($p > 0.50$; $n = 28$ reported no preference). Notably, three-quarters of the sample experienced previous psychological problems and one-quarter was treated with medication for longer than a year. In both groups, about 85% of partners participated ($p = 0.94$).

Quality control

Adherence to MBCP (following ITT) was assessed by the number of sessions attended (mean 6.8 ± 2.85; 87% attended four to nine sessions, and 21% of whose attended all nine sessions) and time spent on formal meditation practices per week (mean 85.05 ± 58.96 minutes). No significant difference was observed in W-DEQ-A scores at T1 between participants who received a minimum intervention dose (98.81 ± 22.10) and those who did not (89.92 ± 23.20; t (139) = −0.83, $p = 0.83$). Adherence to ECAU was also assessed by the number of consultations attended (98% followed at least one of the two sessions). In the ECAU group, significantly more ($p < 0.001$) pregnant women followed a prenatal educational course (41%; $n = 27$) than in MBCP (9%, $n = 7$). In addition, mindfulness awareness was assessed using the Five Facet Mindfulness Questionnaire (FFMQ; de Bruin et al., 2012) in both conditions. HLM analyses showed that mindfulness awareness only increased in MBCP (T2 = (−)0.17; condition = 0.03; T2*condition = 0.77; $SE = 0.17$, $p < 0.001$).

Figure 1.

CONSORT 2010 transparent reporting of trials: Flow diagram ECAU = enhanced care as usual; ITT = Intention to treat; MBCP = Mindfulness-Based Childbirth and Parenting; PP = Per protocol



Note. * No statistically significant difference in the W-DEQ-A scores at T1 between participants who did receive a minimum intervention dose and those who did not (t (139) = -0.83; p = 0.83). ** No statistically significant difference in lost-to-follow-up between groups ($\chi 2$ = 1.05, p= 0.31).

Table 1.
Baseline characteristics of participants for the intention-to-treat population at pre-assessment (T1)

	MBCP (*n* = 75)	**ECAU (*n* = 66)**	***p***
Demographic characteristics			
Age, mean (*SD*)	33.11 (3.92)	32.72 (3.86)	0.55
Ethnic origin, *n* (%)			0.19
White	57 (76.0)	41 (62.1)	
Other	17 (22.7)	25 (37.9)	
Missing	1 (1.3)	-	
Education level, *n* (%)			0.19
High	61 (81.3)	50 (75.8)	
Middle to low	11 (14.7)	16 (24.2)	
Missing	3 (4.0)	-	
Employment, *n* (%)			0.16
Yes	64 (85.3)	51 (77.3)	
No	10 (13.3)	15(22.7)	
Missing	1 (1.4)	-	
Married/leaving together (*yes*), *n* (%)	68 (90.7)	65 (98.5)	0.05
Partner participated in intervention (*yes*), *n* (%)	64 (85.3)	56 (84.8)	0.94
Obstetric characteristics			
Parity (*n, %)*			0.20
Nulliparous	51 (68.0)	38 (57.6)	
Multiparous	24 (32.0)	28 (42.4)	
Echelon of care (*n*, %)			0.80
Midwife-led care (*yes*)	66 (88.0)	59 (89.4)	
Obstetrician-led care (*yes*)	9 (12.0)	7 (10.6)	
Anamnesis (*n*, %)			
Caesarean birth in history (*yes*)	4 (5.3)	7 (10.6)	0.24
Intrauterine foetal death in history (*yes*)	4 (5.3)	1 (1.5)	0.22
Current labour*			
Gestational age in weeks mean (*SD*)	39.43(1.73)	39.52 (1.44)	0.75
Induction (*n, %)* (**yes**)	11(15.9)	9 (16.1)	0.98
Dilatation period in hours mean (*SD*)	8.09 (5.45)	7.81 (5.05)	0.80
Mental health characteristics			
W-DEQ-A, mean (*SD*)	94.72 (19.55)	92.33 (17.35)	0.45
Psychological/psychiatric care in history (*yes*), *n* (%)	56 (74.7)	50 (75.8)	0.88
Psychological/psychiatric care present (*yes*), *n* (%)	13 (17.3)	15 (22.7)	0.44
Missing	2 (2.7)	1 (1.5)	

	MBCP (*n* = 75)	ECAU (*n* = 66)	*p*
Medication for psychological problems > 1 year (*yes*), *n* (%)			0.20
Past	23 (30.7)	14 (21.2)	
Present	3 (4.0)	2 (3.0)	
Psychiatric hospitalisation in history (yes), *n* (%)	4 (5.3)	2 (3.0)	0.50

Note. Abbreviations: ECAU = Enhanced Care As Usual; MBCP = Mindfulness-Based Childbirth and Parenting; W-DEQ-A = Wijma Deliver Expectation Questionnaire
*Sample without primary caesarean birth (*n* = 14)

Primary outcomes

Tables 2 and 3 summarize the results of the HLM of the primary outcome as a function of time (T2 versus T1), intervention (condition MBCP versus ECAU), and interaction between time and intervention (T2*condition). Fear of childbirth mean scores (assessed by W-DEQ- A) decreased after MBCP and ECAU (significant effect for T2), but the decrease was significantly larger for MBCP (significant interaction T2*condition). To explore the clinical effect of this finding, total W-DEQ-A scores were dichotomized into normal and high (≥66; O'Connell et al., 2017). The risk of a high W-DEQ-A score at T2 was 36% lower after MBCP compared with ECAU (*RR* 0.64, 95% CI [0.45-0.91], *p* = 0.01; *RRR* 36%, 95% CI [9%-55%]). MBCP needs to be offered to five pregnant women to decrease FOC to a normal level in one pregnant woman (*NNT* 4.5, 95% CI [2.5-20.3]). Labor anxiety disorder (assessed by DSM-5 PAD-L) did not change between pre-and postassessment, nor was there a significant difference between conditions. Catastrophizing labor pain (assessed by CLP) decreased significantly after MBCP and ECAU; however, participants receiving MBCP showed a significantly larger decrease than those receiving ECAU. Labor pain acceptance (assessed by LPAQ) increased significantly after MBCP and ECAU but increased significantly more for MBCP than for ECAU. Preferring non-urgent obstetric interventions (assessed by WAOI) did not change in ECAU but decreased significantly in MBCP. To explore the clinical effect of this, total WAOI scores were dichotomized (cutoff ≥28; Green & Baston, 2007). MBCP participants were 40% less likely to prefer non-urgent obstetric interventions than ECAU participants (*RR* 0.60, 95% CI [0.41-0.88], *p* = 0.04; *RRR* 40%, 95% CI [12%-59%]). At T1, 35% (*n* = 26/74) of MBCP and 28% (*n* = 18/65) of ECAU preferred sCB as the mode of delivery (*p* = 0.30). At T2, 14% (*n* = 8/57) of the MBCP and 53% (*n* = 20/53) of the ECAU participants preferred sCB as the mode of delivery ($p < 0.001$). MBCP needs to be offered to seven pregnant women to change this preference in one pregnant woman (NNT 7, 95% CI [3.7-77.1]). Similar results as in ITT-analyses were found in PP-analyses (see Table S1). Significant findings in both analyses remained after *p*-value adjustment (see Table 3 and S1).

Table 2.
*Hierarchical multi-level analyses of the primary outcomes for the intent-to-treat population with time, condition (MBCP versus ECAU) and the interaction (time*condition) as predictors*

	Parameter estimate	Standard error	*t*	*p*	*p'*	95% CI	
						lower	upper
W-DEQ-A							
T2[a]	-0.68	0.11	-6.43	< 0.001		-0.80	-0.40
Condition[b]	-0.01	0.14	-0.04	0.97		-0.29	0.28
T2*Condition	-0.41	0.15	-2·74	0.01	0.020	-0.70	-0.10
DSM-5 PAD-L							
T2[a]	-0.20	0.15	-1.33	0.19		-0.49	0.10
Condition[b]	-0.15	0.20	-0.76	0.45		-0.53	0.24
T2*Condition	-0·21	0.21	-1·04	0.30	0.300	-0.62	0.19
CLP							
T2[a]	-0.49	0.11	-4.61	< 0.001		-0.69	-0.28
Condition[b]	-0.06	0.15	-0.43	0.67		-0.36	0.23
T2*Condition	-0.52	0.15	-3.57	0.001	0.005	-0.81	-0.23
LPAQ							
T2[a]	0.33	0.12	2.75	0.01		0.09	0.56
Condition[b]	-0.03	0.16	-0.16	0.87		-0.35	0.30
T2*Condition	0.56	0.16	3.42	0.001	0.005	0.24	0.89
WAOI							
T2[a]	-0.02	0.11	-0.16	0.87		-0.23	0.19
Condition[b]	0.09	0.18	0.51	0.61		-0.27	0.45
T2*Condition	-0.48	0.15	-3.29	0.001	0.005	-0.76	-0.19

Note: Outcome variables are standardized and as such parameter estimates can be interpreted as an effect size (Cohen's *d*).
Abbreviatons: CLP = Catastrophizing Labour Pain; DSM-5 PAD-L = DSM-5 Perinatal Anxiety Disorder-Labour; LPAQ = Labour Pain Acceptance Questionnaire; WAOI = Willingness to Accept Obstetrical Interventions; W-DEQ-A = Wijma-Delivery Expectation Questionnaire.
[a] post intervention as compared to pre-intervention,
[b] MBCP as compared to ECAU. Cohen (1992) reports the following intervals for *d*: 0.1-0.2: small effect; 0.2-0.5: medium effect; > 0.8: large effect. *p'* = *p*-value after Holm-Bonferroni correction.

Table 3.
Pre- (T1) and post-assessment (T2) scores on primary outcomes' measures and MBCP and ECAU effectiveness for the intention-to-treat population

	MBCP					ECAU				
	T1 M (SD)	***n***	**T2 M (SD)**	***n***	***d***	**T1 M (SD)**	***n***	**T2 M (SD)**	***n***	***d***
W-DEQ-A	97.99 (23.32)	75	69.26 (24.75)	57	1.20	98.12 (21.08)	66	79.61 (24.21)	56	0.82
DSM-5 PAD-L	26.76 (7.89)	63	23.53 (7.11)	47	0.43[a]	27.80 (7.84)	55	26.27 (5.58)	47	0.22
CLP	46.62 (12.13)	74	33.12 (10.50)	57	1.18	47.48 (10.93)	65	40.36 (13.35)	53	0.59
LPAQ	60.22 (10.77)	74	69.60 (8.25)	57	-0.96	60.55 (8.52)	65	64.19 (9.44)	53	-0.41
WAOI	23.01 (7.44)	70	19.25 (5.43)	55	0.57	21.82 (6.02)	60	22.12 (6.56)	51	-0.05

Note. Due to a technical error in data transmission, a part of the DSM-5 PAD-L data was lost.
Abbreviations: CLP = Catastrophizing Labour Pain; DSM-5 PAD-L = DSM-5 Perinatal Anxiety Disorder-Labour; ECAU = Enhanced Care As Usual; LPAQ = Labour Pain Acceptance Questionnaire; MBCP = Mindfulness-Based Childbirth and Parenting; WAOI = Willingness to Accept Obstetrical Interventions; W-DEQ-A = Wijma-Delivery Expectation Questionnaire.
[a] Cohens' *d* is based on: *(M* T1 - *M* T2) / pooled *SD*.

Table 4.
Differences in the secondary outcomes between the MBCP and ECAU for the intention-to-treat population

								Childbirth outcome		
Pregnant women	**MBCP (*n* = 75)**	***n*** [b]	**ECAU (*n* = 66)**	***n***	X^b	***p***	***p'***	**RR (95%CI)**	**RRR % (95%CI)**	**NNT (95% CI)**
Used EA in labour (yes)[a]	27	69	33	56	4.854	0.028	0.084	0.64 (0.43 – 0.96)	36 (4 - 57)	5.0 (2.7 - 39.5)
Underwent sCB (yes)	1	74	8	65	6.860	0.009	0.036	0.49 (0.36 – 0.67)	51 (33 - 64)	4.4 (2.6 - 12.9)
Had an unmedicated birth (yes)	35	74	14	65	10.05	0.002	0.010	2.00 (1.23 – 3.20)	-	3.9 (2.4 - 9.6)
Newborns	**M (SD)**	***n*** [b]	**M (SD)**	***n*** [b]	***t***	***p***	***p'***	**Mean difference**	**95%CI**	
1-minute APGAR score	9.03 (0.84)	71	8.64 (1.21)	64	-2.17	0.030	0.084	-0.38	-0.74 - (-)0.03	
5-minute APGAR score	9.76 (0.64)	71	9.61 (0.92)	64	-1.12	0.280	0.280	-0.15	-0.42 - 0.12	

Note. Abbreviations: EA = Epidural Analgesia; ECAU = Enhanced Care As Usual; MBCP = Mindfulness-Based Childbirth and Parenting; sCB = self-requested Caesarean Birth.
[a] Sample without primary CB (*n* = 14);
[b] Sample size depending on availability of medical files data.
p' = *p*-value after Holm-Bonferroni correction.

Secondary outcomes

MBCP participants were 36% less likely to undergo EA (*RR* 0.64, 95% CI [0.43-0.96], *p* = 0.03), and 51% less likely to undergo sCB (*RR* 0.49, 95% CI [0.36-0.67], p= 0.01). The MBCP participants were twice as likely to undergo unmedicated childbirth relative to ECAU (*RR* 2.00, 95% CI [1.23-3.20], *p* = 0.002). MBCP needs to be offered to five pregnant women to prevent one EA in labor (*NNT* 5.0, 95% CI [2.7-39.5]), to nine women to prevent one woman from undergoing sCB (*NNT* 9.0, 95% CI [5.2-36.8]), and to four women to result in one unmedicated childbirth (*NNT* 4.4, 95% CI [2.7-12.9]). The 1-minute Apgar score in new-borns was higher in MBCP than ECAU (*DM* −0.39, 95% CI [−0.74 to −0.03], *p* = 0.03), but no difference was seen in the 5-minute Apgar score (*p* = 0.28). Note, that after *p*-values adjustment, MBCP and ECAU still differed significantly on the outcome variables "underwent sCB" and "unmedicated childbirth" (see Table 4), but no longer on "EA in labor" and "1-minute APGAR score."

Similar results as in ITT-analyses were found in PP-analyses (see Table S2). Note that in PP analyses, all birth outcomes including "used EA in labor" remained significant after *p*-value adjustment; however, '1-minute Apgar score' was no longer significant.

Discussion

Main findings

Our findings suggest that MBCP is more effective than ECAU in reducing FOC, catastrophizing labor pain, preferences for non-urgent obstetric interventions, and rates of self-requested CB, and in increasing acceptance of labor pain, and unmedicated childbirth. This was found both in ITT and PP analyses and after *p*-values adjustment. In addition, the PP analyses showed that MBCP participants used epidural analgesia less often than ECAU participants. Moreover, newborn's 1-minute Apgar score was higher after MBCP than ECAU, but only in ITT analyses and without adjustment for multiple testing.

Strengths and limitations

The strengths of this study include the adequate statistical power, an active control group, the use of self-reported (subjective) and childbirth measures (objective) derived directly from the medical files, the use of a study protocol, corroborative ITT and PP analyses, adjustment of *p*-values for multiple testing to decrease type 1 errors and blinding of the outcome assessor to group allocations. Both conditions were presented as equal and delivered by trained midwives. Mean scores at both pre-assessments did not differ between MBCP and ECAU, indicating successful randomization.

This study had the following limitations. First, we did not include self-reported questionnaires to monitor possible adverse events. However, no problems were reported after the sessions, and therefore, it seems unlikely that there were clinically relevant

adverse reactions. Second, due to the low number of occurrences of certain events (such as sCB), generalization is more difficult. Replication of the study, preferably with a larger sample size and in other cultures where sCB is more common, is required. Third, we cannot rule out that greater effect of MBCP (9 group couple sessions) compared with ECAU (2 individual couple consultations), both delivered within ten weeks, was due to a dose difference. However, it should be noted that significantly more participants in ECAU (41%) than in MBCP (9%) followed additional prenatal educational courses, which may have compensated for the dose difference. Fourth, pre-intervention assessments were conducted after allocation, which could have caused a measurement bias due to knowing to which condition participants were allocated. However, we did not find evidence of baseline differences between conditions, and no differences between participants who were and were not allocated to their preferred condition were found. Finally, a substantial proportion of the postassessment data (24%) was missing. This could have impacted the results. However, participants with and without missing postassessment data did not differ on pre-assessment measurements and overall missing data were at random. In addition, birth outcome data were retrieved from medical files also for those participants that did not complete the postassessment. Furthermore, the percentage of participants missing postassessment data seems to be common in studies on pregnant women with high FOC (Klabbers et al., 2019).

Interpretation

Although mean pre-assessment fear of childbirth scores (W-DEQ-A=98) indicated almost phobic levels (O'Connell et al., 2017), both groups showed a substantial decrease. However, the MBCP participants were 40% less likely to report high FOC scores on the dichotomized post-assessment measurement (W-DEQ-A≥66) than the ECAU participants, demonstrating an even greater effect for MBCP. Similar findings in favor of MBCP were found for catastrophizing labor pain, acceptance of labor pain, and preferences for non-urgent obstetric interventions during childbirth. However, no difference between conditions was found on the newly developed scale assessing labor anxiety disorder, which could be explained by less power since 36% of this data was missing due to technical errors. This scale is not yet validated. Our finding of reduced FOC in MBCP corroborates evidence from several, mostly small, uncontrolled, and controlled (but largely underpowered) studies on the effects of different mindfulness-based interventions on improvements in mental health conducted across different populations of pregnant women, care systems, and countries (Dhillon et al., 2017). Before the current study, there was not adequately powered RCT evaluating a mindfulness-based intervention or MBCP on FOC (W-DEQ-A≥66) and/or on childbirth outcomes. One well-powered RCT showed that MBCP is more effective in decreasing perceived stress (p = 0.038, d = 0.30) and being at risk for perinatal depression (p = 0.004, d = 0.42) as compared with a Lamaze childbirth course (Lönnberg et al., 2020). Furthermore, MBCP effects seem to be comparable to the effects of educational

interventions reducing high FOC (W-DEQ-A≥66; respectively, *MD* −0.41 and *SMD* −0.46; Moghaddam Hosseini et al., 2018). Lastly, only one RCT evaluated the effect of a non-clinical intervention on reducing CB. It was found that a childbirth training workshop (as compared to routine maternity care) reduced the number of CB (*RR* 0.59, 95% CI [0.37-0.94]). However, this RCT was of low quality as evaluated by Cochrane (Chen et al., 2018), and therefore, caution about the interpretation of this result is needed.

In this study, the effectiveness of MBCP in reducing non-urgent obstetric interventions in labor (EA by almost 40%; sCB 50%) is promising. After *p*-value adjustment for multiple testing, the reduced use of EA after MBCP compared with ECAU was no longer significant in ITT analysis; as such, this finding is somewhat uncertain. The low use of sCB in MBCP (1.4%) is particularly interesting given the relatively high percentage (35%) of participants in this group who a prior stated a preference for nonmedically indicated CB. The higher 1-minute Apgar scores in new-borns of mothers participating in MBCP could result from less intrapartum EA use (Ravelli et al., 2020; Törnell et al., 2015) in MBCP (39%) compared with ECAU (59%) participants. However, results are somewhat uncertain as after *p*-value adjustment this effect was no longer significant. In addition, Apgar scores in new-borns 5 minutes after birth did not differ between the two groups. More research with larger samples is needed to draw more definite conclusions about the outcomes for new-borns.

Considering the relatively low *NNT*, MBCP may be a promising intervention to ameliorate severe FOC and reduce non-urgent obstetric interventions such as sCB (and EA), and substantially increase the frequency of unmedicated childbirths. The relatively low rate of sCB in this study can be explained by the structure of Dutch midwifery health care system, which is based on the idea that pregnancy and childbirth are natural processes that occur under the care of midwives. This care system is designed to minimize medically unnecessary interventions of any kind. However, according to Dutch national data, 71% of pregnant women in 2018 gave birth with an obstetrician, and the rate of CB was 15% (Perined, 2018). The global rate of CB has doubled in the past 15 years to 21% and is increasing annually by 4%.48 The rate of CB exceeds 40% in at least 15 countries (Boerma et al., 2018). The Dutch national cohort study concluded that: “compared to vaginal birth, maternal mortality after cesarean section was three times higher following exclusion of deaths that had no association with surgery” (Kallianidis et al., 2018). Although CB is a relatively safe obstetric intervention, keeping the CS rate as low as possible should be in the interests of all pregnant women. The WHO has emphasized the need for non-clinical interventions to reduce unnecessary CB and to support unmedicated childbirth, for example, by tailoring information and support about FOC, pain relief, and the advantages and disadvantages of medical interventions in childbirth (WHO, 2018). Our research shows that MBCP could potentially contribute to achieving these goals.

Conclusions

Our findings suggest that offering mindfulness training to pregnant women suffering from high FOC and their partners is effective in decreasing FOC and non-urgent obstetric interventions such as sCB, and substantially increasing unmedicated childbirths. The nine-week MBCP programme adapted for pregnant women with high FOC, and their partners appears an acceptable and effective intervention for midwifery care. The increase of FOC and use of non-urgent obstetric interventions during childbirth are worldwide concerns. Whether our findings have wider application deserves further study and attention from health care policy makers.

CHAPTER 6

Mindfulness-Based Childbirth and Parenting (MBCP) programme versus enhanced care as usual in pregnant women with high fear of childbirth: a cost-effectiveness study

This chapter is submitted:
van Steensel, F.J.A., Veringa-Skiba, I.K., Sauer, A., de Bruin, E.I., Bögels, S.M., Mindfulness-Based Childbirth and Parenting (MBCP) programme versus Enhanced Care as Usual in pregnant women with high fear of childbirth: A cost-effectiveness study

Abstract

Introduction: High fear of childbirth (FOC) is associated with negative consequences including childbirth with medical intervening or receiving a Caesarian Section. Mindfulness-Based Childbirth and Parenting (MBCP) seems to be effective in targeting FOC, however, the cost-effectiveness of MBCP is unknown. Therefore, we examined the cost-effectiveness of MBCP compared to enhanced care as usual (ECAU).

Methods: Participants were 54 pregnant women suffering from high FOC (W-DEQ-A ≥ 66); 32 women were randomized to MBCP and 22 women to ECAU. Costs were measured using a retrospective cost-questionnaire, including health care and non-health care costs. The scores on the W-DEQ-A (measuring FOC) and the EQ-5D (measuring quality of life) scores were used as measures of effect in the primary analyses. In the secondary analyses, different estimates of effects and costs were considered to test the robustness of the primary analyses.

Results: The cost-effectiveness analyses indicated that in all but one scenario MBCP was dominant to ECAU (i.e., more effects, lower costs) with the probability of MBCP to be cost-effective (at a willingness to pay of zero) ranging from 70% to 94%.

Conclusions: Findings indicate that MBCP is a cost-effective intervention to treat FOC in pregnant women. A next step would be to replicate the study findings in other countries with other health care systems, and to see how MBCP can be further implemented in midwifery care.

Keywords: fear of childbirth, MBCP, cost-effectiveness, pregnant women, RCT

Introduction

The number of caesarean sections (CSs) are increasing worldwide, now accounting for more than 1 in 5 (21%) of all childbirths (Betrán et al., 2016; WHO, 2018). This is alarming as CSs are associated with negative outcomes for both mother and child (e.g., Sandall et al., 2018). Therefore, the World Health Organization (WHO) stresses the need for non-clinical interventions (defined as 'interventions applied independently of a clinical encounter between a health-care provider and a patient in the context of patient care', WHO, 2018, p. 8) to reduce CS (WHO, 2018). Fear of childbirth (FOC) - which is a negative emotional state characterized by high stress levels and maladaptation to pregnancy and childbirth (Hofberg & Ward, 2004) might be an important factor to target. FOC is usually measured with the Wijma Delivery Expectation Questionnaire (W-DEQ-A; Wijma et al., 1998) and often a cut-off of ≥85 is used to indicate severe FOC. Prevalence rates of women demonstrating substantial symptoms of FOC range up to 30% (Areskog et al., 1981; Geissbuehler & Eberhard, 2002; Hall et al., 2009; Heimstad et al., 2006; Hildingsson et al., 2011; Poggi et al., 2018). FOC has been linked to a variety of problems: sleep disturbances, depressive symptoms, more daily stressors, fatigue and less social support (Hall et al., 2009), nightmares, physical symptoms, lack of concentration at work or at home (Saisto & Halmesmäki, 2003), negative childbirth experience (Elvander et al., 2013; Karlström et al., 2011; Nilsson et al., 2012), and postpartum depression and post-birth trauma (Alder et al., 2011; Hollander et al., 2017; Robertson et al., 2004; Söderquist et al., 2009). Furthermore, women with FOC are more likely to experience unbearable pain during labour (Junge et al., 2018; Nettelbladt et al., 1976), prolonged duration of labour (Adams et al., 2012), and induction of labour (Sydsjö et al., 2012) and - most importantly when considering the WHO call - FOC is significantly related to receiving more psychotropic medication (Nordeng et al., 2012), increased requests for CS and epidural analgesia without experiencing pain (Alehagen et al., 2005; Nieminen et al., 2009; Van den Bussche et al., 2007; Waldenström et al., 2006). Therefore, non-clinical interventions aimed at reducing FOC in pregnant women may also (indirectly) stimulate unmedicated childbirths and decrease CS.

Over the years Mindfulness-Based Interventions (MBIs) have been evaluated for reducing FOC in pregnant women. Large within group effects have been reported for MBIs on reducing FOC (Duncan & Bardacke, 2010; Goodman et al., 2014; Guardino et al., 2014; Vieten & Astin, 2008), however, most studies used (uncontrolled) within group designs and/or had small sample sizes. Notably in this respect is the study of Pan et al., (2019) who compared the Mindfulness-Based Childbirth and Parenting programme (MBCP) (n = 52) to conventional education about childbirth (n = 52) in an RCT. They found that participants in the mindfulness programme scored lower on stress and depression and higher on mindfulness and childbirth self-efficacy after treatment compared to the control group. In addition, in the study of Veringa-Skiba, de Bruin, et al., (2022) women with high FOC (W-DEQ-A≥66) were randomized to MBCP

(*n* = 75) or enhanced care as usual (ECAU; *n* = 66). The authors found that the MBCP group had lower FOC scores after treatment and more childbirth without medical intervening compared to the ECAU group. Thus, MBCP seems an effective intervention to decrease FOC and may lead to an increase in natural childbirths.

A next step towards implementing MBIs for pregnant women with high FOC is to evaluate not only whether an intervention is effective, but also to what costs an intervention. Of relevance here is the study of Nieminen et al. (2017), who compared health care consumptions and costs of 43 women with severe FOC (W-DEQ-A≥85) to 107 women with low FOC (W-DEQ-A≤60). They found that women with severe FOC used more health care resources and had higher societal costs than women with low FOC. More specifically, their postpartum costs and sick leave costs were higher. This finding suggests that severe FOC is associated with higher societal costs and it implies that when severe FOC can be effectively targeted, societal costs may be lowered.

In cost-effectiveness studies, effects and costs of a 'new' intervention are compared to effects and costs of an 'old' intervention (e.g., care as usual), in order to calculate the chance that a new intervention is cost-effective. Such information can be an important factor to consider for policy and health care insurance companies before adopting and implementing an intervention. However, cost-effectiveness studies are sparse for pregnant women endorsing high FOC in general, and – to the authors' best knowledge – absent for MBIs targeting FOC in pregnant women. That is, only psychoeducation interventions have been evaluated for pregnant women with clinical FOC (W-DEQ-A≥100). First, the study of Rouhe et al., (2015) did not perform a full economic evaluation (i.e., evaluate costs and effects simultaneously), but did report similar total costs for the intervention (psychoeducation) group and the control group. This finding suggests that initial higher intervention costs (in the psychoeducation group) may lead to similar total (societal) costs due to lower costs latter on (for example in that study the number of spontaneous vaginal delivery with no complications was higher for the intervention group), and that together with the author's previous findings (Rouhe et al., 2013; Rouhe et al., 2014) targeting high FOC may be very well worth the intervention costs. In addition, Toohill et al., (2017) compared the health care costs for women in an intervention group (psychoeducation) to a control group (care as usual) and calculated the incremental health care costs to prevent one CS using the intervention (psychoeducation). It was found that health care costs (excluding the intervention costs) did not differ between groups, and that the number of women needed to be treated with the intervention in order to prevent one CS was 5. The authors calculated the incremental costs to prevent one CS which were AUS$ 145. In light of the high costs associated with CS (Toohill et al., 2017), this finding suggests that it would be cost-effective to implement the psychoeducation intervention. A full economic evaluation by Turkstra et al., (2017) however showed that the probability of the psychoeducation intervention being more effective (in terms of increased quality

of life) than care as usual was only 12%, while the probability that the psychoeducation intervention would cost less was 58%. Although acceptability curves (representing the chance that an intervention is cost-effective at different ceiling rates) were not presented by the authors, the finding suggests that the chance for psychoeducation as an intervention to be cost-effective for women with high FOC is uncertain. However, the study only used quality of life as a measure of effect (which was not directly the target of intervention) and did not consider all relevant costs (i.e., only health care costs were considered).

To summarize the above, high FOC is highly prevalent and associated with negative consequences including childbirth with medical intervening or CS. MBCP seems effective in targeting FOC, however, in order to be implemented in for instance regular midwifery practice it is relevant to consider the cost-effectiveness of the intervention. Previous work only just started to evaluate the cost-effectiveness for interventions targeting FOC in pregnant women. Studies were limited to evaluating psychoeducational interventions and only one study performed a full economic evaluation (which was limited to health care costs and did not include societal costs). In addition, studies evaluating health care costs at the level of high FOC (W-DEQ-A≥66) are missing. Therefore, in the current study, we examined the cost-effectiveness of MBCP as compared to ECAU for pregnant women with high FOC (W-DEQ-A≥66).

Methods

Study design

The study design was a randomized controlled trial (RCT; with a block randomization) with an experimental group who received MBCP (Bardacke, 2012) and an active control group who received ECAU. Participants were pregnant women suffering from high FOC (W-DEQ-A≥66). We have chosen to only include women with high FOC, as a large Australian study (*N* = 1386) showed that high (W-DEQ-A≥66-84) and severe FOC (W-DEQ-A≥85) are both strongly related to mental health problems in pregnant women and medical childbirths (Toohill et al., 2015).

Several midwifery practices participated and referred pregnant women with FOC. The study had four assessments at which participants completed questionnaires online: pre intervention (T1 = 16-26 weeks' pregnancy), post intervention (T2 = 26-36 weeks' pregnancy), after childbirth (T3 = 2-4 weeks' postpartum) and at 16 weeks follow-up (T4). Information about birth and childbirth outcomes were derived from medical files. For more details of the study see Veringa et al. (2016) and Veringa-Skiba, de Bruin, et al., (2022) for the results. Data was gathered between April 2014 and July 2017.

Participants

For the current cost-effectiveness study only women who completed the cost-questionnaires were selected (NB. cost-data could not be reliably estimated following imputation methods for missing data). In total 54 women (38.3%) completed the cost-questionnaires which is a subsample of the total sample (*N* = 141) that participated in the RCT. We compared the subsample of women in the current study (i.e., who completed the cost questionnaires) to the women which we needed to exclude (i.e., who did not complete the cost questionnaires) on demographics (e.g., age, education level), FOC (measured with W-DEQ-A), and intervention effect on FOC. No significant differences were found (see appendix), indicating that our subsample is representative for the total sample in the RCT. Thus, our current sample consists of 54 pregnant women with high FOC who were randomized to either MBCP (*n* = 32) or ECAU (*n* = 22). No significant differences in baseline variables were found between women in MBCP and ECAU (see Table 1). Also, no significant difference between conditions with respect to costs measured at pre assessment were found; the bootstrapped cost difference between conditions was € -801, CI 95% € -2,777 to € 1,082.

Table 1.
Baseline characteristics of the women in MBCP and ECAU

	MBCP (*n* = 32)	**ECAU (*n* = 22)**	***p***
Age, M (SD)	32.90 (4.37)	33.02 (4.51)	0.928
Gestational age, M (SD)	39.63 (1.89)	39.87 (1.22)	0.599
FOC (W-DEQ-A total score), M (SD)	98.03 (23.61)	98.27 (21.73)	0.970
Health related index (EQ-5D), M (SD)	0.74 (0.20)	0.72 (0.19)	0.766
Educational level			0.322
Middle level	4	5	
High level (bachelor degree)	28	17	
Born in the Netherlands:			0.941
Yes	25 (78.1%)	17 (77.3%)	
No	7 (21.9%)	5 (22.7%)	
Parity			0.243
Nulliparous	25 (78.1%)	14 (63.6%)	
Multiparous	7 (21.9%)	8 (36.4%)	

Note. ECAU: enhanced care as usual; EQ-5D: EuroQol-5D; FOC: fear of childbirth; M: mean; MBCP: mindfulness-based childbirth and parenting; SD: standard deviation; W-DEQ-A: Wijma Delivery Expectation Questionnaire

Interventions

MBCP

MBCP is an adaption of Mindfulness-Based Stress Reduction (Kabat-Zinn, 1990), developed by Nancy Bardacke (Bardacke, 2012) for parents expecting a child. Formal and informal mindfulness meditations are combined with the knowledge of psychobiological processes regarding pregnancy, childbirth, breastfeeding, and postpartum adjustment as well as the psychobiological needs of infants. MBCP aims to reduce stress during pregnancy, cultivate mindfulness skills that help with dealing with pain and fear of childbirth, as well as cultivating general mindfulness skills like wisdom, kindness and connection. The programme included nine weekly sessions of three hours, which were provided by experienced midwives certified in MBCP.

ECAU (control group)

Due to the inclusion criterion of pregnant women with high FOC, care as usual was enhanced in this study by adding two structured consultations on FOC. These two consultations consisted of (1) an explanation of the Biopsychosocial Model (Engel, 1977) and (2) the Childbirth Plan of the Royal Dutch Organization of Midwives (KNOV Geboorteplan, n.d.).

Measures

Costs

The cost questionnaire was completed at all assessments, each retrospectively covering the previous three months, therefore covering the entire pregnancy plus the period of maternity leave. Participants were asked about the frequency of their resource usage (e.g., how many times they visited a general practitioner retrospectively for three months). Additionally, they were asked about costs related to paid and unpaid work and productivity loss (e.g., how many hours they were not able to perform daily activities around the house, got help from friends and family, sick leave, and their partners' sick leave). The Dutch guidelines for cost-research (Hakkaart-van Roijen et al., 2015) were followed. The costs were calculated based on a societal perspective, which means that all possible costs were considered. This includes health care (e.g., visit to the GP, hospital, medication use) and non-health care (e.g., loss of work hours, daily activities, help from family and friends) costs. A unit costs list (see Appendix Table 4) was created based on guidelines of the Dutch care institute (Nederlandse Zorginstituut), Dutch care authority (Nederlandse Zorgautoriteit) and Pharmaceutical Compass. Shadow prices were used if an official price unit was not available, and the friction cost method was used to calculate productivity losses. The total costs per participant was calculated by multiplying individual resource usage with the unit price. Inflation correction was respected by adjusting all costs to consumer price index (CPI) of 2017.

Intervention costs were calculated for the MBCP and ECAU participants. For MBCP: the time spent by the midwife to provide the intervention (9 sessions of three hours + one hour of preparation time per session = 36 hours) was multiplied by the tariff of € 94.44 per hour (a tariff for (psychological) therapy, see Appendix, Table 4) and divided by the average number of (6) participants (couples) per group. In addition, costs for participants' time were added and calculated by multiplying the hours spent on following the intervention (27 hours) by the tariff for loss of daily activities (i.e., € 14.32 per hour, see Appendix, Table 4). Total intervention costs for MBCP amounted 953.28 Euros per pregnant woman. For ECAU, four hours was spent on (preparation of) the intervention (3 hours of which the midwife spent face-to-face time with the individual couple and one hour of preparation time), and participants' (loss of daily activities) time (3 hours) was added. Total intervention costs for ECAU amounted 420.72 Euros.

Effectiveness

The primary outcome was high FOC. This was examined with the W-DEQ-A (≥66; Wijma et al., 2002) which is a 33-item self-report measure assessing anticipated and experienced levels of FOC e.g. "What do you think you will feel during the labour and delivery?" with answers such as "lonely" and "safe" rated on a 6-point Likert scale from "not at all" (score 0) to "extremely" (score 5). The W-DEQ-A covers several dimensions of FOC such as general fear, loneliness, lack of self-efficacy, negative appraisal, lack of positive anticipation and concerns about the child (Garthus-Niegel et al., 2011). Sum scores were calculated with higher scores indicating a higher level of FOC. In addition, participants reported about their quality of life assessed with the EuroQol-5D (EQ-5D; EuroQol Group, 1990). The EQ-5D consists of five dimensions of health-related quality of life: self-care, mobility, activities, pain/discomfort, anxiety/depression with scores ranging from 1-3 (1 indicating no problems and 3 indicating severe problems). Psychometric properties are reported to be good (Brooks, 1996). Based on the EQ-5D scores a health index (utility score) can be derived by adding preference weights (Lamers et al., 2006). The health index can then be used to calculate Quality Adjusted Life Years (QALYs). QALYs assign each time period a value reflecting a participant's health index for that time period. These values usually lie between *zero* indicating death, and *one* indicating full health (Dolan, 2001).

Statistical analysis

First, effects and costs between the groups were examined separately. To evaluate differences in the presence of high FOC (W-DEQ-A≥66) between conditions (MBCP versus ECAU) chi-square analyses were used. To evaluate differences in QALYs, non-parametric Mann Whitney U tests were used. To examine differences in costs a bootstrap analysis was conducted. Second, an economic evaluation was performed evaluating the combined outcomes of costs and effects using a societal perspective (all costs – health care and non-health care costs – were included). Incremental cost-

effectiveness ratios (ICERs) were calculated and represent (1) the cost per woman that shows normal levels of FOC (W-DEQ-A< 66), and (2) the cost per QALY. Next, bootstrap analysis were performed to reflect the uncertainty around costs and cost- effectiveness ratios. A cost-effectiveness plane was used to represent the bootstrapped ICERs. The y-axis reflects the difference in costs between MBCP and ECAU, and the x-axis represents the difference in effect. Cost-effectiveness acceptability curves were used to represent the probability that MBCP is cost-effective at a range of ceiling ratios (i.e., the amount of money that society would be willing to pay for a pregnant woman without clinical FOC/per QALY).

Secondary analyses were performed to evaluate the robustness of the primary cost-effectiveness analyses (Briggs et al., 1997). As different estimates of effect, we used: (1) satisfaction with labor measured by the Salmon's Item List (SIL; Salmon & Drew, 1992); a score above 70 was used as an indicator for a positive birth experience; (Spaich et al., 2013), (2) postnatal depression measured by the Edinburgh Prenatal Depression Scale (EPDS; Cox et al., 1987); a cutoff of ten was used to indicate a clinical score; (Bergink et al., 2011), and (3) parenting stress measured by the Nijmeegse Parental Stress Index-Short Form (NPSI-SF; Brock et al., 1992), a 'high' score following the norms in the manual was considered clinical. As different estimates of costs, we followed a health care perspective (by including only the health care costs) and we calculated total costs (i.e., societal costs + costs related to the child). In addition, we identified one extreme value regarding costs (i.e., societal costs for one case amounted € 110,170 while the second largest societal costs amounted € 60,082). Therefore, we re-analyzed the data leaving this extreme case out.

Finally, we calculated the average amount of money that the midwives received for taking care of pregnant women and compared this between the MBCP and ECAU condition. That is, in the Netherlands, prenatal, natal and post-natal care is delivered in the first line of care and the midwives receive a fixed amount of money for providing prenatal, natal and/or post-natal care. This also means that when women are referred to the second line of care (e.g., referred to the hospital because of analgesia or CS), the midwives do not provide natal care and do not receive the fixed amount of money that is related to that care. Therefore, from a midwifery perspective, it may be relevant to examine how much may potentially be gained (or lost) financially, or how much needs to be invested when considering giving MBCP to pregnant women as part of her profession.

Results

Bootstrap analysis revealed no statistical differences between the two conditions in societal costs, health care costs, or non-health care costs (see Table 2). With respect to health care costs, relatively high childbirth costs were observed in ECAU (compared to MBCP). Considering non-health care costs, costs for sick leave and loss of daily

activities were high in both groups. Costs related to help from family and friends were also high in both groups but seemed particularly high in ECAU. Costs were not equally distributed in time: i.e., costs seemed to be highest (particularly for ECAU) at T3 (covering costs due to mode of childbirth). With regards to the effects, no statistical differences post-intervention were found between MBCP and ECAU with regards to the percentage of women who had normal FOC (W-DEQ-A<66), or with respect to quality of life (QALYs), see Table 3.

Table 2.
Mean costs (in 2017 Euro) for MBCP versus ECAU

Resource	MBCP	ECAU	Mean incremental costs (CI 95%)
Health care costs			
GP regular	70.11	106.16	
GP outside regular working hours	28.22	14.32	
First aid (hospital)	24.84	48.17	
Medical specialist (hospital)	26.18	25.39	
Hospitalization	924.38	1,438.72	
Paramedic/psychological care	349.10	307.22	
Midwife	499.78	630.73	
Gynecologist	420.82	355.43	
Mode of Childbirth	1,917.83	3,003.93	
Postnatal care	104.77	38.11	
Home care	0.00	339.45	
Prescribed medication	9.80	22.74	
Intervention costs	566.64	377.76	
Subtotal	*4,942*	*6,708*	*-1.399 (-4,111 to 1,609)*
Non-health care costs			
Loss of activities	2,108.62	2,948.94	
Sick leave (work)	4,276.06	4,010.39	
Help of family and friends	1,823.34	5,292.54	
Domestic help	3.13	66.23	
Sick leave (work) of partner	1,638.03	2,356.16	
Other expenses	365.56	122.27	
Intervention costs: participants' time	386.64	42.96	
Subtotal	*10,601*	*14,839*	*-4,415 (-15,397 to 4,348)*
Societal costs (Health care + non-health care costs)	15,544	21,548	-5,919 (-29,038 to 9,503)
T2 (pre to post intervention period)	4,375	6,091	
T3 (before to after childbirth period)	8,768	12,569	
T4 (after childbirth to follow-up)	2,399	2,886	

Note. CI: confidence interval; ECAU: enhanced care as usual; GP: general practitioner; MBCP: mindfulness-based childbirth and parenting.

Table 3.
Comparisons between MBCP and ECAU on FOC and QALYs

	MBCP (*n* = 32)	**ECAU (*n* = 22)**		
W-DEQ-A score (< 66)	**n (%)**	**n (%)**	X^2	*p*
T1 (pre assessment)	3 (9.4%)	2 (9.1%)	0.001	.972
T2 (post assessment)	19 (59.4%)	8 (36.4%)	2.761	.097
T3 (after childbirth)	23 (71.9%)	11 (50.0%)	2.675	.102
T4 (16 weeks follow-up)	22 (68.8%)	11 (50.0%)	1.929	.165
	M (SD)	M (SD)	Z	*p*
QALY T1-T2	0.19 (0.03)	0.17 (0.05)	-0.890	.374
QALY T1-T3	0.37 (0.06)	0.45 (0.10)	-0.352	.725
QALY T1-T4	0.55 (0.11)	0.54 (0.14)	-0.018	.986

Note. ECAU: enhanced care as usual; MBCP: mindfulness-based childbirth and parenting; QALY: Quality Adjusted Life Years; W-DEQ-A: Wijma Delivery Expectation Questionnaire

The ICER based on the costs per 'FOC-free' woman (i.e., woman with a W-DEQ-A score < 66) demonstrated that MBCP was dominant to ECAU: that is, the effect of MBCP was 0.19 higher, while the total costs were €6,004 lower (Table 4). The bootstrapped ICERs are presented in a CE-plane (Figure 1) which demonstrates that most of the point estimates (92%) were found on the right side of the vertical axis indicating a high probability that MBCP is more effective than ECAU. In addition, most point estimates (88%) were found below the horizontal axis indicating a high probability of MBCP to cost less than ECAU. More specifically, 7% of the ICERs were falling in the SW-quadrant (MBCP is less effective, and costs are lower), 1% in the NW-quadrant (MBCP is less effective, and cost are higher), 11% in the NE-quadrant (MBCP is more effective, but costs are higher), and 81% in the SE-quadrant (MBCP is more effective, and costs are lower; Table 4). The cost-effectiveness acceptability curve (Figure 2) demonstrates that MBCP has an 88% chance to be cost-effective when the willingness to pay for a woman with normal FOC (W-DEQ-A<66), equals zero. The chance to be cost-effective increases as the willingness to pay increases (see Figure 2 and Table 4).

Figure 1
CE-plane for W-DEQ-A

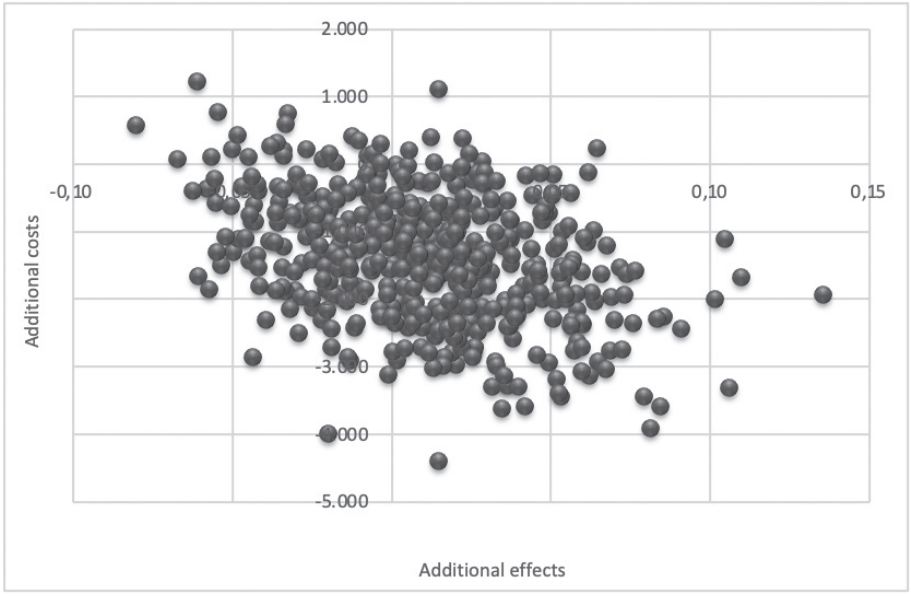


Figure 2
Acceptability curve for W-DEQ-A

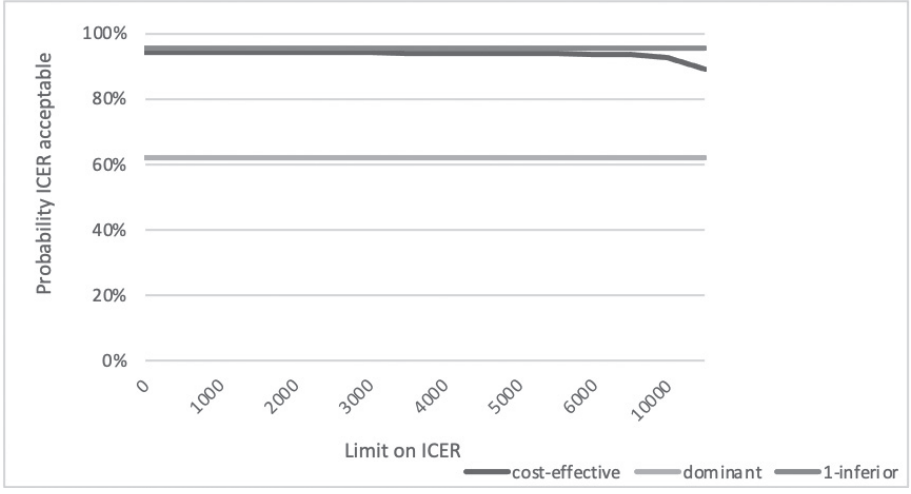


Figure 3
CE-plane for QALY

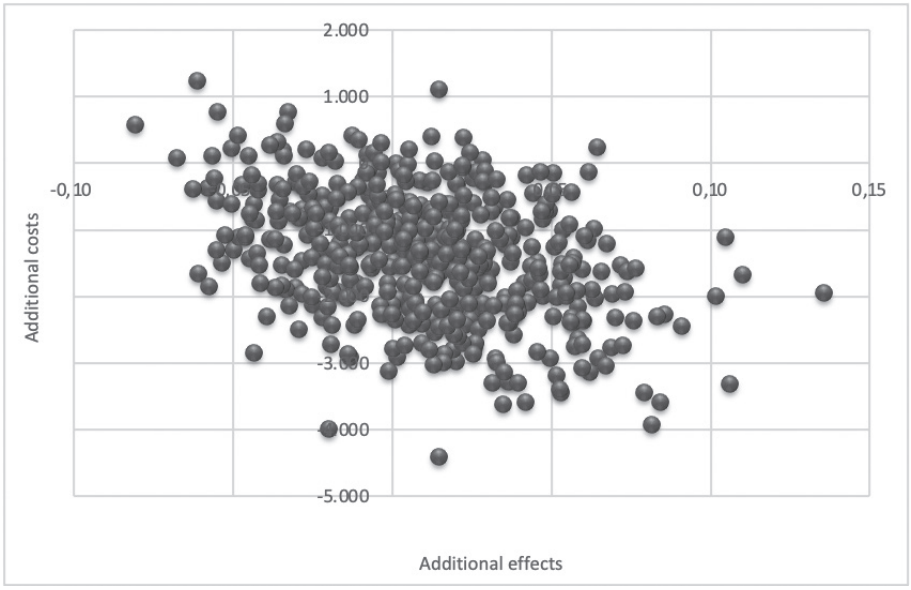


Figure 4
Acceptability curve for QALY

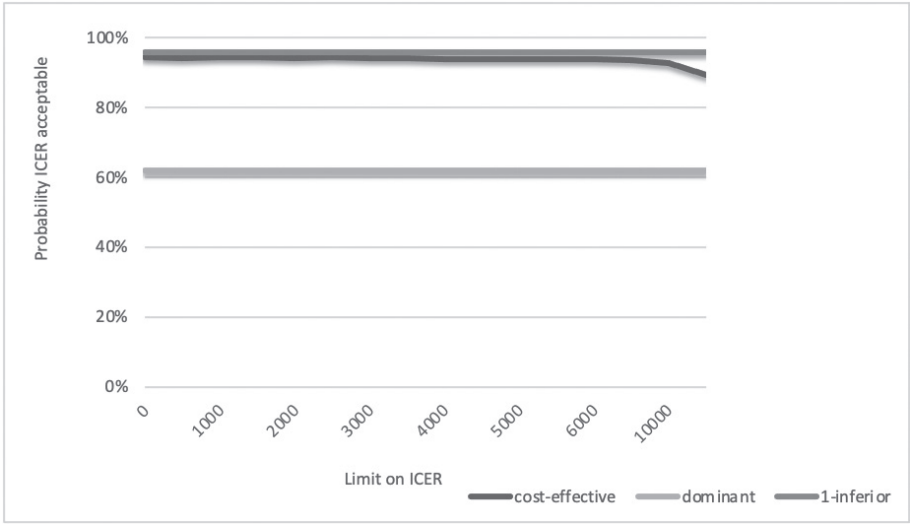


Table 4.

Effects, costs, and cost-effectiveness analyses of MBCP versus ECAU

	MBCP		ECAU		ICER	% ICERs falling in quadrant of CE-plane				Probability (%) that MBCP is cost-effective at a willingness to pay of:			
	Effect	Costs	Effect	Costs		SW	NW	NE	SE	€0	€5,000	€10,000	€20,000
Primary analyses													
W-DEQ-A – societal costs	0.69	15,544	0.50	21,548	Dominant	7	1	11	81	88	91	93	95
QALY – societal costs	0.55	15,544	0.54	21,548	Dominant	28	9	2	62	89	89	89	88
Secondary analyses													
W-DEQ-A – health care costs	0.69	5,329	0.50	6,751	Dominant	7	2	6	86	93	96	96	94
QALY – health care costs	0.55	5,329	0.54	6,751	Dominant	32	4	1	62	94	94	93	89
W-DEQ-A – total costs (societal + child costs)	0.69	18,333	0.50	22,258	Dominant	6	2	22	70	76	81	84	89
QALY – total costs (societal + child costs)	0.55	18,333	0.54	22,258	Dominant	20	19	6	56	75	75	75	74
W-DEQ-A – without extreme case	0.69	15,544	0.52	17,320	Dominant	8	3	27	61	70	78	84	89
QALY – without extreme case	0.55	15,544	0.54	17,320	Dominant	31	25	6	38	70	68	67	66
Satisfaction with childbirth (SIL) – societal costs	0.69	15,544	0.64	21,548	Dominant	27	6	6	62	89	88	88	87
Postnatal depression (EPDS) – societal costs	0.69	15,544	0.73	21,548	€150,952	52	9	6	33	86	85	84	80
Parenting stress (NPSI-SF) – societal costs	0.91	15,544	0.77	21,548	Dominant	10	1	12	78	87	90	92	95

The ICER based on the costs per QALY demonstrated that MBCP was dominant to ECAU: the effect of MBCP was 0.01 higher while costs were € 6,004 lower (see Table 4). The CE-plane (Figure 3) demonstrates that over half of the point estimates (64%) were found on the right side of the vertical axis indicating that the probability that MBCP is more effective than ECAU is quite uncertain. However, most point estimates (80%) were found below the horizontal axis indicating a rather high probability of MBCP to cost less than ECAU. Inspecting the point estimates in the four quadrants, 28% of the ICERs fell in the SW-quadrant (MBCP is less effective, and costs are lower), 9% in the NW-quadrant (MBCP is less effective, and cost are higher), 2% in the NE-quadrant (MBCP is more effective, but costs are higher), and 62% in the SE-quadrant (MBCP is more effective, and costs are lower) (Table 4). The cost-effectiveness acceptability curve (Figure 4) demonstrates that MBCP has a 89% chance to be cost-effective when the willingness to pay for a QALY equals zero. This chance stays rather stable across different willingness to pay thresholds (see Figure 2 and Table 4).

In the secondary analyses, we evaluated the robustness of the findings from the primary analyses by varying the estimates of effect and costs (see Table 4). In most cases, the results were similar to the primary analyses (MBCP has a higher chance to be more effective and to cost less). That is, in all but one scenario, MBCP was dominant to ECAU (more effects, less costs) with probability rates of MBCP being cost-effective compared to ECAU ranging between 70% and 94% at a willingness to pay equal to zero. The exception was when postnatal depression was used as a measure of effect. In this scenario, 39% of the point estimates felt on the right side of the y-axis (demonstrating higher effectiveness for MBCP compared to ECAU), while 61% of the point estimates felt on the left side of the y-axis (demonstrating lower effectiveness for MBCP compared to ECAU). MBCP, however, still had a rather high chance to be cost-effective in this scenario (the probability that MBCP would be cost-effective compared to ECAU was 86%) due to lower costs in MBCP.

With regards to the midwives' perspective, the average amount of money the midwives received for providing care to a woman in the MBCP condition was € 1,324 compared to € 1,125 in ECAU. The bootstrapped mean difference in the average amount of money between conditions was significant; incremental cost = € 193 (95% CI €15 – €371).

Discussion

This study was the first to evaluate the cost-effectiveness of MBCP versus ECAU for pregnant women with high FOC (W-DEQ-A≥66). Results demonstrated that MBCP was more effective and had lower costs. This resulted in a good chance to be cost-effective compared to ECAU: i.e., the probability for MBCP to be cost-effective was 88% considering W-DEQ-A scores, and 89% considering QALYs. Secondary analyses mostly confirmed the findings of the primary analyses, but also demonstrated a different result

regarding postnatal depression as a measure of effect: i.e., in this scenario, MBCP had a higher chance to be less effective than ECAU, but - as costs were lower for MBCP - the chance that MBCP was cost-effective was still quite high.

Although costs and effects did not differ between MBCP and ECAU when they were analyzed separately, the cost-effectiveness analyses demonstrated that MBCP had a higher chance to be more effective than ECAU while costs were lower. This finding is in line with other studies demonstrating the effectiveness of MBCP for pregnant women with high FOC (Duncan & Bardacke, 2010; Goodman et al., 2014; Guardino et al., 2014; Pan et al., 2019; Vieten & Astin, 2008). When considering the costs for MBCP and ECAU, we noticed relatively high childbirth costs and non-health care costs (help from family and friends) in ECAU. These higher childbirth costs in ECAU can be explained by significantly more unmedicated childbirths in the MBCP condition than in the ECAU condition (Veringa-Skiba, de Bruin, et al., 2022). Subsequently, women in the ECAU condition may have had longer recovery periods due to these medicated childbirths (e.g., recovery after CS) which in turn may be related to more help from family and friends. Thus, considering the effects and costs togethers, it seems that MBCP is a cost-effective intervention to treat FOC in pregnant women. However, some issues need to be considered.

First, when examining the different measures of effect in the primary analyses (W-DEQ-A and QALY), it needs to be noted that the difference in effect between MBCP and ECAU regarding QALYs was very small (0.55 versus 0.54, see Table 4), and the point estimates were more equally distributed across the y-axis (indicating more or less similar effects for MBCP and ECAU) for quality of life (QALYs). This was different in the scenario were FOC (W-DEQ-A) was used as a measure of effect: MBCP had a high probability that MBCP was more effective than ECAU. An important distinction here in the measures of effect is the use of condition-specific measures versus a more generic measure (such as the EQ-5D that was used in the present study). In a review by Payakachat et al., (2015) it was reported that in 45% of the (56) specific conditions the EQ-5D was responsive to change, while in 48% of the conditions the EQ-5D demonstrated limited or mixed evidence of responsiveness (and in 7% the EQ-5D was not responsive). Further, Turkstra et al., (2017) who evaluated the cost-effectiveness of a psycho-education intervention (compared to care as usual) for pregnant women with high FOC (W-DEQ-A≥66) also used the EQ-5D in their study and reported the possibility that the EQ-5D was not responsive (enough) to measure important changes. Therefore, the EQ-5D (generic measure to evaluate someone's quality of life) might have been less responsive to change than the other more condition-specific measures in our study (such as the W-DEQ-A).

Second, in contrast to the other measures of effect used in the current study, for postnatal depression (assessed by the EPDS) results indicated a low probability for

MBCP to be more effective than ECAU. In fact, most point estimates (61%) were found on the left side of the y-axis indicating less effect for MBCP as compared to ECAU. An explanation for this finding is that MBCP was not specifically targeting depression or depressive symptoms, but primarily focused on targeting fear of childbirth. Prior to intervention, about one third of the women had high scores and this percentage had not changed after intervention. In addition, note that the difference in effect for the EPDS between MBCP and ECAU was rather small (i.e., 69% of the women in MBCP and 73% of the women in ECAU had normal EPDS scores at follow-up).

Third, in the scenario were one case (with extreme high costs) was excluded from analysis, MBCP was still dominant compared to ECAU (more effects and lower costs) but the chance that MBCP would be cost-effective dropped to 70%. This finding makes the results more uncertain, and a replication of the study (with a larger sample size) is therefore recommended.

Strengths of the study include the detailed administration of cost including both health care as well as non-health care costs (such as help from friends and family), the chosen time frame which covered the entire pregnancy and maternity leave, and the use of different measures of effect. Another strength of the study is the active control group (ECAU), especially considering that all the pregnant women were suffering from high FOC and were offered help in some way.

Limitations of the study also need to be noted. In the current study a subsample (n = 54, 38.3%) was used instead of the total sample (N = 141) due to the low number of women who completed all cost-questionnaires at T2, T3 and T4 (and cost data could not be reliably estimated). The use of a smaller subsample might have led to less power to compare differences in effect between MBCP and ECAU (e.g., in the total sample significant differences on W-DEQ-A and other outcomes were found in favor of MBCP; Veringa-Skiba, de Bruin, et al., 2022). Fortunately, no differences between the selected and excluded sample were found on baseline variables (such as FOC and costs measures at T1), and also no baseline differences between MBCP and ECAU were found, indicating that the subsamples were representative for the total sample. In addition, cost-effectiveness analyses are non-parametric and rely less on sample size. Regarding the representativeness, it should be noted that countries differ in their (costs for) health care systems and that the Netherlands have a quite unique system compared to other Western countries regarding childbirth care. The Dutch midwife-led healthcare system is based on the idea that pregnancy and childbirth are natural processes under the primary care of independent midwives (Hessing-Wagner, 1991). Pregnant women in midwife-led care at the onset of childbirth are considered to have low risk of complications. Therefore, the pregnant women can choose between a homebirth or a planned hospital childbirth (both are under the responsibility of independent midwives). In the event of complications (anticipated or otherwise) any

time during pregnancy, childbirth or postpartum, women are referred to obstetric care in the hospital, known as obstetrician-led care (Crébas, 1990). If pregnant or labouring women need to be referred to obstetrician-led care due to obstetric or paediatric risk, then the responsibility of the independent midwife in the pregnant woman's care ends. The risk selection and a clear division of tasks in midwife- and obstetrician-led care are based on the national List of Obstetric Indications (KNOV, 2003), and both types of care receive a fixed amount of money for the care that they provide to the pregnant women (but note that obstetrician-led care is more expensive). Considering this unique system in the Netherlands, it is uncertain how well our results generalize to other countries with different health care systems and different ways to reimburse health care costs.

To summarize, this study was the first to evaluate the cost-effectiveness of MBCP for women suffering from high FOC compared to ECAU. Due to the relation between high FOC and medical interventions during pregnancy and childbirth, as well as the associated (childbirth) costs, the results of this study yield important information for society by not only considering the effects of an intervention but also considering an economic perspective. It seems that MBCP is a cost-effective intervention to treat FOC in pregnant women, both from a societal as well as a health care perspective. A next step would be to replicate the findings in other countries, and to see how MBCP can be further implemented in midwifery care.

CHAPTER 7

Mindful awareness as a mechanism of change for natural childbirth in pregnant women with high fear of childbirth: a randomized controlled trial

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Abstract

Background: Mindfulness-Based Childbirth and Parenting (MBCP) is effective in increasing natural childbirth in pregnant women with high fear of childbirth (FOC) as compared to enhanced care as usual (ECAU). We aimed to examine through which pathway of action MBCP reaches this effect, based on a model of approaching or avoiding the challenges related to childbirth.

*Methods***:** One hundred eleven pregnant women with high FOC were measured pre- and post-intervention on FOC (emotion pathway), catastrophic beliefs about labour pain (cognition pathway) and mindful awareness (attention pathway). A multiple mediation model was used to examine through which pathway the mechanism of change operated in relation to approach (i.e., natural childbirth) versus avoidance (i.e., self-requested caesarean section).

Results: It was found that greater mindful awareness (18% R^2 = 0.18, F [1,107] = 22.77, $p < 0.0001$) was the only significant mechanism of change operating through the attentional pathway leading to natural childbirth. More specifically, nonreactivity to inner experience (a facet of mindful awareness) showed to be the strongest mechanism of change. More extensive meditation practice was positively associated with natural childbirth; however, the number of completed MBCP sessions was not associated with the outcome.

Conclusions: An increase in mindful awareness was the strongest mechanism of change for better adaptation to the challenges of childbirth. Decreases in neither FOC nor catastrophic beliefs about labour pain were identified as mechanisms of change. Additionally, the more one meditated, the more one was inclined towards a natural childbirth. MBCP enhances adaptation to the challenges of childbirth and less use of obstetric interventions in the presence of high FOC.

*Keywords***:** Fear of childbirth, Mindfulness, MBCP, Natural childbirth, Obstetric interventions

Background

Mindfulness-Based Programmes (MBPs) have shown to be effective for a variety of psychological and physical conditions including depression, anxiety, stress and chronic pain in clinical and non-clinical populations (Alsubaie et al., 2017; Goyal et al., 2014; Reiner et al., 2013). MBPs also showed potential in reducing anxiety, depression and stress in pregnant women as demonstrated with pooled results of uncontrolled studies (Dhillon et al., 2017). However, pooled results of controlled studies did not show the same outcomes (Dhillon et al., 2017). Promising are new findings from two randomized controlled trials (RCTs) from Sweden and The Netherlands on the effects of the Mindfulness-Based Childbirth and Parenting (MBCP) programme in pregnant women on perceived stress and symptoms of depression (Lönnberg et al., 2020), and high levels of fear of childbirth (FOC; Veringa-Skiba, de Bruin, et al., 2022). The Swedish RCT showed that MBCP is more effective in decreasing perceived stress and being at risk for perinatal depression as compared to a Lamaze childbirth course (Lönnberg et al., 2020). The Dutch RCT focused on pregnant women with high FOC and contributed to the research by measuring, next to fear of childbirth, the actual childbirth process as outcome variable. Approach versus avoidance of childbirth was assessed, with better adaptation expressed as natural childbirth versus maladaptation expressed as a childbirth with (unneeded) obstetric interventions. MBCP, in comparison to enhanced care as usual (ECAU), was found to have a medium positive effect on the reduction of FOC and catastrophic beliefs about labour pain; a large effect on the reduction in willingness to undergo obstetric interventions in the absence of obstetric indications; a reduction in received self-requested caesarean section (sCS) and epidural analgesia (EA); and remarkably, women after MBCP were two times more likely to undergo natural birth (spontaneous vaginal birth without obstetric interventions; Moscucci, 2003). Yet, it is unknown *how* MBCP has impacted an increase in natural childbirths in the presence of high levels of FOC.

To answer this question, we have presented a theoretical model of two opposite behavioural responses to the challenges of childbirth, namely avoiding versus approaching (Veringa et al., 2016). This model was derived from cognitive theory (Beck, 1976) on fear and anxiety, which emphasizes the interrelationship between negative emotions (anxiety/fear), biased cognitions (catastrophic beliefs), biased attention (threat-focused), and maladaptive behaviours (avoiding) (Beck et al., 2016). Avoiding is a maladaptive behaviour since it becomes more harmful than helpful in dealing with the challenges of childbirth, such as undergoing a sCS. The proposed model has been robustly supported with empirical findings that pregnant women, who plan to avoid the challenges of a natural childbirth by requesting and undergoing obstetric interventions such as sCS or EA, experienced high FOC (Badaoui et al., 2019; Dehghani et al., 2014; Dencker et al., 2019; Möller et al., 2017; Ryding et al., 2015); had catastrophic beliefs about labour pain (Kwissa-Gajewska & Dołęgowska, 2017;

Rondung et al., 2019); and appraised childbirth as threatening and focused attention on potential threatening aspects of childbirth (Kwissa-Gajewska & Dołęgowska, 2017; Veringa et al., 2011). Further, high FOC is also associated with poorer adaptation to childbirth, thus a longer duration of dilatation period during labour (Adams et al., 2012), and even the use of an emergency CS (Molgora et al., 2020). On the other hand, balanced emotions, realistic beliefs and unbiased attention (mindful awareness) would lead to more adaptive behaviour such as approaching the challenges of childbirth, by undergoing a natural childbirth. It can be concluded that high FOC is strongly related to obstetric interventions during childbirth due to pregnant women's requests or problems occurring during birth.

In our model, three possible pathways of action leading to avoiding or approaching the challenges of childbirth in pregnant women with high FOC were hypothesized as: (I) an emotion pathway - a change in FOC, (II) a cognition pathway - a change in catastrophic beliefs about labour pain, and (III) an attention pathway - a change in mindful awareness. Particularly, the change in mindful awareness, was hypothesised to be an important mechanism of change by which specifically MBCP would help in approaching rather than avoiding the challenges of childbirth (Veringa et al., 2011).

The attention pathway in this study is defined as mindful awareness of the moment-to-moment experience, and it can be cultivated during mindfulness meditations (Baer, 2003). Mindfulness meditation is at the core of MBPs, and mindful awareness is typically described as "a form of non-judgmental, nonreactive attention to experiences occurring in the present moment, including cognitions, emotions, and bodily sensations as well as sights, sounds, smells, and other environmental stimuli" (Baer, 2009). During mindfulness meditations, participants observe a variety of experiences that may arise, while cultivating an attitude of open interest to these experiences. This allows the experiences to exist, despite a residual willingness or reactivity to change or a desire to escape from them, even if they feel unpleasant. Mindfulness meditation helps the practitioner to realize that physical sensations, thoughts and emotions are continuously changing, as they are arising and disappearing in the awareness. Mindfulness meditations are born from Eastern meditation traditions, which emphasize that the practice of mindfulness leads to less suffering and more wisdom, compassion and equanimity (Shonin et al., 2016).

Traditional mindfulness meditations have been successfully adapted for use in Western mental health approaches. For instance, Mindfulness-Based Stress Reduction (MBSR; Kabat-Zinn, 1990) and Mindfulness-Based Cognitive Therapy (MBCT; Segal et al., 2002) have become widely used in health care settings and with both clinical and non-clinical populations to reduce human suffering caused by psychological and physical vulnerabilities. Extensive research on the mechanisms of change, in which MBSR and MBCT influenced negative experiences in people with physical and/or

psychological conditions, suggested mindful awareness as a universal mechanism of positive change (Alsubaie et al., 2017). Behavioural self-regulation and increased behaviour adaptation under stressful circumstances are examples of positive change with mindful awareness (Gratz & Roemer, 2004; S.C.Hayes et al., 2006). Other research on mindful awareness also found that a greater mindful awareness acted as a mechanism of change for MBSR in non-pregnant populations with anxiety disorders in reducing worries (Hoge et al., 2015), anxiety, and avoidance symptoms (Vøllestad et al., 2011). One of the instruments to measure mindful awareness is the five facets of mindfulness as defined by Baer et al., (2006).

Methods

Aims

In the present study, we evaluated three possible pathways of action of avoiding (e.g., having a sCS) versus approaching (e.g., having a natural childbirth) the challenges of childbirth in pregnant women with high FOC. We hypothesized that following MBCP, several mechanisms of change would contribute to natural childbirth: the change from high to lower FOC (emotional pathway), the change from high to lower catastrophic beliefs about labour pain (cognitive pathway), and the change from low to higher mindful awareness (attention pathway). Additionally, we tested whether the number of completed MBCP sessions and the minutes of meditation practice at home were associated with the outcome.

Procedure and subjects

In this study, we analysed the 'I've Changed My Mind' RCT-data in which 141 pregnant women without a priori (medical) restrictions for natural childbirth experiencing high FOC were randomized to MBCP (n = 75) or ECAU (n = 66) (Veringa-Skiba, de Bruin, et al., 2022). There were no significant pre-intervention differences between conditions for demographic predictors and outcome measures (Veringa-Skiba, de Bruin, et al., 2022). Below, a summary of the methodological details most pertinent to the current study are presented. The study's procedure, which includes the rates of recruitment, reasons for refusal, exclusion, withdrawal and attritions, as well as the course of randomization and masking, has been published previously (Veringa-Skiba, de Bruin, et al., 2022). Inclusion criteria were an age ≥ 18 years, fluent in the Dutch or English language, between 16 and 26 weeks pregnant at baseline, and high levels of FOC as indicated by a score ≥66 on the Wijma-Delivery Expectation Questionnaire (W-DEQ-A; Wijma et al., 1998). Exclusion criteria were psychotic episodes, suicidal risk, substance use and dependency, borderline personality disorder, current trauma or traumatic stress disorder, HIV infection, multiple gestations, high risk for premature labour, or participation in other MBPs in the past year.

Intervention: Mindfulness-Based Childbirth and Parenting (MBCP)

The intervention consisted of the face-to-face, the group-based MBCP programme for expectant parents published as the course book "Mindful Birthing" (Bardacke, 2012). MBCP was originally designed to teach life-skills and to promote healthy pregnancy and childbirth to all expectant parents. In our trial, we adapted it for pregnant women with FOC. Adaptations were focused on facilitating participants in every session with skilful responding to anxiety- and fear-related responses in guided meditations and enquiry. The nine weekly sessions, with up to six couples in a group, lasted three hours, and were delivered by experienced midwives certified in MBCP. Sessions included: mindfulness meditation practice (e.g., body scan, sitting and walking meditations, speaking and listening meditation on fear and happiness, yoga) and enquiry; and teachings about psychobiological processes in childbirth (e.g., physiology of labour pain, dilatation, delivery and postpartum) and in new-borns. Participants were asked to commit to daily meditation practices at home for 30 minutes. MBCP was free of charge, and the sessions took place at mindfulness centres in Amsterdam and The Hague, The Netherlands. MBCP feasibility and participant's attendance are presented elsewhere (Veringa-Skiba, de Bruin, et al., 2022).

Active control condition: enhanced care as usual (ECAU)

ECAU consisted of two individual fear of childbirth consultations of 1.5 hours for the expectant couple. Both consultations were spread over a nine-week period (similar to MBCP) and were delivered by trained midwives. ECAU was developed specifically for anxious pregnant women by the research team to reduce FOC by gaining insight into the factors causing and maintaining fear and stress around pregnancy, birth and the postpartum period (the first consultation); and making a coping plan to deal with fears and stressors and discuss psychoeducation about fear (the second consultation). More specifically, the first consultation was based on the Biopsychosocial Model (Engel, 1977), and the second consultation consisted of writing the commonly used Childbirth Plan of the Royal Dutch Organization of Midwives (KNOV Geboorteplan, n.d.). ECAU was free of charge, and the consultations took place at the couple's home.

Measures

Time

Measurements of FOC, catastrophic beliefs about labour pain, and mindful awareness were collected at pre-intervention (T1) and post-intervention before childbirth (T2). The childbirth mode including obstetric interventions used during childbirth were collected after birth (T3). Participant characteristics were collected at T1.

Pathways of action

Emotion pathway: fear of childbirth. The emotion pathway was operationalized as FOC and assessed with the 33-item W-DEQ-A (Bardacke, 2012). The questionnaire operationalizes emotions around childbirth (e.g., 'How do you expect you will feel during delivery; 'lonely, strong, confident, scared, happy, proud') as covering general fear, negative appraisal, loneliness, lack of self-efficacy, lack of positive anticipation, and concerns about the child (range 0-165). Higher scores indicate more FOC: *high* (W-DEQ-A≥66); *severe* (W-DEQ-A≥85); and *phobic* FOC (W-DEQ-A≥100; Nilsson et al., 2018). The W-DEQ-A showed good reliability in an average sample of pregnant women at 16-26 weeks pregnancy (α = 0.94; Veringa-Skiba et al., 2022). Cronbach's α at T1 and T2 in the present study was 0.95.

Cognition pathway: catastrophic beliefs. The cognition pathway was operationalized as catastrophic beliefs about labour pain, and it was assessed by the 12-item Catastrophizing Labour Pain (CLP; range 0-60). This subscale is derived from the Labour Pain Cognitions and Coping List (LPCCL; Veringa et al., 2011). A higher score on the CLP represents more catastrophizing of labour pain (e.g., "The pain of childbirth will be overpowering"). In the aforementioned study, the CLP showed good reliability in an average sample of pregnant women (30-34 weeks pregnant) with a Cronbach's α of 0.84. Cronbach's α in the present study at T1 was 0.88 and at T2 was 0.92.

Attention pathway: mindful awareness. The attention pathway in our model was operationalized as mindful awareness. Mindful awareness was assessed with the Dutch version of the 24-item Five Facet Mindfulness Questionnaire (FFMQ; range 24-120; de Bruin et al., 2012). The FFMQ consists of five subscales: Observing (e.g., "When I'm walking, I deliberately notice the sensations of my body moving"); Describing (e.g., "I can easily put my beliefs, opinions, and expectations into words"); Acting with awareness (e.g., "When I take a shower or bath, I stay alert to the sensations of water on my body"); Nonjudging of inner experience (e.g. "I tell myself that I shouldn't be thinking the way I'm thinking"); and Nonreactivity to inner experience (e.g., "I watch my feelings without getting lost in them"). Higher scores indicate greater mindful awareness. Cronbach's α in the present study at T1 was 0.73 and at T2 was 0.79.

Intervention outcome: gradient of childbirth mode

Gradient of childbirth mode was operationalized into an ordinal scale consisting of five categories, with higher scores indicating childbirth with more advanced obstetric interventions: 0 = natural childbirth as birth without any obstetric interventions; 1 = spontaneous childbirth with some obstetric intervention (e.g., augmentation with oxytocin or assisted delivery) not including EA; 2 = spontaneous childbirth with EA; 3 = childbirth with obstetric indication for CS made during childbirth; and 4 = childbirth by sCS.

Attendance and practice

The minutes of meditation practice at home were registered by the participants. This data and the presence of participants at MBCP sessions were collected at each of the nine weekly intervention sessions by a MBCP trainer.

Statistical Analysis

The primary analysis was performed using the completers data. The allocation process was concealed from the independent outcome assessor. To test our hypotheses of the three pathways of action in the theoretical model of avoiding versus approaching the challenges of childbirth (Veringa et al., 2016), we ran (1) a parallel, multiple mediation model with our hypothesized mediators and (2) single mediation models to further delineate indirect effects. Each variable was transformed to account for the difference between T1 and T2 (i.e., the change scores (D), T2-T1). Our independent variable was dichotomous (i.e., ECAU denoted with 0 and MBCP as 1). According to A. F. Hayes, (2018), utilizing an ordinal variable as a continuous variable (as we did with our outcome variable) in a statistical mediation model is acceptable (A. F. Hayes, 2018). No additional covariates were added to the models since randomization of condition assignment was successful (Veringa-Skiba, de Bruin, et al., 2022).

We conducted mediation analyses using the SPSSv25 PROCESSv3.3 macro (Crane et al., 2014) to test the hypothesized mediators' effects of the type of intervention (i.e., MBCP or ECAU) on the gradient of childbirth mode. One model with the following mediators was run: (D) W-DEQ-A for FOC; (D) CLP for catastrophic beliefs about labour pain; and (D) FFMQ for mindful awareness. If a significant indirect effect was found, the effect size for each mediator was estimated using the bootstrapping procedure recommended by (A. F. Hayes, 2018). It accounts for a nonparametric distribution and retains power in the model. We tested whether the specific indirect effect was significantly different from zero by constructing 95% confidence intervals using 10.000 bootstrap samples. If zero is contained in the interval, then the indirect effect is non-significant, suggesting the data do not support the proposed indirect effect. Coefficients, standard errors, and *p*-values were generated [see Additional file 1]. Their corresponding bootstrap confidence intervals were calculated and are documented in Table 3. Note that coefficients are unstandardized, but the bootstrap confidence intervals are standardized (A. F. Hayes, 2018). Additionally, indirect paths are partially standardized, which signify the number of standard deviations by which the gradient of childbirth mode is expected to increase/decrease per a change in mediator of size unstandardized coefficient (*a*) (Preacher & Kelley, 2011). In addition, to assess the relationship between outcome measure and number of completed MBCP sessions and quantity of meditation practice at home per week, Spearman's rank-order correlations were calculated.

Table 1.

Pathways of action: descriptive statistics of variables by total sample and condition

		Intervention condition	
	Total (*N* = 139) ***M (SD)***	**MBCP (*n* = 74)** ***M (SD)***	**ECAU (*n* = 65)** ***M (SD)***
ΔEmotion - FOC (W-DEQ-A)	-23.04 (21.70) (*n* = 113)	-28.46 (21.35) (*n* = 57)	-17.54 (20.82) (*n* = 56)
ΔCognition - Labour Pain (CLP)	-9.48 (10.73) (*n* = 109)	-12.89 (10.57) (*n* = 56)	-5.87 (9.76) (*n* = 53)
ΔAttention - Mindful Awareness (FFMQ)	2.41 (11.30) (*n* = 111)	6.84 (9.82) (*n* = 56)	-2.11 (10.99) (*n* = 55)

Note. Δ: difference in post-assessment - pre-assessment; CLP = Catastrophizing Labour Pain; ECAU = Enhanced Care As Usual (control group); FFMQ = Five Facet Mindfulness Questionnaire; FOC = Fear of Childbirth; *M* = mean; MBCP = Mindful-Based Childbirth and Parenting; *SD* = standard deviation; W-DEQ-A = Wijma Delivery Expectancy Questionnaire.

Table 2.

Pathways of action: descriptive statistics of variables by mediation sample and condition

		Intervention condition	
	Total (*N* = 109) ***M* (*SD*)**	**MBCP (*n* = 56)** ***M* (*SD*)**	**ECAU (*n* = 53)** ***M* (*SD*)**
ΔEmotion - FOC (W-DEQ-A)	-22.46 (21.20)	-27.80 (20.96)	-16.81 (20.15)
ΔCognition - Labour Pain (CLP)	-9.48 (10.73)	-12.89 (10.57)	-5.87 (9.76)
ΔAttention - Mindful Awareness (FFMQ)	2.29 (11.23)	6.84 (9.82)	-2.53 (10.67)

Note. Δ: difference in post-assessment - pre-assessment; CLP = Catastrophizing Labour Pain; ECAU = Enhanced Care As Usual (control group); FFMQ = Five Facet Mindfulness Questionnaire; FOC = Fear of Childbirth; *M* = mean; MBCP = Mindful-Based Childbirth and Parenting; *SD* = standard deviation; W-DEQ-A = Wijma Delivery Expectancy Questionnaire.

Results

Participants' characteristics

There were no significant pre-intervention differences between participants at T1 in each condition for demographic predictors and outcome measures (Veringa-Skiba, de Bruin, et al., 2022). Of the 141 participants, two medical files reporting childbirth outcomes were missing (MBCP, *n* = 1; ECAU, *n* = 1). The final sample used for mediation analysis in this study consisted of 139/141 (99.3%) pregnant women with high FOC. Further, we found that the pre- and post-interventions pathways' measurements were filled in by 113 (81.3%) participants for W-DEQ-A, 109 (78.4%) participants for the CLP, and 111 (79.9%) participants for the FFMQ. There were no statistically significant differences between the participants who did or did not have missing outcome data in the pre-intervention participant characteristics (i.e., group assignment, parity, age and FOC) per pathway.

Table 3.
Effects of intervention condition (X) on gradient of childbirth mode (Y) with parallel mediation

			95% Confidence Interval[a]	
	Partial Std Effect	**SE**	**Lower**	**Upper**
Model 1				
Total effect of X on Y	-0.652***	0.243	-1.354	-0.390
Direct effect of X on Y	-0.385[b]	0.263	-1.036	0.007
			Bootstrap 10.000 Times 95% Confidence Interval, Standardized	
Cond – Total Indirect Effect – Y	-0.267	0.105	**-0.480**	**-0.066**
Cond – ΔEmotion: FOC (W-DEQ-A) – Y	-0.093	0.069	-0.246	0.026
Cond – ΔCognition: Labour Pain (CLP) – Y	0.072	0.087	-0.096	0.257
Cond – ΔAttention: Mindful Awareness (FFMQ) – Y	-0.246	0.084	**-0.428**	**-0.093**

Note. $N = 109$. Δ: difference in post-assessment - pre-assessment; CLP = Catastrophizing Labour Pain; FFMQ = Five Facet Mindfulness Questionnaire; W-DEQ-A = Wijma Delivery Expectations Questionnaire.
[a]Bootstrap confidence intervals are fully standardized (Hayes, 2018). Bolded bootstrap CI indicate significant indirect paths. If zero is contained in the interval, then the indirect effect is non-significant, suggesting the data do not support the proposed indirect effect. Indirect, direct, and total effects are partially standardized (std).
[b]The direct effect is partially standardized here whereas in Figure 1 it is unstandardized.
$^*p \leq 0.05$, $^{**}p < 0.01$, $^{***}p < 0.001$.

The sample consisted of 62.6% (n = 87) nulliparous and 37.4% (n = 52) multiparous pregnant women with an average age of 33 years (M = 32.97, SD = 3.89). About 75.5% (n = 105) of participants reported psychological/psychiatric problems in the past, 25.9% (n = 36) used medication for psychological problems more than one year, and 19.4% (n = 27) were currently in care. The entire sample was characterized with severe FOC (W-DEQ-A, M = 93.38, SD = 17.90) at the screening, per W-DEQ-A guidelines with a score >85 indicating severe FOC (Wijma et al., 1998). Descriptives of each pathway of action measurement are presented in Table 1.

The study's participants had the following gradient of childbirth mode: 35% (n = 49) natural childbirth as spontaneous birth without any obstetric interventions; 6.5% (n = 9) spontaneous childbirth with some obstetric intervention (e.g., augmentation with oxytocin or assisted delivery) not including EA; 33.8% (n = 47) spontaneous childbirth with EA; 18% (n = 25) childbirth with obstetric indication for CS made during childbirth; and 6.5% (n = 9) childbirth by sCS. All groups were mutually exclusive.

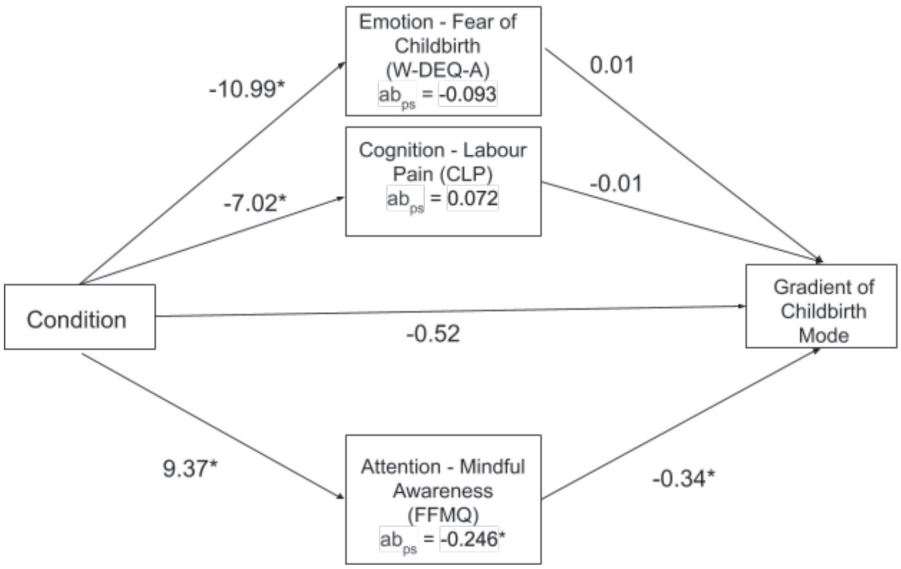
Further, the average number of completed MBCP sessions was almost 7 out of 9 (n = 73, M = 6.90; SD = 2.83). The average number of minutes per week spent on meditation practice at home within the MBCP programme was 85 (n = 73, M = 85.05, SD = 58.96).

Mediation model

After listwise deletion of participants with missing values, our sample was 109. Descriptives of this sample across pathways of action measures by condition can be found in Table 2.

Results indicated that the direct effect in the full model including mediators was non-significant (p = 0.0529; 95% CI [-1.036, 0.007]). The indirect effect (ab_{ps} = -0.246) of mindful awareness was significant (95% CI [-0.428, -0.093]). These results indicate a full mediation with the mediators, however, note that the direct effect is approaching significance. Moreover, approximately 21% of the variance (R^2 = 0.21, F [4,104] = 6.896, p = 0.0001) in the gradient of childbirth mode was accounted for by these mediators. This is indicated by the indirect effect (ab_{ps} -0.267 units; 95% CI [-0.480, -0.066]). When examining each of the three indirect effects, we found that catastrophic beliefs of labour pain and FOC were non-significant mediators (see Figure 1). Note that mindful awareness accounts for a large portion of the effect in the total indirect effect. See Table 3 for total, direct and indirect effects.

Figure 1.
Parallel mediation results of pathways of action



Note: n = 109. Unstandardized regression coefficients (b) for the relationship of intervention condition on the gradient of childbirth mode as mediated by FOC, catastrophizing beliefs of labour pain, and mindful awareness. Indirect paths are partially standardized (ab_{ps}), and pathways are change scores between the difference in post-assessment and pre-assessment. *p < 0.05.

Table 4.
Intervention condition (X) on gradient of childbirth mode (Y) through FFMQ subscale mediators - single and parallel Mediation

			95% Confidence Interval	
	Partial Std Effect	**SE**	**Lower**	**Upper**
Single Mediation				
Total effect of X on Y	-0.659***	0.239	-1.347	-0.401
Direct effect of X on Y	-0.549**	0.234	-1.192	-0.266
Indirect: Cond – ΔNOR – Y	-0.110	0.061	**-0.247**	**-0.006**
Total effect of X on Y	-0.659***	0.239	-1.347	-0.401
Direct effect of X on Y	-0.596**	0.244	-1.274	-0.308
Indirect: Cond – ΔNOJ – Y	-0.063	0.045	-0.158	0.018
Total effect of X on Y	-0.657***	0.239	-1.347	-0.401
Direct effect of X on Y	-0.652***	0.251	-1.362	-0.368
Indirect: Cond – ΔACT – Y	-0.007	0.064	-0.127	0.133
Total effect of X on Y	-0.659***	0.239	-1.347	-0.401
Direct effect of X on Y	-0.577**	0.251	-1.264	-0.269
Indirect: Cond – ΔDES – Y	-0.081	0.060	-0.207	0.030
Total effect of X on Y	-0.659***	0.239	-1.347	-0.401
Direct effect of X on Y	-0.598**	0.236	-1.260	-0.326
Indirect: Cond – ΔOBS – Y	-0.061	0.050	-0.173	0.021
Parallel Mediation				
Total effect of X on Y	-0.657***	0.239	-1.347	-0.401
Direct effect of X on Y	-0.474*	0.250	-1.125	-0.132
Indirect				
Cond – Total – Y	-0.185	0.104	-0.380	0.029
Cond – ΔNOR – Y	-0.091	0.065	**-0.216**	**<0.001**
Cond – ΔNOJ – Y	-0.065	0.049	-0.170	0.023
Cond – ΔACT – Y	0.019	0.068	-0.102	0.177
Cond – ΔDES – Y	-0.001	0.063	-0.118	0.139
Cond – ΔOBS – Y	-0.047	0.042	-0.146	0.017

Note. n = 111. Δ: difference in post-assessment - pre-assessment; ACT = Acting with awareness; DES = Describing; FFMQ = Five Facet Mindfulness Questionnaire; NOJ = Nonjudging of inner experience; NOR = *Non-reactivity* to inner experience; OBS = Observing.
[a]Indirect, direct, and total effects are partially standardized (std).
[b]Indirect effects reflect a 10.000 bootstrap sampling with confidence interval (CI) of 95%, and CIs are fully standardized (Hayes, 2018). Bolded bootstrap CI indicate significant indirect path. If zero is absent from the interval, then the indirect effect is significant, suggesting the data support the proposed indirect effect.
*$p \leq 0.05$, **$p < 0.01$, ***$p < 0.001$.

Mindful awareness as a mediator

As our results show, mindful awareness is the only significant mediator, which accounts for approximately 18% (R^2 = 0.18, F [1,107] = 22.77, p < 0.0001) of the variance in the gradient of childbirth mode outcome. To further understand the specifics behind the mechanism of change in mindful awareness, we conducted post-hoc, exploratory analyses with the entire sample who completed the mindful awareness measure (FFMQ; n = 111). We ran single mediation analyses with each of the five subscales of mindful awareness. For coefficients, standard errors, p-values and R^2 [see Additional file 2]. *Nonreactivity to inner experience* significantly mediated the effect of intervention condition on the gradient of childbirth mode (ab_{ps} = -0.110; 95% CI = [-0.247, -0.006]). The other four subscales showed non-significant indirect effects. To understand the variance amongst the five subscales, we ran a parallel model where all five subscales were included. For coefficients, standard errors, p-values and R^2, [see Additional file 3]. This model accounts for approximately 23% (R^2 = 0.23, F [6,104] = 5.17, p = 0.0001) of the variance in the gradient of childbirth mode outcome. All five subscales had a non-significant indirect effect though *Non-reactivity to inner experience* was nearly significant (ab_{ps} = -0.091, 95% CI = [-0.2162, -0.0004]), and it accounted for the largest effect in the model as compared to the other four mindful awareness subscales. See Table 4 for total, direct and indirect effects.

Amount of mindfulness practice

There was no association between the gradient of childbirth mode and number of attended MBCP sessions (r_s = 0.020, p = 0.08, n = 73). However, there was a significant moderate, positive correlation between total minutes per week meditated at home and the gradient of childbirth mode (r_s = 0.39, p = 0.001, n = 72).

Discussion

Main findings

The aim of this study was to clarify *how* participation in MBCP could lead to a natural childbirth (the lowest gradient of childbirth mode) in pregnant women with high FOC. For this purpose, we examined three pathways of action that would operate with adaptation to childbirth through natural childbirth: emotion (FOC), cognition (catastrophic beliefs about labour pain) and attention (mindful awareness). Our results showed that MBCP increases natural childbirths through an increase in mindful awareness, and in particular, non-reactivity to inner experiences. Neither a decrease in FOC or catastrophic beliefs about labour pain were found to be mechanisms of change. In addition, natural childbirth was positively associated with minutes of meditation practice. The more one meditated, the more one was inclined towards a natural childbirth and vice versa. No relation was found between the attendance to MBCP sessions and natural childbirth.

Interpretation

These results are new and interesting in the field of psychosomatic care for pregnant women, as they lead us to draw several conclusions. The main conclusion is that the change in the quality of attention (increased mindful awareness) in pregnant women with high FOC, and not the change in their negative cognitive-emotional states (decreased FOC and catastrophic beliefs), is the important mechanism of change. This mechanism leads to being able to approach the challenges of childbirth and adapt to them, rather than avoid them. Extant research has focused on the contribution of the cognitive-emotional state of pregnant women in relation to the use and requests for obstetric interventions during childbirth (Adams et al., 2012; Badaoui et al., 2019; Dehghani et al., 2014; Dencker et al., 2019; Kwissa-Gajewska & Dołęgowska, 2017; Molgora et al., 2020; Möller et al., 2017; Rondung et al., 2019; Ryding et al., 2015; Veringa et al., 2011). However, our results show that the quality of attention (increased mindful awareness) seems to be superior in approaching and adapting (natural childbirth) the challenges of childbirth in pregnant women with high FOC.

Research on mindful awareness and behaviour regulation in populations with emotion dysregulation showed that approaching and observing their intense emotions may improve their ability to tolerate negative emotional states and cope with them effectively (Baer, 2003; Gratz & Roemer, 2004; S. C. Hayes et al., 2006). It is likely that pregnant women who attended a MBCP training developed the ability to approach and to notice their FOC and catastrophic beliefs, and thus, were able to tolerate them during childbirth. Mindfulness practice in a MBCP training encourages awareness of all cognitive, emotional and bodily states related to childbirth while being non-judgmental and nonreactive, and allows the challenges belonging to childbirth to exist. In other words, maintaining a mindful awareness towards fearful emotions and catastrophic beliefs about childbirth, without judgment and without reactivity, may help to regulate behaviour from being reactive and avoiding the challenges of childbirth to shift to being more responsive and approaching, and adapting to the childbirth process.

Our study shows that being non-reactive to the inner experience (a facet of mindful awareness) caused more adaptation to childbirth (more natural childbirths). The adaptation to childbirth through non-reactivity to inner experience may be explained by less stress. This suggestion is supported by (Lönnberg et al., 2020), who found that an increase in non-reactivity to inner experience was significantly correlated with a reduction in perceived stress in pregnant women in MBCP as compared to Lamaze childbirth classes (Lönnberg et al., 2020). It could be concluded that after MBCP, pregnant women in our study experienced childbirth as less stressful or threatening and allowed themselves to undergo and to adapt more to the processes of natural childbirth than pregnant women in the control group. In light of these findings, it would be relevant to study the biological effects of mindful awareness in pregnant women with high FOC by measuring perceived stress symptoms and levels of the maternal

stress hormone cortisol. High levels of maternal cortisol limit the DNA expression in children born from mothers with high FOC (Palma-Gudiel et al., 2015). By reducing the maternal cortisol level, the health potential of a new-born could be improved (Palma-Gudiel et al., 2015).

Further, our results demonstrate that natural childbirth was positively related to more extensive home meditation practice. This finding is supported by a study of home meditation practice for depression relapse-prevention, which showed that more minutes spent on mindfulness meditation was associated with a lower hazard of relapse to depression (Crane et al., 2014). However, Lönnberg's study showed no relationship between minutes spent on mindfulness meditation and change in perceived stress in pregnant women (Lönnberg et al., 2020). Based on our results, it could be concluded that more extensive home meditation practice is associated with natural childbirth and vice versa thus indicating better adaptation to the challenges of childbirth through more extensive mindful awareness. Noteworthy, the actual number of MBCP sessions attended in our study was not related to the gradient of childbirth mode. However, most MBCP participants attended at least seven out of nine sessions. It could be interpreted that apparently practicing on a regular, daily basis seems to be extra important for the effect than being only present during MBCP sessions.

Importantly, in accordance with psychological theories such as cognitive theory (Beck, 1976) and experiential avoidance theory (S. C. Hayes et al., 1996), it is not the actual negative emotions, negative beliefs or unpleasant sensations, but how one responds to them (approaching versus avoiding), that is linked to a wide range of mental health issues. In view of these theories, avoiding experiences that are appraised as threatening may reduce distress in the short term in pregnant women with high FOC, but it may maintain and even reinforce fear and anxiety in future pregnancies and childbirths. So far, only cognitive behaviour therapy (CBT) delivered by psychotherapists has demonstrated improved adaptation to childbirth with an increase in natural births and a decrease in the use of sCS in pregnant women with high FOC (Striebich et al., 2018). CBT is a clinical and relatively expensive intervention when compared to MBCP, which is a non-clinical intervention that can be delivered by other professionals caring for pregnant women. Given that high FOC is quite prevalent (25%) (Richens et al., 2018) and childbirth medicalisation is growing worldwide (WHO, 2018), effective care that addresses these issues is of paramount importance, both for health-economic (e.g., cost of medical care) and health-psychological (e.g., emotional burden of high FOC and associated requested obstetric interventions) reasons. On the other hand, pregnant women with high FOC who underwent natural childbirth possibly without adequate preparation, experienced childbirth as traumatic, and even developed post-traumatic stress disorder, post-partum depression and persistent pain after childbirth (Hollander et al., 2017). Noteworthy is that several factors complicate intrapartum care for pregnant women with high FOC: the impact of FOC on additional mental health

issues; the advantages and disadvantages of EA and CS; and pregnant women's right to demand the care they prefer. To tackle this complexity in the care for pregnant women with high FOC, interventions should be offered that: support pregnant women in dealing with the challenges of childbirth; and provide tailored information and support about FOC, as well as about the advantages, and disadvantages of obstetric interventions in childbirth.

Given that natural childbirth optimally supports production of oxytocin in the mother's brain and positively influences maternal physiology and behavior during childbirth, and motherhood (Uvnäs-Moberg et al., 2019), natural childbirth with an optimal oxytocin level could be seen as an important intervention in treatment of internalizing and externalizing problems in mothers and their children (Priel et al., 2019). Having a spontaneous childbirth without obstetric interventions may reduce the chance for postpartum depression and/or development of posttraumatic stress disorder (Hollander et al., 2017). Positive body and mind experiences may empower motherhood and improve the mother-child relationship especially in the context of fear (Priel et al., 2019).

To further this line of work, future studies should be performed in large and heterogeneous populations of pregnant women and in a multicentered design. Further studies exploring the active ingredients of the MBCP programme and implementation factors related to the delivery of MBCP such as the quality of trainer, as well as time spent on the meditation practice and attendance to the sessions in adaptation to childbirth in pregnant women with high FOC, could be of interest. Importantly, the effect of MBCP on the perceived stress reduction and the reduction in maternal cortisol level require more attention in future research, given the knowledge about the extended harmful effects for the unborn child in pregnant women with high FOC (Davis & Sandman, 2010; Dean et al., 2018). However, the most pressing recommendation is a replication of this study to confirm our findings and reinforce the implications.

Strengths and limitations

To the best of our knowledge, this study is the first to explore mechanisms of change operating through three psychological pathways of action, for adaptation to childbirth in pregnant women with high FOC, by comparing the effects of MBCP with ECAU. Our results contribute to a richer understanding of underlying psychological mechanisms through which adaptation to a (natural) childbirth may operate. Second, the study design and statistical analyses generally meet the standards of mechanisms of change study guidelines, as defined in a systematic review on RCTs examining potential mechanisms of change in MBPs (Alsubaie et al., 2017). The mediation analyses were conducted in an RCT with an active control group and the outcome assessor was blinded to the allocation process. The mechanisms of change hypothesized in this study were drawn

from a psychological model of the potential pathways of action already introduced in a protocol study, which presented substantiation for the model and the expected changes (Baer et al., 2006). Importantly, in our mediation analyses, change in the mediator preceded the change in the outcome in time (i.e., temporal precedence; A. F. Hayes, 2018) with this, an alternative explanation for the change in mindful awareness and change in the gradient of advanced obstetric interventions used during childbirth were eliminated. Consequently, this study provides sufficient evidence to conclude that increased mindful awareness is the causal mechanism that explains more adaptation to natural childbirth and a decrease in obstetric interventions during childbirth, as observed in the MBCP participants compared to ECAU participants.

This study had several limitations. Our sample mainly consisted of Caucasian, highly educated pregnant women, which limits generalizability of the results to more diverse populations. Although our analyses indicated that there was no selective drop-out or missing values, selective attrition could be a limitation, and this may also have limited the power to detect effects. More studies with larger and more diverse populations are warranted.

Conclusions

Cultivation of greater mindful awareness, and more specifically non-reactivity to inner experience, in pregnant women with high FOC during the nine-week MBCP programme appears to be a mechanism of change leading to natural childbirths and less use of obstetric interventions, such as sCS. In addition, meditating more often appears to be related to a higher degree of natural childbirth, and vice versa, but higher attendance to MBCP sessions was not. Whether these findings have wider application deserves further study and attention from healthcare providers and policymakers.

CHAPTER 8

General discussion

The aims of this thesis were (1) to examine assessment of FOC in pregnant women and improve its utility, (2) to evaluate the effects of Mindfulness-Based Childbirth and Parenting (MBCP) versus enhanced acre as usual (ECAU), (3) to evaluate cost-effectiveness of MBCP versus ECAU in treatment of FOC, and (4) to explore the possible working mechanisms of MBCP in adaptation to childbirth in pregnant women with high FOC. Each chapter of the thesis focused on another aspect of these aims. In *Chapter 2*, we evaluated the assessment of fear of labour pain in pregnancy by means of labour pain cognitions (catastrophizing, external and internal pain control and coping) in predicting the pregnant woman's request for advanced pain relief during labour. In *Chapter 3*, we compared a standard assessment of FOC to a one-item general assessment of FOC to examine the predictive value of high FOC in pregnant women who explicitly request non-urgent obstetric interventions during pregnancy and/or undergo non-urgent obstetric interventions during labour. In *Chapter 4*, we presented our protocol-study in which the rationale and execution of the randomized controlled trail on the (cost)- effectiveness of MBCP versus ECAU in a population of pregnant women with high FOC were described. In *Chapter 5*, we investigated whether MBCP is more effective than ECAU in: reducing FOC, catastrophizing labour pain, preferences for non-urgent obstetric interventions, and in increasing acceptance of labour pain and unmedicated childbirths. In *Chapter 6*, subsequently, we described the evaluation of the cost-effectiveness of MBCP in relation to ECAU. In *Chapter 7*, we proposed and examined the pathways of action in which MBCP could operate with adaption to childbirth (e.g., unmedicated childbirth) in pregnant women with high FOC. In this final chapter, the results of these five studies will be synthesized and discussed. First, I will reflect on our general approach in assessment of FOC in non-clinical setting. Second, I will reflect on the problem of neglecting FOC in midwifery care. Third, I will reflect on the use of a multinational perspective on treatment of FOC in midwifery care. Fourth, I will discuss the outcomes in pregnant women with high FOC after MBCP and enhanced care as usual (ECAU). Fifth, I will discuss the cost-effectiveness of MBCP, also in the perspective of the Dutch midwifery health system. Sixth, I will discuss the impact of mindful awareness on the increase in adaptation to the challenges of childbirth (from avoiding to approaching in pregnant women with high FOC. Seventh, I will reflect on the working ingredients of Cognitive Behavioural Therapy (CBT) and Mindfulness-Based Programmes (MBPs) in adaptation to stressors. Finally, I will provide strengths and limitations of our studies, and make some suggestions for clinical implications and recommendations on how to improve care for pregnant women with high FOC in midwifery care, and present ideas for future studies.

A general approach to assessing fear of childbirth

In this dissertation, we approached the assessment of FOC from a broader and more general perspective on fear; namely that fear is a fundamental emotion covering fear of pain and death, and fear of the unknown (Carleton, 2016). In our conceptualization

of FOC, we considered all possible pregnant women's fears about childbirth and their corresponding consequences in childbirth and postpartum. Thereby, we suggested to assess the pregnant women's appraisal of the current experience of FOC and preferably in the first half of pregnancy.

To assess fear in relation to childbirth and postpartum, we evaluated pregnant women's individual idiosyncratic FOC through a very short and general assessment using the one-item Fear of Childbirth and Postpartum - Visual Analogue Scale (FOCP-VAS, *Chapter 3*). The question - 'Please rate your current degree of FOC and the postpartum period?'- was scored from zero (not fearful at all) to ten (very much fearful). Importantly, we asked pregnant women to evaluate their degree of current FOC without suggesting how they could imagine feeling during various stages of anticipated childbirth. Unlike common measurements of FOC, we did not ask participants to rank proposed cognitive-emotional appraisals during anticipated childbirth because our intention was to operationalize pregnant women's immediate experience (rather than an imagined future) of the fear of the unknown without prompting what, how or when to fear. As such the FOCP-VAS allowed us to appraise the fear of the unknown in the moment. Such a short, general (one item) assessment of pregnant women's immediate FOC experience is applicable to the non-clinical setting of midwifery care and to the time constraints given by the course of pregnancy and to the time constrictions for check-ups.

For application of the FOCP-VAS, we evaluated the FOCP-VAS by comparing it to the commonly used 33-items Wijma Deliver Expectation Questionnaire (W-DEQ-A; Wijma et al., 1998), and we found that pregnant women who scored W-DEQ-A≥66 [range 0-175] scored FOCP-VAS≥5 [range 0-10]. Importantly, we found that this short, general assessment of FOC (FOCP-VAS≥5) showed high predictive value in identifying pregnant women who planned and avoided the course of a natural childbirth by using non-urgent obstetric interventions (e.g., medical pain treatment, caesarean section), and had more predictive value than a detailed assessment of FOC with the W-DEQ-A. In fact, the W-DEQ-A did not contribute over and above the FOCP-VAS to the prediction of non-urgent obstetric interventions in the face of high level FOC (*Chapter 3*). Almost the same cut-off for FOCP-VAS was found in the study of Rouhe et al. (2009), in which it corresponded with W-DEQ-≥100 and the pregnant women's requests for caesarean sections. This finding suggests that the use of the FOCP-VAS (due to its high clinical sensitivity) may improve care for pregnant women in supporting them towards a childbirth with less unneeded medical intervening. That is, this instrument could frequently be used as a tool to discuss difficult emotions related to childbirth. In this way pregnant women with high FOC could easily be recognized and desired treatment of FOC could be considered. Also, in our first study on labour pain cognitions in relation to pregnant women's request and use of medical pain treatment during labour, a general approach to fear of labour pain was confirmed. It showed that operationalizing labour pain as pain cognitions and coping concepts originating from general pain knowledge

paved the way for our general approach to FOC in the later studies. In this study, we found that catastrophizing labour pain, with the aforementioned operationalization, was the strongest predictor for women to use medical pain treatment already during starting labour. This led us to assert that concepts such as fear-avoidance of pain, which have been studied in chronic pain (Vlaeyen & Linton, 2000) can also be applied to labour pain. Further, we found in both above mentioned studies that pregnant women's preferences and use of non-urgent obstetric interventions during anticipated childbirth could be already predicted by FOC measures which were assessed many weeks before the onset of labour. Thus, timely and general assessment of FOC gives room for intervening and to offer treatment that can increase resilience in pregnant women with high FOC.

This dissertation may contribute to the evidence that a general assessment of FOC in relation to predicting unneeded medical childbirths seems to be valid and reliable. This can be valuable for midwives; to learn more about FOC from a general perspective and to be more sensitive in timely signalling high FOC. Early screening on FOC by means of the FOCP-VAS may significantly improve the care for pregnant women. However, there is more research needed to answer the question whether FOC can be approached from this general perspective and can effectively be assessed under the care of midwives.

Fear of childbirth as 'a neglected dilemma'

The problem of accepting pregnant women's preferences for the mode of childbirth without knowing their motivation was already addressed by the Finnish researchers Saisto and Halmesmäki, (2003). They underlined that a vivid discussion on the woman's right to choose the mode of childbirth was continuing without considering that FOC may amount to the requests for caesarean section. This state of noninterest for FOC in obstetric literature and practice, they called "a neglected dilemma" (Saisto & Halmesmäki, 2003).

Results of this thesis, almost 20 years later, suggests that FOC is still a neglected problem in care for pregnant women. That is, in our study on general assessment of FOC in midwifery care (*Chapter 2*), we found that 34% of pregnant women reported high FOC (W-DEQ-A≥66) but only 3% received some kind of treatment for their fears. It seems that in midwifery practices FOC is not commonly identified and is not being considered for treatment. Additionally, screening for FOC is not standard for midwifery practices. Besides, in the Dutch midwifery practice, there is no guideline about how and when to perform FOC assessment in pregnancy, and how to treat it. This could explain FOC being persisted to be unnoticed and untreated. However, the pregnant women's requests for non-urgent obstetric interventions for avoiding the challenges of childbirth (e.g., such as labour pain, process of delivery) were well documented in medical files. The findings are considered representative for the Dutch primary

midwife-led care since an average of midwifery practices participated in our study; characterized by different sizes of practice, different areas of location (rural or urban) spread out over the Netherlands. It can be stated that FOC, although a prevalent problem, is still neglected in the Dutch midwifery practices as well.

Once assessed, FOC can be ambiguous to interpret. In the general assessment study (*Chapter 2*), we found the score of five on the FOCP-VAS, a mid-point on the scoring scale, corresponded to high FOC according to W-DEQ-A≥66. We might assume that the score of five in the range between zero and ten shows mediocre FOC. Yet, the opposite seems to be true. The average rating of five corresponding to high FOC (based on W-DEQ-A) may mean that pregnant women's expression of FOC could be withheld or muted by their certain considerations. It may suggest that pregnant women found it difficult to accept the ambivalence of feelings of being happy with having a baby and fearful about their upcoming childbirth. Possibly, they chose to have a more positive estimate of their FOC, or they avoided negative emotions. It could also be an explanation why FOC seems to be difficult to signal in midwifery practice. Another kind of a possible ambiguity/suppression of FOC severity we observed in the effectiveness study (*Chapter 4*). For this study we recruited pregnant women who told their midwives about being afraid to give birth. After measurement of their FOC we found that these women experienced on average a severe, almost clinical, level of FOC based on the W-DEQ-A. Also, in this effectiveness study a FOC assessment by means of a valid measure was not documented by midwives, however the pregnant women's requests for non-urgent obstetric interventions for avoiding the challenges of upcoming childbirth were well documented. This stresses the need for recognition of FOC as a midwife should be alerted when women rate their FOC as 'only' average (five on FOCP-VAS) or when she shares her feelings about being afraid to give birth.

Besides the high levels of FOC in our study population, we were surprised by the severity of mental health characteristics of pregnant women in the effectiveness study (*Chapter 5*). Screening on in- and exclusion criteria has revealed their mental health histories. Three quarters of these women received psychological/psychiatric care in the past, one quarter used medication for psychological issues longer than one year in the past, and one in five of these women was receiving psychological/psychiatric care during the study. Based on these findings, it can be concluded that FOC is a symptom of other psychological vulnerabilities women may take to midwifery care. Yet, FOC was not measured in the pregnant women with psychological vulnerabilities. It may suggest that midwifery care is more focused on the bodily than psychological predictors in care for pregnant women.

Given the persistent absence of guidelines about how to assess and to treat FOC in care of pregnant women, and the presence of well documented pregnant women's preferences for the use of medical interventions in upcoming childbirth, it can be stated

that FOC is still "a neglected dilemma", also in Dutch midwifery care. The additional findings in this thesis address the persisting dilemma in care of pregnant women, who have the right to give birth in the way they wish to, including their request for medical interventions, and the reasons and consequences of these requests for their health and well-being.

The use of a multidimensional approach to treating fear of childbirth in non-clinical settings

In this dissertation, we approached the treatment of FOC from a multidimensional perspective. Specifically, we drew from Beck, (1976) the view that fear has emotional, cognitive, behavioural, and attentional dimensions, and we have applied this frame to a non-clinical intervention (non-clinical population and provider outside psychological setting). Application of a multidimensional approach to treat FOC in non-clinical midwifery care settings is new (*Chapters 5* and *7*). We assumed that the behavioural dimension – avoidance of the challenges of childbirth – is a tangible visible symptom of FOC in pregnant women. We proposed a theoretical model of avoidance (and its contrast, participation) in childbirth in relation to FOC (*Chapter 3*). Within the model, we assumed that pregnant women with high FOC would avoid the challenges of childbirth by requesting and using non-urgent obstetric interventions (e.g., medical pain treatment), and in this way, cope with the unknown of experiencing labour pain or vaginal delivery. Our assessment (*Chapters 2* and *3*) and effectiveness (*Chapters 5* and *7*) studies, performed in different cohorts of pregnant women, showed a strong relationship between high levels of FOC and pregnant women's requests, and use of non-urgent obstetric interventions during childbirth. Our findings confirm already existing results about avoidance in FOC (Nieminen et al., 2009; Sluijs, 2020). Importantly, in accordance with the experiential avoidance theory (S. C. Hayes et al., 1996), when a pregnant woman requests non-urgent obstetric interventions during childbirth due to high FOC, and thus might be susceptible to avoidance, acceptance of such a request without further treatment can reinforce FOC in future pregnancies and childbirths. These implications also reach mental health; timely recognition of FOC and timely offering of an effective treatment to increase participation in childbirth could benefit the well-being of women. Further, our research on the possible pathways of action through which the childbirth mode could be improved in the MBCP group demonstrated the positive influence of the attentional dimension (i.e., an increase in open awareness) in pregnant women with high FOC (*Chapter 7*). This finding confirms the usefulness of working with the attentional dimension of fear and thus confirms the usefulness of a multidimensional perspective of FOC.

The results of this thesis suggest that a multidimensional perspective on FOC, with its emotional, cognitive, behavioural, and attentional dimensions as proposed by CBT, is plausible and may shape the directions for future research and care. More research is

needed to answer the question which pathways of FOC play a role in maladaptation versus adaptation to the challenges of childbirth. This knowledge can contribute to our understanding of how to provide efficient support and treatment to pregnant women suffering from FOC.

Outcomes in pregnant women with high fear of childbirth

In this dissertation, we assumed that FOC is successfully treated when all dimensions of fear (emotions, cognitions, behaviour, and attention) have been improved. Results of the effectiveness study revealed that in general both interventions MBCP and ECAU showed improvements on FOC reduction (*Chapter 5*). However, MBCP proved superior to ECAU, since all four above mentioned dimensions of FOC were improved more in MBCP post-intervention. We observed that the risk of high FOC (emotional dimension) was significantly lower after MBCP compared with ECAU (*Chapter 5*). Also, after the experience of vaginal childbirth, which can be seen as an *exposure*, FOC (W-DEQ-B) was still lower in MBCP than ECAU, and the satisfaction of childbirth was higher (Van der Meulen et al.; submitted to *Midwifery,* May 2022). Decrease in FOC during pregnancy and after childbirth, and being satisfied with the childbirth experience, can be seen as protective factors for post-partum depression and/or childbirth trauma (Söderquist et al., 2009; Stramrood et al., 2011). Further, catastrophic as well as accepting beliefs about labour pain (cognitive dimension) improved more in MBCP than in ECAU. Besides, the pregnant women's preferences to undergo non-urgent obstetric interventions during upcoming childbirth were significantly less following MBCP than ECAU. And finally, only pregnant women following MBCP improved in open awareness (attentional dimension). All in all, we can conclude that MBCP treated high FOC more successfully compered to ECAU. Importantly, the effects of MBCP are dependent on the choice for the type of control group treatment, which is discussed in the *Strength and limitations* section.

Despite the wealth of research evaluating prevalence, causes and risk factors, as well as the reduction of FOC in pregnant women, no non-clinical intervention has proven being effective on impacting the childbirth mode (behavioural dimension of FOC) in pregnant women with high FOC. Until now, several non-clinical interventions such as antenatal group education, individual antenatal psychoeducation, individual counselling, writing a childbirth plan, haptotherapy and CBT provided by midwifery and obstetric care providers were evaluated in randomized controlled trials. Yet, these studies either did not report or did not improve childbirth mode (e.g., fewer medical childbirths) in pregnant women with high FOC relative to a control group (Aguilera-Martín et al., 2021; Badaoui et al., 2019; Stoll et al., 2018; Striebich et al., 2018). Interestingly, we found that MBCP did improve the childbirth mode as compared to ECAU. MBCP not only reduced the chance of the use of epidural anaesthesia during childbirth, but, more importantly,

MBCP halved the chance of medically unnecessary caesarean births and doubled the chance of an unmedicated, natural, childbirth in pregnant women with high FOC (*Chapter 5*). Also, the new-born's Apgar score (a test to get a quick impression of a new-born's general condition) 1 minute after birth was significantly higher following MBCP than ECAU, and the new-born's Apgar score 5 minutes after birth was trending in being effective. However, this effect was no longer significant after correcting for multiple testing.

The results presented in this dissertation showed convincing evidence for future implementation of MBCP in midwifery care to reduce high FOC and to reduce the use of non-medically necessary interventions during childbirth. These findings can be of great importance for the care of pregnant women and new-borns, not only in the Netherlands, but also in other countries. One of the goals of the World Health Organisation (WHO, 2018) is the reduction of FOC and the related use of non-medically necessary and risky interventions in childbirth. Worldwide, the use of caesarean section during childbirth has increased enormously and they are hypothesized to continue increasing over this current decade (WHO, 2018). The findings of this thesis suggest that by implementing MBCP, the increasingly growing use of medical interventions in childbirth in Western countries might be reduced.

MBCP for pregnant women with high FOC as a cost-effective intervention

In this dissertation we evaluated the cost-effectiveness of MBCP in comparison with ECAU for the treatment of high FOC. In our study protocol we expected MBCP to be superior to the control group. The cost-effectiveness was carried out from a societal perspective including health care costs (e.g., contact with the health care system, including type, duration, medications used, and professional support) and non-health care costs (e.g., number of days absent from work, production losses, and support of others). Direct and indirect costs were monitored throughout the whole pregnancy, childbirth and 16 weeks following childbirth.

Overall, the results of the cost-effectiveness analyses indicated that MBCP has a high probability (ranging from 70% to 94%) to be cost-effective compared to ECAU at a willingness to pay of zero. Relatively high childbirth costs and costs related to help from family and friends were observed in ECAU as compared to MBCP, which are hypothesized to be related to less natural childbirths in ECAU. In most secondary analyses, results were robust and demonstrated dominance of MBCP as compared to ECAU. In addition, midwives received more money from insurances for the care for pregnant women in MBCP, probably due to providing more natal care (more childbirths without medical intervening or less referrals to obstetric care).

In the current situation in the Netherlands, pregnant women who suffer from FOC and related psychological vulnerabilities are referred to the obstetrician-led care. In addition, they may be referred to the Psychiatry-Obstetrician-Paediatrician care units (POP-poli). The costs for treatment of FOC in the POP-poli could be higher than MBCP given the number of professionals involved and the intensity of (individual) consultation visits. However, no consensus about the guidelines and payment for FOC treatment in the POP-poli seems to exist. Yet, FOC deserves to be treated given that FOC is prevalent and women with FOC have a six-fold risk of developing PTSD following childbirth (Söderquist et al., 2009), and treating PTSD may lead to additional (health care) costs in the long term. Another possibility to treat FOC is to refer pregnant women to a psychologist working outside the obstetrician-led care. However, the costs for a psychological trajectory for one pregnant woman with FOC are comparable with the commonly asked costs for three women plus their partners in MBCP (NZA, n.d.). Thereby, the psychological care in the Netherlands struggles with long waiting lists of approximately between 14 and 20 weeks of waiting until the first consultation. This waiting time is an insurmountable obstacle given that the duration of pregnancy continues, and the delivery is imminent. In addition, 'regular' psychologists may not have the specific knowledge of childbirth and parenting or skills to treat FOC in pregnant women. Although we have not empirically tested this, when taking these issues into consideration, it seems that a referral of women with high FOC to (specialized) psychological care does not seem a very cost-effective option. Furthermore, the care for pregnant women with high FOC should be readily available, not limited by small number of caregivers, and preferably delivered by midwives since they have a final responsibility in the care of pregnant women.

A business case was proposed on the micro (midwifery practice) and macro (public health costs) level based on the insurance perspective of national yield. In this business case we assumed that the midwifery practices would carry the costs of the MBCP intervention within their own business financing. From the cost-effectiveness study, it was found that the midwife would receive (on average) € 193 more for a woman with high FOC who received MBCP as compared to a woman with high FOC who received ECAU (due to more natural childbirths). However, for this extra amount of money, they would need to do more (i.e., provide MBCP to pregnant women with high FOC and provide care in more natural childbirths). This seems unrealistic. Therefore, in a more realistic scenario, the health care costs of a MBCP intervention for one pregnant couple was estimated to be € 567, These costs could be covered by health care insurances since MBCP had lower costs for childbirths, which means lower costs for health care insurances. Taking these costs into account, the macro business case looks as in table 1.

Table 1.
Macro costs and savings of introducing MBCP-Fear in the Dutch Birthcare system

	%	*N*	Costs/savings p.p.w.	Total costs/ savings
Pregnancies starting in first line		140.000 [a]		
Women with high level of FOC	34 [b]	47.600		
Women wanting to participate in the intervention	75 [c]	35.700		
Effectiveness and costs of intervention	50 [d]		567	-20,2 million
Costs of longer stay in first line			500	-8.9 million
Reduction and savings of referrals		17.850	4000	71,4 million
Total savings				**42,3 million**

Note. [a]: (Perined, 2018), [b]: (Veringa-Skiba, de Bruin, et al., 20220, [c]: estimated, [d]: (Veringa-Skiba, Ziemer, et al. 2022)

The balance is € 42,3 million per a year that may be potentially saved. These numbers suggest that implementing MBCP for pregnant women with high FOC, perhaps supplemented with interventions that have the same effectiveness and costs, will save € 42,3 million to spent on other urgent health issues. It means a saving of 7,5 % of a total maternity care of € 560 million (2018).

In a global context, care for pregnant women in the Netherlands is safe and well organized. However, health care costs are increasing due to the trend of more medicalization of childbirth; high rates of induction of onset of labour, failure to progress with need for augmentation with oxytocin and medical pain relief (Amelink-Verburg et al., 2009; Offerhaus et al., 2013). This, in Western countries observed by WHO, medicalization of childbirth trend is called “too much, too soon” (Miller et al., 2016). Providing too much and too soon medical care in childbirth is not only expensive but it can also be harmful for the mother and her child. Most evident in the worldwide problem of medicalization of childbirth is the use of “unnecessary” caesarean sections (WHO, 2018). Also, the number of women giving birth under the responsibility of midwives at the hospital as well as at home is decreasing due to pregnant women’s preferences for a childbirth with medical labour pain relief (Perined, 2021). It is suggested that the increase in referral rates to obstetrician-led care could also be due to the one-sided attention of the Dutch media on the potential risks and dangers of midwifery care and unmedicated births (Christiaens et al., 2013). However, at the same time pregnant women want to keep the possibility of being able to choose for a mode of childbirth. Within this challenging context, the Royal Dutch Organisation of Midwives (KNOV) and her members trying to consider the pregnancy and childbirth as normal and safe by investing in an evidence based working coalition so that all women can receive continuity of care from a midwife plus the additional care of a specialist (obstetrician) when necessary – “right care on the right place” (KNOV, 2020).

The positive results of the cost-effectiveness analyses of MBCP, estimated from the first weeks of pregnancy through the childbirth till the latest week of the maternity leave, presented in this dissertation, may open new ways in organizing more cost-effective care for pregnant women with high FOC in the Dutch midwifery care. It may even positively influence the global trend of medicalization of childbirth and growing expenses while improving the care of pregnant women.

Mindful awareness increases adaptation to childbirth

In this thesis, we explored the pathways of action of MBCP, through which the possibility of the increased adaption to childbirth in pregnant women with high FOC could be explained (*Chapter 7*). Based on the assumption of multidimensionality of FOC, we conducted concomitant analyses of the hypothesized pathways of action which were assumed to change an avoiding strategy into an approaching strategy to deal with the challenges of childbirth and thereby resulting in unmedicated childbirths. The hypothesized pathways were: emotion (FOC), cognition (catastrophic beliefs about labour pain) and attention (mindful awareness). We found that a change in the attentional pathway - an increase in mindful awareness - helped pregnant women with high FOC in approaching an unmedicated childbirth. Surprisingly, a decrease in FOC and a decrease in catastrophic beliefs about labour pain was *not* found to be a pathway of action to an unmedicated childbirth. More specifically, unmedicated childbirths were positively associated with the number of minutes of meditation practice suggesting that cultivating mindful awareness through mindfulness meditations was helpful for pregnant women to deal with the challenges of childbirth despite their high FOC.

These findings are compelling since they suggest that the change in attentional dimension (from threat-focused to open awareness) through meditation practices in pregnant women with high FOC mediates the change in behaviour - (from avoiding to approaching the challenges of childbirth). The change in the quality of attention following MBPs is a known effect of mindfulness meditation practice, and it can be viewed through the improvements of one's relationality to different experiences in body and mind (Alsubaie et al., 2017; Baer, 2009; Goyal et al., 2014).

Interestingly, CBT also targets the change in the quality of attention as a working mechanism in changing unhealthy behaviours in individuals with psychological vulnerabilities (Beck, 1976), but in a different way. Comparatively in CBT, it can be viewed through the improvements in cognitive-emotional information processing. CBT uses *exposure* and *cognitive modification,* and mindfulness uses *decentring* as a key for these improvements. In CBT, this is accomplished by bringing all experiences (thoughts, emotions, physical feelings, and actions) front-and-centre to change problematic thinking such as catastrophizing and problematic behaviour (e.g., avoiding certain situations or/and experiences). In MBCP, and largely in MBPs, various

experiences (thoughts, emotions, physical feelings, and actions) are decentered through mindfulness meditation and inquiry. Decentring means having the ability to notice an experience and not react, and to have no judgments to the observed experiences (or at least postpone judgement). In this way, an experience such as anxiety may exist without disapproval.

Further, in mindfulness meditation, all difficult cognitive-emotional processes are met through the experiences in the body (e.g., hyperactivity or pain), a key difference from CBT. In mindfulness meditation, the attention is focused on the parts of the body that are affected by cognitive-emotional processes, the cognitive-affect cycle is given the space to be able to deal with that cycle in a decentred and observing manner. Paying open attention to difficult thoughts and emotions by being able to feel them through the body, explore them with curiosity, attend to them without any need to change them, makes the difference between mindfulness meditation and CBT techniques (Segal et al., 2002, 2013). In CBT, experiences are viewed and discussed through the cognitive process of the mind and the behaviour process of avoidance. So, while MBCP and CBT both focus on open awareness, the differences in how each method is used could have important implications for pregnant women.

The effects of CBT in pregnant women with FOC, delivered by psychotherapists, has been increasingly investigated. Different studies reported different effects of CBT in pregnant women with FOC or anxiety. Saisto et al. (2006) were the first to evaluate CBT (delivered by psychotherapists) for treating severe FOC. This Swedish study demonstrated a decrease of FOC and a decrease in self-requested caesarean births as compared to care as usual. However, in two other studies where CBT was delivered by psychotherapist-obstetricians during obstetric check-ups (Saisto, Salmela-Aro, et al., 2001) or by internet as a self-therapy (Rondung et al., 2019), CBT targeted to reduce FOC was not more effective than treatment in control groups. Several studies found that CBT delivered by psychotherapists reduced generalized anxiety symptoms in pregnant women (Loughnan et al., 2018; Nillni et al., 2018). However, in contrast, in a recent Dutch study comparing CBT delivered by psychotherapists with a control group, an *increase* in anxiety in pregnant women in the CBT condition was reported (Burger et al., 2020). Considering the heterogeneity (e.g., inclusion criteria, type and the manner of delivery of intervention and control group) of the studies as well as their mixed findings of FOC, further research into the effectiveness of CBT to target high FOC in pregnant women is warranted.

Future research could compare the similarities and differences in effects of CBT and MBCP in targeting FOC. Research into this topic would enrich the growing evidence for "third-wave" cognitive-behavioural therapies (Dimidjian et al., 2016). In "third-wave" therapies, the holistic approach to psychological and behavioural processes related with health and well-being are prioritized. Concepts such as mindfulness,

acceptance, metacognition and personal values are blended into traditional behavioural interventions. In this way, a therapy can be more sensitive to the context, processes, and functions of how a person relates to internal experiences in body and mind (S. C. Hayes et al., 2013).

Decentering (MBCP) compared to exposure and cognitive modification (CBT) could be a future pathway to study. Pregnant women in our MBCP group were likely able to notice fearful feelings and thoughts about childbirth through the body (i.e., bodily sensations of fear and stress), but they developed the ability to not react to these experiences by avoidance. They continued to focus on the various experiences in pregnancy and later in their labouring body. Comparatively, one CBT study reported less than ideal outcomes. The already mentioned study of Burger et al. (2020) on the effectiveness of CBT in pregnant women with mental health problems in the Netherlands, showed an increase in anxiety in pregnant women following CBT as compared to the control group. The authors explained this finding as a possible result of the exposure component of CBT. Exposure to fear-evoking stimuli could increase anxiety and even stimulate a stress reaction in pregnant women resulting in a lower birthweight of new-borns in the CBT group through higher levels of stress hormones (Burger et al., 2020).

MBCP could offer a better approach to decreasing stress in pregnant women. The Swedish RCT showed that MBCP is more effective in decreasing perceived stress in pregnant women who are at risk for perinatal depression as compared to a Lamaze childbirth course (Lönnberg et al., 2020). Also, in our study, we found that greater non-reactivity to inner experience, a subquality of mindful awareness, correlated with less perceived stress in the MBCP group. This finding prompted us to evaluate whether there was any association between the level of stress as assessed by the Depression Anxiety Stress Scale (DASS-21) and the level of mindful awareness (FFMQ). However, these results are not included in our publications due to after-the-fact insights. Nevertheless, we found a significant negative correlation between scores on a subscale of stress of the DASS-21 and mindfulness scores on the FFMQ in pregnant women in MBCP (r = -0.47, $p < 0.001$), indeed indicating that higher levels of mindfulness (FFMQ) are related to lower levels of stress (DASS-21).

In light of the "third-wave" therapies, MBCPs' mindfulness meditations could also be studied in CBT for pregnant women with severe psychological vulnerabilities under the care of psychotherapists in order to improve the outcomes of a CBT therapy. CBT is an internationally recommended intervention for treating depression and anxiety disorders during the perinatal period (National Institute for Health and Care Excellence, 2014), however, more research is needed to understand from which approach (exposure and cognitive modification or decentering) pregnant women and their new-borns could benefit the most.

While we have explained the potential benefits of MBCP's decentring, there are two other factors that might have contributed to the effects of MBCP: (1) participation in a group of pregnant couples and (2) the experience of unpleasant sensations by the use of ice cubes, while meditating. The participation in MBCP allows for vicarious learning (i.e., sensing, feeling, and evaluating) from the experiences of others (Bandura, 2004). In this way, the group process in MBCP could strengthen pregnant women's self-efficacy by hearing and seeing other participants successfully overcoming their barriers and accomplishing desired skills for childbirth. The group effect in changing unhealthy behaviours and improving pregnancy and childbirth outcomes has already been hypothesized to play an important role in other treatments and methods, such as the Centering Pregnancy method (Massey et al., 2006), which demonstrated positive effects on maternal and birth outcomes in many populations of pregnant women (Liu et al., 2021). Additionally, the use of ice cubes while meditating, in three out of nine sessions, possibly taught the MBCP participants how to deal with stressful, unpleasant sensations in their hands by focusing their attention on breathing or on the stressful sensations in the body. Making contact with the cold ice for an extensive period of time potentially cultivated a specific state of mind; one of non-reactivity, calm and confidence to embrace the challenges of unpleasant sensations. Practicing this in the group and with their own partners experiencing what it is like to ask for and receive help from their own partner could reinforce vicarious learning even more when dealing with suffering. However, we did not explore the effects of vicarious learning in this dissertation. More research on this topic in pregnant women with high FOC could be interesting.

This thesis contributed to pioneering research in the exploration of mechanisms that play an important role in a better adaption to the challenges of childbirth in pregnant women with high FOC. We found that the effectiveness of MBCP on developing more adaptation to childbirth may operate through psychological (e.g., decentering through mindfulness meditations) and social (group format and participation of partner) components in changing avoiding behaviours in pregnant women with high FOC. More research is needed to understand which components are essential for the effects of MBCP.

Strengths and limitations

We have discussed limitations and strengths for each study specifically in each chapter and therefore I will now limit this reflection to the most important issues for this dissertation, namely: representativeness of our studies' samples, the new assessment of FOC, the randomization procedure, the intervention conditions, and the applied statistical analyses.

Representativeness of the samples

A strength of this thesis is the high representativeness of our studies' samples in terms of various recruitment locations and participant diversity (i.e., location, language).

First, participants were recruited from midwifery care settings during consultation hours. In the study on labour pain cognitions, 12 midwifery practices participated, and they recruited 270 pregnant women (*Chapter 2*). In the study about the one-item FOCP-VAS, 549 pregnant women were recruited by 12 midwifery practices (different than in *Chapter 2*) varying in size and location (*Chapter 3*). In addition to the assessment of emotions, participants also agreed to anonymously share their medical files. The access to these medical files made our studies' results of high clinical relevance. In the study on the effects of MBCP, 28 midwifery practices from Amsterdam and The Hague participated in the recruitment of 219 pregnant women who experienced high levels of FOC (*Chapter 5*). Amsterdam and The Hague are cities with high multinationalism, which somewhat increased the heterogeneity of the sample. Also here, the participating midwifery practices helped to collect childbirth data by sharing with us the pregnant women's medical records. The study was in tandem with the local community of midwives and data shows that results are more credible with a trusted third party. It can be said that these studies were carried out "for midwives by midwives". These various recruitment locations, connections with different midwives, and different cities bolstered our heterogeneity and study compliance. However, most of our samples were Caucasian and highly educated women, which is a limitation of the representativeness of the samples of our studies. In the assessment studies, the ability to understand the Dutch language was required. But in the effectiveness study, in addition to Dutch, English-speaking participants could also participate, which increased sample heterogeneity and generalizability.

For our effectiveness study (*Chapter 5*), we recruited pregnant women experiencing high levels of FOC (W-DEQ-A≥66). When examining extant literature, this is a rarity in FOC studies not only in the Netherlands but also globally (Striebich et al., 2018). Most studies deal with severe FOC (W-DEQ-A≥85). Despite our lower FOC cut-off, our sample revealed relatively vulnerable pregnant women of whom 75% struggled in the past with psychological problems and of whom 25% reported having current psychological problems. Our choice for the lower cut-off FOC can be seen as a strength since it exposes the unknowns about FOC.

Several limitations impact the representativeness of our sample. Measurement and treatment attrition are frequently reported obstacles in intervention studies, especially in pregnant women experiencing psychological vulnerabilities. In our assessment study (*Chapter 3*), the attrition rate was low (10%), and in the effectiveness study (*Chapter 5*), a substantial proportion of the post-assessment data (24%) was missing. This could have impacted the representativeness of our results. However, participants with and without missing post-assessment data did not differ on pre-assessment measurements, and overall missing data were at random. Importantly, childbirth outcome data (objective data) were collected for all participants, those who did and did not complete the post-assessment questionnaires (subjective data) in all

the studies and thus strengthens the findings from the RCT (*Chapter 5*). Finally, our samples were recruited within the Dutch health system, that is known for its primary care and home birth culture. This is critically different from other healthcare systems and may decrease the generalizability of our study results.

In summary, despite existing differences in the Dutch midwifery care system and the aforementioned issues related to the representativeness, we also want to highlight that pregnancy and childbirth are universal and given the wealth of available data for analyses, we believe that the results of our studies are highly relevant for other Western countries.

New assessments of fear of childbirth issues

Another strength of this thesis is the use of new, more general and pragmatic assessments of FOC for use in midwifery care. As previously mentioned, our fear conceptualization draws from various literature not specific to pregnant women. Given this, some of the measures used in this thesis were not yet validated with pregnant women and should be considered with caution. First, the Labour Pain Cognitions and Coping List (LPCCL) originated from the Pain Cognitions and Coping List, which assesses chronic pain and avoidance of physical activity in non-pregnant populations. The Cronbach's α for each subscale of the LPCCL was calculated and proved to be satisfactory for pregnant populations (*Chapter 2*). Second, in combination with the LPCCL, the FOCP-VAS showed high clinical sensitivity in identifying pregnant women with requests for non-urgent obstetric interventions for use in anticipated childbirth, as well as with pregnant women who used these interventions during actual childbirth (*Chapters 2 and 3*). Due to its one-item construction, it was not possible to calculate Cronbach's α and thus evaluate the FOCP-VAS's reliability. Also, we did not examine the test-retest reliability of this measure.

Several measures were developed in this work to capture various concepts (i.e., labour pain acceptance, labour anxiety disorder) in our multidimensional fear framework. To measure an opposite cognition to catastrophizing, we developed the Labour Pain Acceptance Questionnaire (LPAQ; *Chapter 5*). The LPAQ was based on the Chronic Pain Acceptance Questionnaire (CPAQ; McCracken et al., 2004); *Chapter 5*), which is used with chronic pain patients to assess acceptance of pain in relation to participation in daily life. The LPAQ was not validated in pregnant women, but at pre-test, it showed good reliability with Cronbach's α 0.82 (not presented in this thesis).

The use of new, however, not validated measures can be seen as a limitation due to the uncertainty of measured latent traits. But if a developed assessment is based on a sound theory and is developed in accordance with the specific scientific requirements, it can be seen as bolstering this limitation into a strength. In summary, we used a wealth

of new and existing tools to capture FOC in its multidimensionality with a pragmatic, and thus suitable application for midwifery care. Frequent application of these tools in care for pregnant women could possibly help in timely recognition and assessment of FOC, and possibly address related mental health vulnerabilities.

Randomisation

Two possible ambiguities, when it comes to the randomisation process used in this thesis, need to be discussed. A first ambiguity can arise due to a different qualification of the type of randomisation in our effectiveness study (a random allocation; *Chapter 5*) as compared to our protocol study (a quasi-random allocation; *Chapter 4*). In our publication of the study protocol (2016), we indeed defined the randomization design as a quasi-randomized. However, over time we have realized, as noted by peers, that the study design actually is more a randomized than a quasi-randomized study, since it ensures an equal chance to be allocated into one of the study's' conditions. That is, we used a permuted block randomization, which is almost as valid as a simple unconstrained way of randomization (Xiao et al., 2011). A randomized scheme of the sequence of blocks of both conditions (MBCP or ECAU) was made prior to the recruitment and allocation process. However, the number of women in the MBCP block determined the number of women in the next ECAU block to protect a predetermined ratio of 1:1. In this way a close balance of the number in each group at any time during the trial was ensured. Further, the participants' assignment to the condition was based on chance since the sequence of registration was operated by an independent research assistant. In this way, our study's design and allocation process met the standards of the CONSORT guideline (Schulz et al., 2010). Therefore, the assigned condition was determined by chance and could not be predicted, thus making it a randomisation. In contrast, quasi-randomization is a method of allocating participants without an equal chance of being in one group or the other what was not the case in our study. Accordingly, we have chosen to change the qualification of our allocation into a random allocation.

Second, another possible ambiguity in terms of a randomization is our choice, for practical reasons, to randomise before pre-intervention measurement. The decision for a priori allocation to a pre-intervention's measurement was based on a steadily increasing gestational age, dependence on recruitment speed and efficiency, required minimum group size, and adherence to an equal length of time (maximum 2 weeks) between T1 assessment and the start of MBCP/ECAU. Importantly, we screened the participants on the level of FOC *a priori* to allocation. However, the pre-intervention assessment found place after allocation. We were aware that a pre-intervention measure following the assignment could have caused a measurement bias due to knowing to which condition participants were allocated. This is why we also assessed participants' preferences for condition. Finally, we did not find evidence of baseline

differences between conditions, and no differences between participants who were and were not allocated to their preferred condition (*Chapter 5*). However, we cannot rule out a measurement bias for knowing to which condition one has been allocated.

Intervention conditions

There are several strengths related to the intervention's conditions. First, both MBCP and ECAU were delivered by midwives, who were specifically trained for this research. This is advantageous because it indicates easy implementation of the interventions in midwifery care in the future since these interventions were already embedded in midwifery care during this research stage. Second, the satisfactory adherence of pregnant women with high FOC and their partners to both conditions indicated an important clinical feasibility strength of the conditions. About 87% of participants followed almost seven out of the nine MBCP sessions, and 98% followed at least one of the two ECAU sessions. Given this high adherence, both conditions have high acceptability. Third, we accounted for fidelity to the MBCP and ECAU curriculums by using checklists during each session and consultation.

Further, MBCP was compared to an active control group, which allows for more robust results when interpreting the effectiveness of an intervention. However, a critical issue in evaluating the effects of MBCP was the choice of the control group. An ideal situation to evaluate the effects of a new intervention is to use a treatment that already exists as a comparison (care as usual). Unfortunately, in the Dutch midwifery care, there is no procedure about how to treat FOC by midwives. Additionally, in the situation of pregnant women with high FOC, there is an ethical problem of non-treatment for the participants suffering from FOC. Therefore, in this study, care as usual was enhanced. Two extra midwifery consultations were added; the first session was based on the Biopsychosocial Model (Engel, 1977) and the second was based on the childbirth-plan of the Royal Dutch Organization of Midwives (*Chapter 4*). The ECAU condition seems therefore to be more than care as usual. Since MBCP was more effective than ECAU (*Chapter 5*), and the fact that ECAU could be more than care as usual, the difference in effect might be even larger for MBCP when compared to 'true' care as usual.

There could be potential consequences of substituting ECAU for care as usual. The choice for an enhanced comparison group (ECAU) could have decreased the possibility of a *participant-response bias*. This bias is also known as the *Hawthorne effect* which occurs when the participants alter their appraisal or behaviour depending on what they think the study is designed for (Franke & Kaul, 1978). This can result in an improvement just from the participation in the study and not the improvement by an intervention. It could be expected that all study participants would improve on self-reported outcomes. Nevertheless, a significant difference in improvements between the two study's conditions was observed (*Chapter 5*). From this point of view, the

choice for an enhanced comparison group (ECAU) strengthens the internal validity of MBCP. However, on the other hand, the influence of the difference in treatment dose between MBCP (9 sessions, each of 3 hours in 10 weeks) and ECAU (2 consultations, each of 1 ½ hours in 10 weeks) on the outcomes remains unknown. It is possible that the difference in intensity, cannot be ruled out as a possible reason for the greater impact of MBCP as compared with ECAU.

We also did not explore the group effect of MBCP in reducing FOC. That is, it could be that pregnant women found a forum for peer support, becoming stronger as they share their feelings and experiences with other pregnant women dealing with FOC. Possibly, they could feel less isolated by their condition and develop an even greater sense of normalcy due their common humanity experience (Slivjak et al., 2022). However, it should be noted that significantly more participants in ECAU (41%) than in MBCP (9%) followed additional prenatal educational group-courses, which may have compensated for the dose difference and possible benefits of group's peer support. A further limitation is that we did not include self-report questionnaires to monitor possible meditation-related adverse events (e.g., fatigue or hyperarousal, or worsening psychological wellbeing; Britton et al., 2021). However, no problems were reported after the sessions, and therefore, it seems unlikely that there were clinically relevant adverse reactions.

In summary, both intervention conditions can be seen as effective (given the stability of FOC during pregnancy found in our observational study; *Chapter 2*), safe (given no harm has been reported), acceptable (given high frequency in participation in both interventions), and feasible (given the study was embedded in midwifery care). However, MBCP is more favourable than ECAU, given its positive effects on childbirth outcomes and greater effect on the reduction of FOC.

Statistical analyses

A strength of this thesis is its rigor and large variety in applying specific statistical analyses, in all our studies, to avoid a possible overestimation of the results. When starting this research, we ensured adequate statistical power for the assessment and the (cost-) effectiveness studies. We also registered and followed a study protocol for the effectiveness study (*Chapter 4*). In the assessment studies (*Chapters 2* and *3*), we used hierarchical multiple logistic models for concomitant evaluations of the strongest predictors. The results of the effectiveness study (*Chapter 5*) were evaluated through corroborative intention-to-treat and per-protocol analyses. Using hierarchical linear models, we considered missing data and time as a predictor. Additionally, we adjusted *p*-values for multiple testing to decrease type 1 errors and blinded the statisticians and research assistants to group assignment. Further, to make our study results understandable for clinicians, we presented clinical effect sizes such as

relative risks (RR), relative risks reduction (RRR) and number needed to treat (NNT). Finally, we extensively described all our statistical analysis to ensure the replication of our studies' results for future, scholarly use.

In summary, we applied sound statistical standards to evaluate our studies' results and addressed common obstacles in clinical studies. By doing so, our aim is that this research and results will be viewed with the upmost credibility and reduce the gap between science and practice.

Clinical implications

The findings of this dissertation provide several clinical implications for midwifery care. Overall, the findings indicate that FOC can be assessed and treated under the care of midwives. However, research on the brief and general assessment of FOC is in its initial stages. First, I recommend a new practice: screen all pregnant women who visit midwifery and obstetric care by using FOCP-VAS, in both the beginning and during pregnancy. In the event of a score of VAS≥5, various issues could be discussed: first, whether there is indeed high FOC; second, whether intentional avoidance of the challenges of anticipated childbirth is being considered; and third, whether psychological support would be welcomed by the pregnant woman. Second, to ensure continued care for pregnant women, I recommend leveraging the existing collaboration between midwives and the Psychiatric-Obstetric-Paediatric (POP) outpatient clinics to discuss screening and the care path for pregnant women with a score of FOCP-VAS≥5. Third, considering the strength of current evidence on the effects and working mechanisms of MBCP in pregnant women with high FOC, I recommend this intervention for treatment of FOC in midwife-led and POP-led settings. MBCP could be used in the prevention of anxiety and trauma due to FOC following childbirth. Initial steps have already been taken that demonstrate the support of MBCP. For example, as of recent, the Royal Dutch Midwives Organisation (Koninklijke Nederlandse Organisatie van Verloskundigen, KNOV) now considers MBCP as a treatment in the Positive Healthcare (Huber et al., 2011) for pregnant women with high FOC. By timely screening for FOC and offering MBCP, possible cost savings can be made. However, the most important health improvement – the improvement of a child's first 1000 days starting at conception – must be mentioned. Studies show that a baby exposed to stress (e.g., due to fear or anxiety) during these first 1000 days will already start to lag in development and subsequent milestones. A child without an optimal start has a greater chance of physical and mental problems later in life. Investing in the timely and adequate treatment of FOC can therefore be seen as breaking through the intergenerational transmission of poor health and suffering (Aktar et al., 2019).

To improve the above-mentioned issues, I recommend creating and thus educating midwives and other care professionals in the midwifery and obstetric care sphere,

in order to become an MBCP (with a specialization in FOC) professional. Through this initiative, it will make MBCP accessible for pregnant women who may need it. It would be sufficient even if just one of the midwives per midwifery practice is an MBCP professional. MBCP could preferably be delivered in groups to pregnant women and their partners, but also on an individual basis when needed. By delivering MBCP in groups, more pregnant women and their partners could be helped in a shorter time with less costs, while also benefitting from a community of others experiencing the same challenges. Additionally, midwives will have a larger responsibility in preparing pregnant women with high FOC and their partners to a safe and joyful transition into parenthood. Here lies an important and yet unchartered territory in midwifery care: guiding mother and her child, and her partner to a securely attached family. Given a high prevalence of FOC, I recommend that all midwives educate themselves more in the matter of fear and anxiety, and related issues, in the perinatal period. With this in mind, midwives can play a key role in improving psychosomatic care in the 21st century.

Future studies

Future studies on MBCP should focus on its non-clinical (midwifery settings) as well as clinical (psychological/psychiatric settings) applicability. In non-clinical research, first, replication studies of our assessment and effectiveness studies are required, with more heterogeneous (e.g., cultures, socioeconomical status) samples of pregnant women with high FOC. The robustness of our findings could then be evaluated. In addition, a biological component of stress, such as cortisol level measurement in pregnant women could also be examined. This could lead to more established and tangible effects of fear on pregnant woman and the baby. Also, research on the effects of the specific elements of MBCP, such as meditations, psychoeducation, and number of sessions, could provide more insight in the working elements of MBCP on FOC and adaption to childbirth and parenthood. Simultaneously, research on how to shorten MBCP without losing effectiveness could be initiated given the relatively short time and progression of pregnancy. The effects of MBCP on mother and child attachment as well as the functioning of the new family could be studied with the aim of evaluating MBCP as a family intervention. Finally, the implementation of MBCP in midwife- and obstetrician led settings could be evaluated in the future studies. However, I think the most urgent recommendation is to evaluate the effects of MBCP in face of CBT, since the effective clinical treatment for pregnant women suffering from anxiety in the Netherlands seems to be inconclusive.

Conclusions

The present thesis provides insights on general assessment and multidimensional treatment of FOC in midwife-led care settings. The findings indicate that FOC in relation to the mode of childbirth can be assessed in a simple way by using the one-item FOCP-

VAS, within the first half of pregnancy. Pregnant women with high FOC requested and used more frequent non-urgent obstetric interventions during childbirth, such as advanced pain relief and caesarean section, than pregnant women with lower levels of FOC. Preferences and use of non-urgent obstetric interventions during childbirth can be seen as an avoidance of the challenges of childbirth (e.g., uncertainty, labour pain). High FOC and pregnant women's avoidance of the challenges of childbirth can be effectively treated by attending the MBCP course, with a higher mindful awareness as the main working mechanism in approaching natural childbirth. Thereby, the cost-effectiveness of MBCP relative to ECAU showed that MBCP had a higher chance to be more effective and had lower costs. In summary, this thesis indicates that high FOC can be easily assessed and treated in a midwifery care setting, with results demonstrating more unmedicated childbirths and less related costs for those who followed MBCP.

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APPENDICES

Appendices Chapter 5

Table S1.

Hierarchical multi-level analyses of the primary outcomes with time and condition as predictors between the MBCP and ECAU participants for the per-protocol population

	Parameter estimate	Standard error	*t*	*p*	*p'*	95% CI	
						lower	upper
W-DEQ-A							
T2[a]	-0.62	0.11	-5.58	< 0.001		-0.83	-0.40
Condition[b]	-0.01	0.15	0.05	0.96		-0.30	0.31
T2*Condition	-0.57	0.15	-3.70	< 0.001	< 0.001	-0.87	-0.26
DSM-5 PAD-L							
T2[a]	-0.27	0.15	-1.85	0.07		-0.56	0.02
Condition[b]	-0.28	0.21	-1.33	0.19		-0.70	0.14
T2*Condition	-0·14	0.21	-1·69	0.49	0.49	-0.55	0.27
CLP							
T2[a]	-0.43	0.11	-3.95	< 0.001		-0.65	-0.21
Condition[b]	-0.09	0.16	-0.55	0.58		-0.40	0.23
T2*Condition	-0.62	0.15	-4.11	< 0.001	< 0.001	-0.91	-0.32
LPAQ							
T2[a]	0.36	0.12	2.91	0.004		0.11	0.61
Condition[b]	0.04	0.18	0.25	0.81		-0.31	0.39
T2*Condition	0.58	0.17	3.37	0.001	0.003	0.24	0.91
WAOI							
T2[a]	0.02	0.11	0.15	0.89		-0.20	0.24
Condition[b]	0.02	0.20	0.10	0.92		-0.37	0.41
T2*Condition	-0.53	0.15	-3.47	0.001	0.003	-0.84	-0.23

Note. Outcome variables are standardized and as such parameter estimates can be interpreted as an effect size (Cohen's *d*).
CLP = Catastrophizing Labour Pain; DSM-5 PAD-L = DSM-5 Perinatal Anxiety Disorder-Labour; LPAQ = Labour Pain Acceptance Questionnaire; WAOI = Willingness to Accept Obstetrical Interventions; W-DEQ-A = Wijma-Delivery Expectation Questionnaire.
[a] post intervention as compared to pre-intervention, [b] MBCP as compared to ECU. Cohen (1992) reports the following intervals for *d*: 0.1-0.2: small effect; 0.2-0.5: medium effect; > 0.8: large effect.

Table S2.

Differences in the secondary outcomes between the MBCP and ECAU for the per-protocol population

Childbirth outcome										
Pregnant women	**MBCP (*n* = 61)**	***N*[b]**	**ECAU (n = 59)**	***n***	**X[b]**	***p***	***p'***	***RR* (95%CI)**	***RRR* % (95%CI)**	***NNT* (95% CI)**
Used EA in labour (yes)[a]	18	58	32	50	11.737	0.001	0.004	0.48 (0.31 – 0.75)	52 (25 – 69)	3.0 (1.9 – 6.6)
Underwent sCB (yes)	0	61	8	59	8.862	0.003	0.009	0.45 (0.37–0.56)	55 (44 – 63)	7.5 (4.5 – 22.8)
Had an unmedicated birth (yes)	33	61	10	59	18.000	< 0.001	< 0.001	2.74 (1.55–4.83)	-	2.7 (1.9 – 4.7)
Newborns	***M* (SD)**	***N*[b]**	***M* (SD)**	***n*[b]**	***t***	***p***	***p'***	**Mean difference**	**95%CI**	
1-minute APGAR score	9.02 (0.83)	58	8.62 (1.27)	58	-2.00	0.048	0.096	-0.40	-0.79 – 0.00	
5-minute APGAR score	9.78 (0.59)	71	9.59 (0.96)	58	-1.25	0.20	0.20	-0.19	-0.48 – 0.10	

Note. Abbreviations: EA = Epidural Analgesia; ECAU = Enhanced Care As Usual; MBCP = Mindfulness-Based Childbirth and Parenting; sCB = self-requested Caesarean Birth.
[a] Sample without primary CB (*n* = 14);
[b] Sample size depending on availability of medical files data.
p' = *p*-value after Holm-Bonferroni correction

Appendices Chapter 6

Appendix Table 1.
Women who completed the cost questionnaires (subsample for the current study) versus women who were excluded from the current study because they did not complete the cost questionnaires

	Current subsample (*n* = 54)	**Excluded sample (*n* = 87)**	***p***
Age, *M (SD)*	32.95 (4.39)	32.91 (3.56)	0.948
Gestational age, *M (SD)*	39.73 (1.64)	38.87 (4.60)	0.194
FOC (WDEQ total score), *M (SD)*			
T0 (screening)	91.54 (19.81)	94.76 (18.70)	0.327
T1 (pre intervention)	98.13 (22.66)	98.00 (22.08)	0.973
Educational level			0.229
Middle level	9 (16.7%)	17 (11.2%)	
High level (bachelor degree)	45 (83.3%)	49 (74.2%)	
		Missing: *n* = 21	
Born in the Netherlands:			0.070
Yes	42 (77.8%)	55 (63.2%)	
No	12 (22.2%)	32 (36.8%)	
Parity			0.078
Nulliparous	39 (72.2%)	38 (66.7%)	
Multiparous	15 (28.8%)	29 (33.3%)	
		Missing: *n* = 20	

Appendix Table 2.
Multi-level analysis comparing the effect of ECAU on FOC (measured with W-DEQ-A) for women who completed the cost questionnaires (subsample for the current study) versus women who were excluded from the current study because they did not complete the cost questionnaires

	Parameter estimate *(SE)*	***t***	***p***
T2 (post intervention)	-0.63 (0.10)	-5.22	<0.001
T3 (after childbirth)	-1.04 (0.12)	-4.56	<0.001
T4 (follow-up)	-1.05 (0.23)	-4.35	<0.001
Selected sample (0 = excluded sample/ 1 = current subsample)	0.01 (0.18)	0.04	0.967
T2*Selected sample	0.04 (0.19)	0.22	0.825
T3*Selected sample	0.17 (0.35)	0.50	0.618
T4*Selected sample	0.14 (0.37)	0.38	0.707

Note. T2, T3 and T4 as contrasted against T1 (pre intervention). All variables were standardized and as such parameter estimates can be interpreted as Cohen's *d*. Interaction effects were not significant indicating similar effects of ECAU on FOC for the selected subsample and the excluded sample.

Appendix Table 3.

Multi-level analysis comparing the effect of MBCP on FOC (measured with W-DEQ-A) for women who completed the cost questionnaires (subsample for the current study) versus women who were excluded from the current study because they did not complete the cost questionnaires

	Parameter estimate *(SE)*	***t***	***p***
T2 (post intervention)	-0.85 (0.14)	-6.21	<0.001
T3 (after childbirth)	-1.16 (0.22)	-5.30	<0.001
T4 (follow-up)	-1.40 (0.19)	-7.33	<0.001
Selected sample (0 = excluded sample/ 1 = current subsample)	0.00 (0.18)	0.01	0.989
T2*Selected sample	-0.21 (0.19)	-1.10	0.278
T3*Selected sample	-0.19 (0.30)	-0.67	0.506
T4*Selected sample	0.22 (0.26)	0.87	0.391

Note. T2, T3 and T4 as contrasted against T1 (pre intervention). All variables were standardized and as such parameter estimates can be interpreted as Cohen's *d*. Interaction effects were not significant indicating similar effects of MBCP on FOC for the selected subsample and the excluded sample.

Appendix Table 4.
Unit costs list

	Resource	cost in € [a]	Reference and notes
GP	regular consult	33.76	Guidelines of the Dutch Care Institute (2015)
	home visit	51.15	Guidelines of the Dutch Care Institute (2015)
	telephone consult	17.39	Guidelines of the Dutch Care Institute (2015)
GP weekend and night	regular consult	105	Nederlandse Zorgautoriteit (NZa), 2019. The price of a consult varies per GP practice and location. The average price was calculated and used as estimate.
	home visit	158	Nederlandse Zorgautoriteit (NZa), 2019
	telephone consult	25	Nederlandse Zorgautoriteit (NZa), 2019
Hospital	Emergency care	264.96	Guidelines of the Dutch Care Institute (2015)
	Gynecologist	93.09	Guidelines of the Dutch Care Institute (2015). The price for polyclinic visit was chosen as estimate.
	Medical specialist	93.09	Guidelines of the Dutch Care Institute (2015). The price for polyclinic visit was chosen as estimate.
	Hospitalization (per day)	486.95	Guidelines of the Dutch Care Institute (2015)
	Transport via ambulance	526.85	Guidelines of the Dutch Care Institute (2015)
Paramedic care (e.g., physical therapist, osteopath, dietician)		33.76	Guidelines of the Dutch Care Institute (2015). The average of the prices for the different types of paramedic care was taken as an estimate.
Midwifery care (per consult)	regular consult	27.71	Nederlandse Zorgautoriteit (NZa), 2019. The price for preconception consultation shorter than 20 minutes was chosen as estimate.
	home visit	41.97	Nederlandse Zorgautoriteit (NZa), 2019. The prices for a home visit by the midwife was estimated based on the price of the regular consult while taking the GP ratio for regular consult versus home visit into account.
	telephone consult	14.27	Nederlandse Zorgautoriteit (NZa), 2019. The prices for a home visit by the midwife was estimated based on the price of the regular consult while taking the GP ratio for regular versus telephone consult into account.
Midwifery care (fixed amount of money that midwife receives per woman for providing care)	Midwife prenatal care	622.43	Nederlandse Zorgautoriteit (NZa), 2019. Different prices depending on living situation. The average was calculated and used as estimate.
	Midwife natal care	681.32	Nederlandse Zorgautoriteit (NZa), 2019. Different prices depending on living situation. The average was calculated and used as estimate.
	Postnatal care	378.51	Nederlandse Zorgautoriteit (NZa), 2019. Different prices depending on living situation. The average was calculated and used as estimate.

	Resource	cost in € [a]	Reference and notes
Childbirth by midwife	At home	614.27	Hitzler et al., 2017
	At birth center	996.66	Hitzler et al., 2017
	At hospital	1155.31	Hitzler et al., 2017
Childbirth at hospital (by referral)	Spontaneous birth	2225.00	Nederlandse Zorgautoriteit (NZa), 2019
	Instrumental intervening	2670.00	Nederlandse Zorgautoriteit (NZa), 2019
	Epidural procedure	188.59	Hitzler et al., 2017
	Caesarean Section	4195.00	Nederlandse Zorgautoriteit (NZa), 2019
Maternity care	Regular consult	46.91	Nederlandse Zorgautoriteit (NZa), 2019
	Home visit	66.17	Nederlandse Zorgautoriteit (NZa), 2019
	Telephone consult	22.08	Nederlandse Zorgautoriteit (NZa), 2019
Home care		20.46(per hour)	Guidelines of the Dutch Care Institute (2015)
Unpaid work	Loss of daily activities/Help from friends and family	14.32 (per hour)	Guidelines of the Dutch Care Institute (2015)
Sick leave (work)		32.33 (per hour)	Guidelines of the Dutch Care Institute (2015). The price per hour for paid work and productivity loss for women was chosen as estimate of sick leave.
Sick leave (work) of partner		38.77 (per hour)	Guidelines of the Dutch Care Institute (2015). The price per hour for paid work and productivity loss for men was chosen as estimate of sick leave of partner.
Intervention costs		94.44 (per hour)	Guidelines of the Dutch Care Institute (2015). The price for (psychological) therapy per hour was used as estimate.

Note. [a] indexed at 2017

Appendices Chapter 7

Additional file 1.

Regression coefficients, standard errors, and summary information for parallel mediation models of condition on gradient of childbirth mode

		Consequent												
		M_1 (ΔFFMQ)				M_2 (ΔW-DEQ-A)				M_3 (ΔCLP)				Y (Gradient of Childbirth Mode)		
Antecedent		Coeff.	*SE*	*p*		Coeff.	*SE*	*p*		Coeff.	*SE*	*p*		Coeff.	*SE*	*p*
X (COND)	a_1	9.367	1.963	< 0.001	a_2	-10.992	3.942	0.006	a_3	-7.025	1.951	< 0.001	c_1	-0.515	0.263	0.053
M1 (ΔFFMQ)		—	—	—		—	—	—		—	—	—	b_1	-0.035	0.012	0.004
M2 (ΔW-DEQ-A)		—	—	—		—	—	—		—	—	—	b_2	0.011	0.007	0.108
M3 (ΔCLP)		—	—	—		—	—	—		—	—	—	b_3	-0.014	0.014	0.328
Constant	i_{M1}	-2.529	1.407	0.075	i_{M2}	-16.811	2.825	< 0.001	i_{M3}	-5.868	1.399	< 0.001	i_Y	1.964	0.200	< 0.001
		R_2 = 0.175				R_2 = 0.068				R_2 = 0.108				R_2 = 0.210		
		F(1,107) = 22.765,				F(1,107) = 7.776,				F(1,107) = 12.961,				F(4,104) = 12.961,		
		p < 0.001				p = 0.006				p < 0.001				p < 0.001		

*Note. N = 109.*Δ: difference in post-assessment - pre-assessment; *a* = path of X variable to mediator; *b* = path of mediator to outcome *Y*; c1 = direct effect path; CLP = Catastrophizing Labour Pain; FFMQ = Five Facet Mindfulness Questionnaire; W-DEQ-A = Wijma Delivery Expectations Questionnaire.
Coefficients are unstandardized.

Additional file 2.

Regression coefficients, Standard Errors, and summary information for five FFMQ subscales mediating the condition on gradient of childbirth mode

Effect	Gradient of childbirth mode		
	b	***SE(b)***	**95% CI**
ΔNOR			
a	1.677*	0.814	[-1.074, 1.219]
b	-0.087**	0.027	[-0.140, -0.033]
c1	-0.729**	0.234	[-1.192, -0.266]
R2		0.187	
F(2, 108)		12.423***	
ΔNOJ			
a	2.083*	0.868	[0.362, 3.803]
b	-0.040	0.026	[-0.092, 0.012]
c1	-0.791**	0.244	[-1.274, -0.308]
R2		0.128	
F(2, 108)		7.929***	
ΔDES			
a	2.030***	0.583	[0.877, 3.185]
b	-0.053	0.039	[-0.131, 0.025]
c1	-0.766**	0.251	[-1.264, -0.269]
R2		0.124	
F(2, 108)		7.665***	
ΔOBS			
a	0.842	0.575	[-0.299, 1.982]
b	-0.096*	0.039	[-0.173, -0.019]
c1	-0.793**	0.236	[-1.260, -0.326]
R2		0.157	
F(2, 108)		10.067***	
ΔACT	2.317**	0.729	[0.871, 3.762]
a	-0.004	0.032	[-0.067, 0.058]
b	-0.865***	0.251	[-1.362, -0.368]
c1		0.110	
R2		6.643**	
F(2, 108)			

Note. *N* =111. Δ: difference in post-assessment - pre-assessment; ACT = Acting with awareness; DES = Describing; FFMQ = Five Facet Mindfulness Questionnaire; NOJ = Nonjudging of inner experience; NOR = Non-reactivity to inner experience; OBS = Observing. A Coefficients are unstandardized (*b*).
*$p \leq 0.05$, **$p < 0.01$, ***$p < 0.001$.

Additional file 3.

Regression coefficients, Standard Errors, and summary information for the 5 FFMQ subscales parallel mediation of condition on gradient of childbirth mode

		Consequent									
		M_1 (ΔNOR)				M_2 (ΔNOJ)				M_3 (ΔDES)	
		Coeff.	*SE*	*p*		Coeff.	*SE*	*p*		Coeff.	*SE*	*p*
Antecedent											
X (COND)	a_1	1.677	0.814	0.042	a_2	2.083	0.868	0.012	a_3	2.030	0.582	< 0.001
M_1 (ΔNOR)		---	---	---		---	---	---		---	---	---
M_2 (ΔNOJ)		---	---	---		---	---	---		---	---	---
M_3 (ΔDES)		---	---	---		---	---	---		---	---	---
M_4 (ΔOBS)		---	---	---		---	---	---		---	---	---
M_5 (ΔACT)		---	---	---		---	---	---		---	---	---
Constant	i_{M1}	0.073	0.579	0.900	i_{M2}	-0.636	0.617	0.304	i_{M3}	-0.690	0.414	0.098
		R^2 = 0.038				R^2 = 0.050				R^2 = 0.100		
		F(1,109) = 4.241,				F(1,109) = 5.758,				F(1,109) = 12.147,		
		p = 0.042				p = 0.019				p < 0.001		

Note. N =111.Δ: difference in post-assessment - preassessment; ; a = path of X variable to mediator; b = path of mediator to outcome Y; c^1 = direct effect path; ACT = Acting with awareness; DES = Describing; FFMQ = Five Facet Mindfulness Questionnaire; NOJ = Nonjudging to inner experience; NOR = Nonreactivity to inner experience; OBS = Observing.

[a] Coefficients are unstandardized.

	M_4 (ΔOBS)				M_5 (ΔACT)				Y (Gradient of childbirth mode)		
	Coeff.	***SE***	***p***		**Coeff.**	***SE***	***p***		**Coeff.**	***SE***	***p***
a_4	0.842	0.575	0.147	a_5	2.317	0.729	0.002	c_1	-0.629	0.250	0.014
	---	---	---		---	---	---	b_1	-0.072	0.029	0.016
	---	---	---		---	---	---	b_2	-0.042	0.026	0.119
	---	---	---		---	---	---	b_3	-0.001	0.041	0.982
	---	---	---		---	---	---	b_4	-0.074	0.039	0.063
	---	---	---		---	---	---	b_5	0.011	0.032	0.731
i_{M4}	-0.127	0.409	0.756	i_Y	-0.727	0.518	0.163	i_Y	1.922	0.165	<0.001
	R^2 = 0.019				R^2= 0.085				R^2= 0.230		
	$F(1,109)$ = 2.139,				$F(1,109)$ = 10.091,				$F(6,104)$ = 5.168,		
	p = 0.147				p = 0.002				p < 0.001		

SUMMARY

On fear of childbirth and mindfulness

Fear of childbirth (FOC) is a prevalent emotion causing suffering in pregnant women and disabling their adaptation to childbirth process. However, FOC remains undetected and untreated in the Dutch midwifery care. The aims of this thesis were to examine how to improve assessment and treatment of FOC under the care of midwives.

In *Chapter 1*, we introduced the relevant key-points for non-clinical assessment and treatment of fear of childbirth. Firstly, the brief insight into the organization of the Dutch midwifery healthcare system, with its specific features, was presented. Next, the theoretical framework of fear of childbirth as the foundation for this dissertation was described - fear of childbirth as a fundamental, evolutionary and multidimensional emotion. Further, the existing assessment of fear of childbirth, its prevalence and relationship with mental health in general, and the risk factors and consequences of fear of childbirth were highlighted. Also, the distressing problem of Dutch midwifery care to historically neglect fear of childbirth was raised. Nevertheless, to situate this work within a current body of literature, the existing research on non-clinical treatment of fear of childbirth was viewed, and a more universal approach to treatment of fear of childbirth was presented. Finally, a short introduction of Mindfulness-Based Programs in treating fear and anxiety in different populations was provided, as well as the extant literature's effects of the Mindfulness-Based Childbirth and Parenting (MBCP) program. Based on these key-points, we presented the objectives of this dissertation.

In *Chapter 2,* we explored whether labour pain cognitions may predict a poor pain coping behaviour in the first stage of labour - defined as a request for pain relief - in low-risk nulliparous pregnant women. To do so, a concomitant evaluation of catastrophizing labour pain, external and internal labour pain control, and coping with labour pain was performed. We assessed several measures: first, about six weeks before the onset of labour, the labour pain cognitions; second, during the actual labour, the eventual request for pain relief; third, the labour pain intensity experienced at the time of the request, or in the case of non-request, the labour pain intensity experience at the time of full dilatation of the cervix; and fourth, mode of childbirth. To analyse whether and which labour pain cognition was the strongest predictor of the request of pain relief during early labour, logistic hierarchical predictions models were used. We found that catastrophizing about labour pain (endorsing disaster scenarios) and external labour pain control (shifting responsibility for coping with pain to external persons) predicted the request for pain relief during labour after adjusting for relevant demographic and clinical characteristics such as labour pain intensity and the length of dilation period. Catastrophizing was found to be the strongest and independent predictor among the labour pain cognitions while controlling for significant background variables. Additionally, we found that women who requested pain relief had a longer dilatation period and more medical interventions during labor than women who did not. Further, we observed that the educational level or attendance at an antenatal class, even

continued support from the midwife or the doula during labor, had no relationship to the beneficial adaptation to labor pain. With this study, we attempted to provide more insight into the role of pregnant women's expectations about labour pain in the adaptation to labour. These findings might support the suggestion that catastrophizing is an inherent pain cognition and requires intense guidance in order to improve the childbirth outcomes. These findings may imply the need of MBCP in order to change the fearful mindset of pregnant women forward their childbirth.

In *Chapter 3*, we examined whether the commonly used 33-items Wijma Delivery Expectation Questionnaire (W-DEQ-A) and the newly one-item Fear of Childbirth-Postpartum-Visual Analogue Scale (FOCP-VAS), at the level of high fear of childbirth, were useful tools in predicting pregnant women-requested and received non-urgent obstetric interventions during childbirth. To do this, we assessed W-DEQ-A and FOCP-VAS at two timepoints in pregnancy. We found that high fear of childbirth based on W-DEQ-A (≥66) corresponded with FOCP-VAS ≥5. Following childbirth, we derived from medical files the pregnant women's requests and actual use of non-urgent obstetric interventions such as epidural analgesia and self-requested caesarean section. We used hierarchical logistics regression models to evaluate the predictive value of high fear of childbirth based on these measures in identifying pregnant women's requests and use of non-urgent obstetric interventions during childbirth. We found that FOCP-VAS≥5 was the strongest predictor for requested and received non-urgent obstetric interventions. W-DEQ-A≥66 did not contribute over and above FOCP-VAS≥5 to the prediction of non-urgent obstetric interventions. Contrarily, when reversing the sequence of analysis, FOCP-VAS≥5 was still significantly predictive of non-urgent obstetric interventions during pregnancy and labour, over and above W-DEQ-A≥66. With this study, it was shown that the requests and use of non-urgent obstetric interventions could already be predicted in the first half of pregnancy by means of a simple fear of childbirth assessment. Specifically, this study showed that the one-item assessment (FOCP-VAS) of current appraisal of fear of childbirth and the postpartum period was the strongest identifier of non-urgent obstetric intervening in pregnant women. We suggested implementing this easy-to-use one-item screening tool in midwifery care in order to improve mode of childbirth.

In *Chapter 4*, we presented our study protocol for a randomized controlled trial for evaluating the effects of the Mindfulness-Based Childbirth and Parenting (MBCP) program in pregnant women with high FOC. In this protocol study, we described the impetus for this research such as high prevalence of FOC, its far-reaching negative consequences for both mother and child and childbirth, poor management of fear of childbirth in Dutch midwifery care as well as the worldwide increase of the use of non-urgent obstetric interventions during childbirth. We suggested, given the existing literature, MBCP would be more effective on the reduction of high fear of childbirth and on the increase in unmedicated childbirths than an enhanced care as usual (ECAU).

We presented a model of avoiding versus approaching the challenges of childbirth in pregnant women with high fear of childbirth. In this model, we identified mechanisms of action on which MBCP may operate in enabling pregnant women with high fear of childbirth to have an unmedicated childbirth. We have defined a couples of aims of which some are presented in this thesis: 1) to assess the effects of MBCP, as compared to ECAU, on the primary outcome measures of fear of childbirth, labour pain, and willingness to accept obstetric interventions without medical indications in pregnant women with a high fear of childbirth; 2) to assess the effects of MBCP, as compared to ECAU to examine overall mindful awareness, fear of childbirth, and catastrophic beliefs as possible mediating mechanisms underlying the effectiveness of MBCP; 3) to assess the costs of healthcare use due to fear of childbirth and cost-effectiveness of MBCP as compared to ECAU. We suggested to examine these aims examined in three time periods: a) during pregnancy, b) after labour, and c) during the maternity leave period following the birth. Further, we described extensively the methods of the study and the relevance of the significant improvements if founded.

In *Chapter 5*, we investigated whether MBCP or ECAU for expectant couples decreases fear of childbirth and non-urgent obstetric interventions during childbirth and improves newborn outcomes by means of a randomized controlled trial. We found that nine weeks of MBCP was significantly superior to ECAU in decreasing fear of childbirth, catastrophizing of labor pain, preference for non-urgent obstetric interventions, and increasing acceptance of labor pain and unmedicated childbirths. MBCP participants were: one third less likely to undergo epidural anesthesia; half less likely to undergo self-requested caesarean section; and twice as likely to have unmedicated childbirth relative to ECAU. Newborn's 1-minute Apgar scores - an assessment of new-borns' vitality - were higher in MBCP. After correcting for multiple testing, results remained significant in the intention-to-treat and per-protocol analyses, except with epidural anesthesia and 1-minute Apgar. We presented these findings using clinical effects.

In *Chapter 6*, we evaluated the cost-effectiveness of MBCP compared to ECAU. Costs were measured using a retrospective cost-questionnaire, including health care and non-health care costs during pregnancy, childbirth and postpartum, from a bottom-up perspective (i.e., each Euro was counted). The scores on the W-DEQ-A (measuring FOC) and the EQ-5D (measuring quality of life) scores were used as measures of effect in the primary analyses. In the secondary analyses, different estimates of effects and costs were considered to test the robustness of the primary analyses. We found that MBCP had more effects and lower costs with the high probability of MBCP to be cost-effective (at a willingness to pay of zero). Results of the cost-effectiveness analyses indicated this in all-but-one scenario (i.e., decrease in depressive symptoms). Findings indicate that MBCP is a cost-effective intervention to treat FOC in pregnant women. We recommended replicating the study findings in other countries with other health care systems, and to see how MBCP can be further implemented in midwifery care.

In *Chapter 7*, we explored through which pathway of action MBCP was effective in increasing unmedicated childbirths in pregnant women with high fear of childbirth. We based this analyses on a model of approaching or avoiding the challenges related to childbirth. We collected data pre-and post-interventions on fear of childbirth (emotional pathway), catastrophic beliefs about labour pain (cognition pathway) and mindful awareness (attention pathway) to examine through which of these three pathways the mechanism of change leads to unmedicated childbirth. We found that greater mindful awareness was the only significant mechanism of change operating through the attentional pathway leading to unmedicated, thus, natural childbirth. More, specifically, nonreactivity to inner experience (a facet of mindful awareness) showed to be the strongest mechanism of change. Also, we observed that more extensive meditation practice was positively associated with natural childbirth. This study showed that an increase in mindful awareness has a causal relationship with a better adaptation to the challenges of childbirth. Decreases in neither fear of childbirth nor catastrophic beliefs about labour pain were identified as mechanisms of change. These findings deepen our understanding of how non-reactivity to inner experience in childbirth helps one adapt to this process.

In *Chapter 8*, I discussed the main findings of the present thesis and our conceptual ideas as presented in *Chapter 1*. We found that a simple assessment of FOC is a valid one and that MBCP is effective in decreasing FOC and in increasing adaptation to childbirth expressed by more chance for an unmedicated childbirth. MBCP seems to be a cost-effective intervention for use in midwifery care. The working ingredient of MBCP to better adapt to childbirth seems to be an increase in mindful awareness. Based on these findings, an important recommendation for future studies is to evaluate MBCP versus CBT in order to improve the treatment of anxiety in pregnant women. Lastly, our findings were also situated in the perspective of our conceptual ideas, such as: a general approach to assessing FOC; the use of a multidimensional approach to treating FOC in non-clinical settings; the historical neglect of FOC in midwifery care, strengths and limitations of this thesis; and clinical implications.

SAMENVATTING
DUTCH SUMMARY

Over angst voor de bevalling en mindfulness

Angst voor de bevalling is een veel voorkomende emotie die lijden bij zwangere vrouwen veroorzaakt en hun aanpassing aan het bevallingsproces belemmert. Angst voor de bevalling blijft echter onopgemerkt en onbehandeld in de Nederlandse verloskundige zorg. Het doel van dit proefschrift was om te onderzoeken hoe de vaststelling en behandeling van angst voor de bevalling onder de verantwoordelijkheid van verloskundigen kan worden verbeterd.

In *hoofdstuk 1* hebben we de relevante kernpunten voor niet-klinische vaststelling en behandeling van angst voor de bevalling geïntroduceerd. Ten eerste is een kort overzicht gepresenteerd van de organisatie van het Nederlandse verloskundige zorgstelsel, met zijn specifieke kenmerken. Vervolgens werd het theoretische kader van angst voor de bevalling als basis voor dit proefschrift beschreven - angst voor de bevalling als een fundamentele, evolutionaire en multidimensionale emotie. Verder werden de bestaande methoden van vaststelling van angst voor de bevalling, de prevalentie en relatie met geestelijke gezondheid van zwangeren in het algemeen, en de risicofactoren en gevolgen van angst voor de bevalling besproken. Ook het schrijnende probleem dat de Nederlandse verloskundige zorg de angst voor de bevalling aanhoudend onderschat, werd aan de orde gesteld. Om deze thesis binnen de huidige literatuur beter te plaatsen, werd het bestaande onderzoek naar niet-klinische behandeling van angst voor de bevalling samengevat en werd een meer universele benadering van de behandeling van angst voor de bevalling gepresenteerd. Tot slot werd een korte introductie van Mindfulness-Based Programs voor de behandeling van angst in verschillende populaties gepresenteerd, evenals de bestaande literatuur over de effecten van het Mindfulness-Based Childbirth and Parenting (MBCP) programma. Op basis van deze kernpunten zijn de doelstellingen van dit proefschrift geformuleerd.

In *hoofdstuk 2* onderzochten we of baringspijncognities een falend pijncoping gedrag, gedefinieerd als een verzoek om pijnbestrijding in de eerste fase van de bevalling, kunnen voorspellen bij laag risico nullipare zwangere vrouwen. Hiervoor hebben we een gelijktijdige evaluatie van catastroferen over baringspijn, externe en interne baringspijnbeheersing en de coping met baringspijn uitgevoerd. Verschillende metingen vonden plaats: (1) ongeveer zes weken voor het begin van de bevalling werden de baringspijn cognities vastgesteld; (2) tijdens de bevalling werd het uiteindelijke verzoek om pijnbestrijding genoteerd; (3) de intensiteit van de baringspijn die op het moment van het verzoek ervaren werd, of in het geval van geen verzoek, de ervaring van de baringspijnintensiteit op het moment van de volledige ontsluiting werden gevraagd; en (4) de wijze van bevalling werd aan de medische dossiers ontleend. Om te analyseren of en welke baringspijncognitie de sterkste voorspeller was van het verzoek om pijnbestrijding al tijdens het begin van de bevalling, werden logistische hiërarchische voorspellingsmodellen gebruikt. We ontdekten dat catastroferen over

baringspijn (rampscenario's) en externe baringspijnbeheersing (het verschuiven van de verantwoordelijkheid voor het omgaan met baringpijn naar externe personen) het verzoek om pijnbestrijding tijdens de bevalling voorspelden (na correctie voor relevante demografische en klinische kenmerken zoals de intensiteit van de baringsspijn en de lengte van de ontsluitingsperiode). Catastroferen over baringspijn bleek de sterkste en onafhankelijke voorspeller te zijn onder de baringspijncognities, ook na het controleren op significante achtergrondvariabelen. Bovendien ontdekten we dat vrouwen die pijnbestrijding vroegen een langere ontsluitingsperiode en meer medische interventies tijdens de bevalling hadden dan vrouwen die dat niet deden. Verder merkten we op dat het opleidingsniveau of de deelname aan een zwangerschapscursus, en ook continue ondersteuning van de verloskundige of de doula tijdens de bevalling, geen relatie had met betere aanpassing aan baringspijn. Met deze studie probeerden we meer inzicht te geven in de rol van de baringspijncognities (verwachtingen ten aanzien van baringspijn) van zwangere vrouwen in de adaptatie aan de bevalling. Deze bevindingen kunnen de suggestie ondersteunen dat catastroferen een inherente pijncognitie is, die een intensieve begeleiding vereist om de uitkomsten van de bevalling te kunnen verbeteren. De bevindingen kunnen wijzen op de noodzaak van de inzet van MBCP om de angstige mindset van zwangere vrouwen te kunnen veranderen.

In *hoofdstuk 3* onderzochten we of de veelgebruikte 33-items Wijma Delivery Expectation Questionnaire (W-DEQ-A) en de nieuwe one-item Fear of Childbirth-Postpartum-Visual Analogue Scale (FOCP-VAS), bij hoge angst voor de bevalling, nuttige hulpmiddelen waren bij het voorspellen van door zwangere vrouwen aangevraagde en ontvangen niet-dringende obstetrische interventies tijdens de bevalling. Om dit te doen, namen we W-DEQ-A en FOCP-VAS af op twee tijdstippen in de zwangerschap. We ontdekten dat hoge angst voor de bevalling op basis van W-DEQ-A (≥66) overeenkwam met FOCP-VAS ≥5. Na de bevalling hebben we uit medische dossiers de verzoeken van zwangere vrouwen en het daadwerkelijke ontvangen van niet-dringende obstetrische ingrepen zoals epidurale analgesie en zelf aangevraagde keizersnede afgeleid. Door middel van hiërarchische logistische regressiemodellen is de voorspellende waarde van hoge angst voor de bevalling voor verzoeken van zwangere vrouwen en het gebruik van niet-dringende obstetrische interventies tijdens de bevalling geëvalueerd. We ontdekten dat FOCP-VAS≥5 de sterkste voorspeller was voor aangevraagde en ontvangen niet-dringende verloskundige interventies. W-DEQ-A≥66 droeg niet meer dan FOCP-VAS≥5 bij aan de voorspelling van niet-dringende obstetrische interventies. Integendeel, bij het omkeren van de volgorde van analyse was FOCP-VAS≥5 nog steeds significant voorspellend voor niet-dringende obstetrische interventies tijdens zwangerschap en bevalling, beter dan W-DEQ-A≥66. Met dit onderzoek werd aangetoond dat de verzoeken en het gebruik van niet-dringende obstetrische interventies tijdens de bevalling al in de eerste helft van de zwangerschap konden worden voorspeld door middel van een eenvoudige vraag naar angst voor de bevalling. Specifiek toonde deze studie aan dat het one-item assessment (FOCP-VAS) van de eigen beoordeling van

angst voor de bevalling en de postpartumperiode de sterkste determinant was van niet-dringende obstetrische interventie bij zwangere vrouwen. We stelden voor om deze eenvoudige één item screeningstool te gebruiken in de verloskundige zorg te om de zorg rondom de bevalling te verbeteren.

In *hoofdstuk 4* presenteerden we ons studieprotocol voor een gerandomiseerde en gecontroleerde studie voor het evalueren van de effecten van het Mindfulness-Based Childbirth and Parenting (MBCP) programma bij zwangere vrouwen met een hoge angst voor de bevalling. In dit onderzoeksprotocol beschreven we de aanleiding voor dit onderzoek zoals de hoge prevalentie van angst voor de bevalling, de verstrekkende negatieve gevolgen voor zowel moeder als kind en het verloop van de bevalling, het inadequaat omgaan met angst voor de bevalling in de Nederlandse verloskundige zorg en de wereldwijde toename van het gebruik van niet-dringende obstetrische interventies tijdens de bevalling. We suggereerden, gezien de bestaande literatuur, dat MBCP meer effectief zou kunnen zijn in het verminderen van hoge angst voor de bevalling en op de toename van niet-medische bevallingen dan een aangepaste gebruikelijke verloskundige zorg (ECAU). We presenteerden het theoretische model van het vermijden versus benaderen van de uitdagingen van de bevalling bij zwangere vrouwen met een hoge angst voor de bevalling. In dit model identificeerden we werkingsmechanismen waarop MBCP zou kunnen werken om zwangere vrouwen met een hoge angst voor de bevalling in staat te stellen een niet-medische bevalling te ondergaan. We hebben een aantal onderzoeksdoelen gedefinieerd waarvan sommige in dit proefschrift worden gepresenteerd: 1) het beoordelen van de effecten van MBCP in vergelijking met ECAU op de primaire uitkomstmaten zoals angst voor de bevalling, catastroferen en accepteren van baringspijn, en bereidheid om obstetrische interventies zonder medische indicaties te accepteren bij zwangere vrouwen met een hoge angst voor de bevalling; 2) het beoordelen van de effecten van MBCP in vergelijking met ECAU van het open bewustzijn, de angst voor de bevalling en catastrofale overtuigingen te onderzoeken als mogelijke werkende mechanismen die ten grondslag liggen aan de effectiviteit van MBCP; 3) de kosten van het gebruik van de gezondheidszorg als gevolg van angst voor de bevalling en de kosteneffectiviteit van MBCP in vergelijking met ECAU te beoordelen. We stelden voor om deze onderzoeksdoelen in drie tijdsperioden te onderzoeken: a) tijdens de zwangerschap, b) na de bevalling en c) tijdens de zwangerschapsverlofperiode na de geboorte. Verder hebben we de geplande onderzoeksmethoden en de relevantie van de eventuele significante verbeteringen uitgewerkt.

In *hoofdstuk 5* onderzochten we in een gerandomiseerde en gecontroleerde studie of MBCP dan wel ECAU de angst voor bevalling en niet-dringende obstetrische interventies tijdens de bevalling bij de aanstaande ouders vermindert en de gezondheidsuitkomsten van pasgeborenen verbetert. We ontdekten dat negen weken MBCP significant superieur was aan ECAU in het verminderen van angst voor de bevalling, catastroferen

over baringspijn, niet-dringende obstetrische interventies en het vergroten van de acceptatie van baringspijn en niet-medische bevallingen. MBCP-deelnemers hadden: een derde minder kans om epidurale anesthesie te ondergaan; de helft minder kans om een zelf aangevraagde keizersnede te ondergaan; en twee keer zoveel kans op een niet-medische bevalling in vergelijking met ECAU. De Apgar-scores bij 1 minuut van pasgeborenen - een beoordeling van de vitaliteit - waren hoger in MBCP. Na correcties met multipele tests bleven de resultaten significant in de intentie-om-te-behandelen en per-protocol analyses, behalve bij epidurale anesthesie en 1 minuut Apgar score. We presenteerden deze bevindingen met behulp van klinische maten.

In *hoofdstuk 6* evalueerden we de kosteneffectiviteit van MBCP in vergelijking met ECAU. De kosten werden gemeten met behulp van een retrospectieve kostenenquête, inclusief kosten voor gezondheidszorg en niet-gezondheidszorg tijdens de zwangerschap, bevalling en het postpartum, vanuit een bottom-up perspectief (d.w.z. elke euro werd geteld). De scores op de W-DEQ-A (measuring FOC) en de EQ-5D (measuring quality of life) scores werden gebruikt als effectmetingen in de primaire analyses. In de secundaire analyses werden verschillende schattingen van effecten en kosten overwogen om de robuustheid van de primaire analyses te testen. We ontdekten dat MBCP meer effecten en lagere kosten had met een grote kans dat MBCP kosteneffectief was (bij een bereidheid om te betalen van nul). Resultaten van de kosteneffectiviteitsanalyses gaven dit aan in alle scenario's op één na (d.w.z. afname van depressieve symptomen). Bevindingen geven aan dat MBCP een kosteneffectieve interventie is om angst voor de bevalling bij zwangere vrouwen te behandelen. We hebben aanbevolen om de onderzoeksresultaten te repliceren in andere landen met andere gezondheidszorgsystemen en om te verkennen hoe MBCP verder kan worden geïmplementeerd in de verloskundige zorg.

In *hoofdstuk 7* onderzochten we via welk werkingsmechanisme MBCP effectief was in het verhogen van niet-medische bevallingen bij zwangere vrouwen met een hoge angst voor de bevalling. We hebben deze analyses gebaseerd op het theoretische model van het benaderen of vermijden van de uitdagingen met betrekking tot de bevalling. We verzamelden gegevens voor en na interventies, zoals angst voor de bevalling (emotioneel mechanisme), catastrofale overtuigingen over baringspijn (cognitie mechanisme) en het open bewustzijn (aandacht mechanisme) om te onderzoeken welk van deze drie paden tot niet-medische bevallingen zou kunnen leiden. We ontdekten dat een ruimer open bewustzijn het enige significante werkingsmechanisme was, dat opereerde via het aandachtspad en leidde tot niet-medische, dus natuurlijke bevalling. Meer specifiek bleek niet reactief zijn op innerlijke ervaring (een facet van open bewustzijn) het sterkste mechanisme van verandering te zijn. Ook zagen we dat een uitgebreidere meditatiebeoefening positief gecorreleerd was met een natuurlijke bevalling. Deze studie toonde aan dat een toename van open bewustzijn een oorzakelijk verband heeft met een betere aanpassing aan de uitdagingen van de bevalling. Afnames in

noch angst voor de bevalling, noch catastrofale overtuigingen over baringspijn werden geïdentificeerd als mechanismen van verandering. Deze bevindingen verdiepen ons begrip van hoe niet-reactief zijn op innerlijke ervaring bij de bevalling iemand helpt zich aan te passen aan dit proces.

In *hoofdstuk 8* besprak ik de belangrijkste bevindingen van dit proefschrift en onze conceptuele ideeën zoals gepresenteerd in *hoofdstuk 1*. We ontdekten dat een eenvoudige beoordeling van angst voor de bevalling een relevante voorspeller is en dat MBCP effectief is in het verminderen van angst voor de bevalling en in het bevorderen van de aanpassing aan de bevalling, uitgedrukt door meer kans op een niet-medische bevalling. MBCP lijkt een kosteneffectieve interventie te zijn voor toepassing in de verloskundige zorg. Het werkende mechanisme van MBCP om zich beter aan te passen aan de bevalling lijkt een toename van open bewustzijn te zijn. Op basis van deze bevindingen is een belangrijke aanbeveling voor toekomstige studies om MBCP versus cognitieve gedragstherapie te evalueren om de behandeling van angst bij zwangere vrouwen te verbeteren. Ten slotte werden onze bevindingen ook beschreven in het perspectief van onze conceptuele ideeën, zoals: een algemene benadering van het beoordelen van angst voor de bevalling; het gebruik van een multidimensionale benadering voor de behandeling van angst voor de bevalling in niet-klinische setting; de consequente onderschatting van angst voor de bevalling in de verloskundige zorg, sterke punten en beperkingen van dit proefschrift; en de klinische implicaties van de bevindingen.

PUBLICATIONS AND AUTHORSHIP CONTRIBUTIONS

Chapter 2

Veringa I, Buitendijk S, De Miranda E, De Wolf S, Spinhoven P. Pain cognitions as predictors of the request for pain relief during the first stage of labor: A prospective study. J Psychosom Obstet Gynecol. 2011;32(3):119–25. DOI: 10.3109/0167482X.2011.599898

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Chapter 3

Veringa-Skiba, I. K., de Bruin, E. I., Mooren, B., van Steensel, F. J. A., & Bögels, S. M. (2021). Can a simple assessment of fear of childbirth in pregnant women predict requests and use of non-urgent obstetric interventions during labour? Midwifery, 97, 102969. https://doi.org/10.1016/j.midw.2021.102969

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Chapter 6

Francisca J.A. van Steensel, Irena K. Veringa-Skiba, Annick Sauer, Esther I. de Bruin, & Susan M. Bögels (2022). Mindfulness-Based Childbirth and Parenting (MBCP) programme versus Enhanced Care as Usual in pregnant women with high fear of childbirth: A cost-effectiveness study. Manuscript submitted.

Contributions: Veringa-Skiba, de Bruin, and Bögels designed and contributed to the original proposal (in the original protocol Dirksen contributed to the design of the cost-effectiveness data). Self-reported data collection, transporting data and building the dataset was done by Mooren, an independent research assistant. Sauer performed the literature search, co-wrote the introduction and method, and did the data cleaning. Data analyses and data interpretation were performed by van Steensel, who also wrote the first draft of the manuscript. Veringa-Skiba, de Bruin, Bögels and Sauer contributed to, and approved, the final draft.

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Chapter 7

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ABOUT THE AUTHOR
OVER DE AUTEUR

Irena Veringa-Skiba was born on July 16, 1965, in Gorzów Wielkopolski, Poland. In the beginning of her life, she grew up with her mother, her grandmother and one older brother. Her biological father died in a motorcycle accident three weeks before her birth. Later, her stepfather joined the family.

She obtained her high school diploma at the First General Lyceum, named after Madame Marie Skłodowska-Curie, in Szczecin, Poland (1984). Thereafter, she studied midwifery at the Medical Lyceum in Szczecin graduating *cum laude* and obtained a teaching position at that school (1987). In 1986, she met her future husband, Jan Veringa. They married, and she moved to the Netherlands in 1988. In 1989, she received the Certificate - Dutch as a Foreign Language from the Union for the Dutch Language. In the same year, her only daughter was born. Between 1990 and 1992, she graduated *cum laude* at the Midwifery Academy (Kweekschool voor Vroedvrouwen) in Amsterdam. In 1993, she started her own midwifery practice at Leidschendam-Voorburg, where she worked until 2016. During her work as a midwife, she graduated in 2010 as a Master of Science in Midwifery at the University of Amsterdam /Academic Medical Centre in Amsterdam. She began her PhD project in 2014 at the Research Institute of Child Development and Education on fear of childbirth and mindfulness of which the results are presented in this dissertation.

Further, since 2014, she has been active as a Mindfulness-Based Childbirth and Parenting trainer. In 2021, upon graduating from the first Institute for Mindfulness in the Netherlands (led by Johan Tinge), she received her diploma as a Mindfulness-Based Stress Reduction and Mindfulness-Based Cognitive Therapy trainer. In 2018, she founded the Mindfulness Institute for Maternity Healthcare to deliver knowledge obtained from her studies and clinical experience to the midwifery field.

Irena has continued being active in the field of midwifery. Since 2013, she gives lectures on labour pain from a neuroscientific perspective at the midwifery academies. Between 2010 and 2015, she was a board member of the National Knowledge Centre for Psychiatry and Pregnancy (Landelijke Kenniscentrum Psychiatrie en Zwangerschap), and between 2017 and 2020, she was a board member of the Childbirth Trauma Foundation (Stichting Bevallingstrauma).

Irena has been an active member of Soroptimist International (a global volunteer movement advocating for human rights and gender equality) since 2000. Besides, between 2001 and 2017, she was a member of the Board Working Party Sister Cities in Poland (Konstancin-Jeziorna) and the Netherlands (Leidschendam-Voorburg).

Irena Veringa-Skiba werd geboren op 16 juli 1965 in Gorzów Wielkopolski, Polen. In het begin van haar leven groeide ze op met haar moeder, haar grootmoeder en een oudere broer. Haar biologische vader stierf drie weken voor haar geboorte bij een motorongeluk. Later voegde haar stiefvader zich bij het gezin.

Ze behaalde haar middelbare schooldiploma aan het Eerste Algemene Lyceum, genoemd naar Madame Marie Skłodowska-Curie, in Szczecin, Polen (1984). Daarna studeerde ze verloskunde aan het Medisch Lyceum in Szczecin, studeerde *cum laude* af en kreeg op die school een baan als leraar (1987). In 1986 ontmoette ze haar toekomstige echtgenoot, Jan Veringa. Ze trouwden en ze verhuisde in 1988 naar Nederland. In 1989 ontving ze het Certificaat Nederlands als Vreemde Taal van de Unie voor de Nederlandse Taal. In hetzelfde jaar werd haar enige dochter geboren. Tussen 1990 en 1992 studeerde zij *cum laude* af aan de Kweekschool voor Vroedvrouwen in Amsterdam. In 1993 startte zij haar eigen verloskundigenpraktijk in Leidschendam-Voorburg, waar zij tot 2016 werkzaam was. Tijdens haar werk als verloskundige is zij in 2010 afgestudeerd als Master of Science in de verloskunde aan de Universiteit van Amsterdam/Academisch Medisch Centrum in Amsterdam. Ze begon in 2014 haar PhD-project over angst voor bevalling en mindfulness bij het Research Institute of Child Development and Education. De resultaten hiervan worden in dit proefschrift gepresenteerd.

Verder is zij sinds 2014 actief als trainer Mindfulness-Based Childbirth and Parenting. In 2021 behaalde zij na haar afstuderen aan het eerste Instituut voor Mindfulness in Nederland (onder leiding van Johan Tinge) haar diploma als trainer Mindfulness-Based Stress Reduction en Mindfulness-Based Cognitive Therapy. In 2018 richtte ze het Mindfulness Instituut voor de Geboortezorg op om de kennis die ze uit haar studies en klinische ervaring heeft opgedaan, over te dragen aan de verloskundigen.

Irena is nog steeds actief op het gebied van verloskunde. Sinds 2013 geeft ze colleges over baringspijn vanuit een neurowetenschappelijk perspectief aan de verloskundige academies. Van 2010 tot 2015 was zij bestuurslid van het Landelijke Kenniscentrum Psychiatrie en Zwangerschap en van 2017 tot 2020 bestuurslid van Stichting Bevallingstrauma.

Irena is sinds 2000 actief lid van Soroptimist International (een wereldwijde vrijwilligersbeweging die pleit voor mensenrechten en gendergelijkheid). Bovendien was ze tussen 2001 en 2017 lid van de Werkgroep Stedenband Konstancin-Jeziorna (Polen) en Leidschendam-Voorburg (Nederland).

Other publications

Potharst, E. S., Leyland, A., Colonnesi, C., Veringa-Skiba, I. K., Salvadori, E. A., Jakschik, M., Bögels, S. M., & Zeegers, M. A. J. (2021). Does Mothers' Self-Reported Mindful Parenting Relate to the Observed Quality of Parenting Behavior and Mother-Child Interaction? *Mindfulness*, *12*(2), 344–356. https://doi.org/10.1007/s12671-020-01533-0

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Zeegers, M. A. J., Potharst, E. S., Veringa-Skiba, I. K., Aktar, E., Goris, M., Bögels, S. M., & Colonnesi, C. (2019). Evaluating Mindful With Your Baby/Toddler: Observational Changes in Maternal Sensitivity, Acceptance, Mind-Mindedness, and Dyadic Synchrony. *Frontiers in Psychology*, *10*, 753. https://doi.org/10.3389/fpsyg.2019.00753