Gert A. Klabbers

CAN HAPTOTHERAPY REDUCE FEAR OF CHILDBIRTH?

Some first answers from a randomized controlled trial

Colophon

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Gerardus Antonie Klabbers,

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Promotiecommissie

Promotores
Prof. dr. A. J. J. M. Vingerhoets
Prof. dr. K. Wijma

Copromotor
Dr. K. M. Paarlberg

Overige leden
Prof. dr. J. Duyndam
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Renske Harte-Sluman

Content

1. Scope of the thesis
- 1.1. **Fear of childbirth** ... 13
- 1.2. **Haptotherapy** ... 14
- 1.3. **Structure of the thesis** ... 14
- 1.4. **References** ... 15

2. Severe fear of childbirth: Its features, assessment, prevalence, determinants, consequences and possible treatments
- 2.1. **Abstract** ... 21
- 2.2. **Introduction** ... 21
- 2.3. **Method** ... 22
- 2.4. **Definition and features** ... 22
- 2.5. **Clinical criteria** ... 24
- 2.6. **Assessment and measures** ... 24
- 2.7. **Prevalence** ... 25
- 2.8. **Determinants** ... 26
  - 2.8.1. Person characteristics ... 26
  - 2.8.2. Fear of pain ... 27
  - 2.8.3. Fear of being incapable of giving birth ... 27
  - 2.8.4. Fear of becoming a parent ... 27
  - 2.8.5. Abuse and trauma ... 27
  - 2.8.6. Socio-cultural factors ... 28
- 2.9. **Consequences** ... 28
  - 2.9.1. Sterilization ... 29
  - 2.9.2. Termination of pregnancy ... 29
  - 2.9.3. Caesarean section ... 29
  - 2.9.4. PTSD ... 30
- 2.10. **Treatment** ... 30
  - 2.10.1. Psychotherapeutic interventions ... 31
  - 2.10.2. Psycho-education ... 32
  - 2.10.3. Briefing ... 33
  - 2.10.4. Counselling ... 33
  - 2.10.5. Treatment in Aurora clinics ... 33
  - 2.10.6. Haptotherapy ... 34
  - 2.10.7. Treatment based on the PLISSIT model ... 34
  - 2.10.8. Negative outcomes ... 35
- 2.11. **Conclusion** ... 35
- 2.12. **References** ... 36

3. Treatment of severe fear of childbirth with haptotherapy: design of a multicenter randomized controlled trial

3.1. **Abstract** ... 45
3.1.1. Background ... 45
3.1.2. Methods/design ... 45
3.1.3. Discussion ... 45
3.1.4. Trail registration ... 45
3.2. **Background** ... 46
3.2.1. Characteristics of the women with fear of childbirth ... 46
3.2.2. State- and trait-anxiety ... 47
3.2.3. Consequences of severe FOC ... 47
3.2.4. Haptotherapy ... 48
3.2.4.1. *Changing the mindset* ... 49
3.2.4.2. *Changing body-awareness and self-awareness* ... 49
3.2.5. Aims ... 50
3.3. **Methods/Design** ... 51
3.3.1. Study participants ... 51
3.3.2. Ethical approval ... 51
3.3.3. Randomisation ... 51
3.3.4. Procedure ... 51
3.3.5. Measures ... 52
3.3.5.1. *Background variables* ... 52
3.3.5.2. *Fear of childbirth* ... 52
3.3.5.3. *Distress, anxiety, depression, somatization* ... 52
3.3.5.4. *Social support* ... 52
3.3.5.5. *Anxiety and depression* ... 53
3.3.5.6. *Emotional bonding* ... 53
3.3.5.7. *PTSD following childbirth* ... 54
3.3.5.8. *Birth complications* ... 54
3.3.6. Timing of measures ... 54
3.4. **Discussion** ... 56
3.4.1. The haptotherapeutic intervention ... 56
3.4.1.1. *The content of the sessions* ... 56
3.4.2. Psycho-education via Internet condition ... 58
3.4.3. Care as usual group ... 59
3.4.4. Low FOC comparison group ... 59
3.5. **Statistical analyses and power analysis** ... 59
3.5.1. Statistical analyses ... 59
3.5.2. Sample size calculation ... 59
3.6. **References** ... 61

4. Haptotherapy as a new intervention for treating fear of childbirth: a randomized controlled trial

4.1. **Abstract** ... 67
4.1.1. Objective ... 67
4.1.2. Design ... 67
4.1.3. Setting ... 67
4.1.4. Population or sample ... 67
4.1.5. Methods ... 67
4.1.6. Main outcome measures ... 67
4.1.7. Results ... 67
4.1.8. Conclusion ... 67
4.1.9. Clinical trial registration ... 67
4.2. **Introduction** ... 68
4.3. **Method** ... 69
4.3.1. Design ... 69
4.3.2. Interventions ... 69
4.3.2.1. *Haptotherapy* ... 69
4.3.2.2. *Psycho-education via the Internet* ... 70
4.3.2.3. *Care as usual* ... 70
4.3.3. Measures ... 70
4.3.4. Procedure ... 71
4.3.5. Statistical analyses ... 71
4.3.5.1. *Intention to treat analyses* ... 71
4.3.5.2. *Power analysis* ... 72
4.3.5.3. *Effect of treatment as received* ... 72
4.4. **Results** ... 72
4.4.1. Sample characteristics ... 72
4.4.2. Baseline characteristics ... 74
4.4.3. Effect of haptotherapy ... 74
4.4.3.1. *Intention to treat analysis* ... 74
4.4.3.2. *As-treated analysis* ... 75
4.4.4. Secondary data analyses ... 76
4.5. **Discussion** ... 77
4.5.1. Proposed mechanism ... 78
4.5.2. Limitations ... 79
4.5.3. Strengths ... 79
4.5.4. Recommendations for future research ... 79
4.6. **Conclusion** ... 80
4.7. **References** ... 81

5. Resistance to fear of child birth and stability of mother-child bond
5.1. **Abstract** ... 89
5.2. **Background** ... 89
5.3. **Methods** ... 91
5.3.1. Design and procedure ... 91
5.3.2. Study participants ... 91
5.4. **Measures** ... 91
5.4.1. Pictorial Representation of Attachment Measure ... 91
5.4.2. Wijma Delivery Expectancy/Experience Questionnaire ... 92
5.4.3. Four-Dimensional Symptom Questionnaire ... 92
5.4.4. Social Support Questionnaire ... 92
5.4.5. Biographic characteristics ... 93
5.5. **Statistical analyses** ... 93
5.6. **Results** ... 93
5.7. **Discussion** ... 97
5.7.1. Limitations ... 99
5.7.2. Recommendations ... 99
5.8. **Conclusion** ... 99
5.9. **References** ... 100
6. Does haptotherapy benefit mother-child bonding?
6.1. **Abstract** ... 107
6.1.1. Objective ... 107
6.1.2. Population or sample ... 107
6.1.3. Main outcome measures ... 107
6.1.4. Results ... 107
6.1.5. Conclusion ... 107
6.2. **Introduction** ... 108
6.3. **Method** ... 108
6.3.1. Design ... 108
6.3.1.1. Design of the original research protocol ... 108
6.3.1.2. Design of this study ... 109
6.3.2. Measures ... 109
6.3.3. Interventions ... 110
6.3.4. Statistical analyses ... 111
6.4. **Results** ... 111
6.5. **Discussion** ... 114
6.6. **Conclusion** ... 116
6.7. **References** ... 117

7. General discussion
7.1. **Research questions** ... 121
7.2. **Discussion of the results** ... 121
7.3. **Proposed working mechanism in HT** ... 123
7.3.1. Specific factors ... 124
7.3.2. Non-specific factors ... 124
7.3.3. Non-specific factors that are regarded as specific in HT ... 125
7.4. **Strengths and limitations** ... 125
7.5. **Suggestions for future research** ... 126
7.6. **Conclusion** ... 126
7.7. **References** ... 127

Appendices
A: Summary in English ... 133
B: Summary in Dutch (Nederlandse samenvatting) ... 137
C: List of abbreviations ... 141
D: Co-authors and their affiliations ... 143
E: List of publications ... 145
F: Guideline haptotherapy in women with severe fear of childbirth in Dutch (Richtlijn haptotherapie bij bevallingsangst) ... 147
G: Acknowledgements in Dutch (Dankwoord) ... 155
H: About the author in Dutch (Over de auteur) ... 159
I: About the author in English ... 161

1. SCOPE OF THE THESIS

1.1 Fear of childbirth

Although pregnancy is generally associated with positive feelings, this is not always the case for every woman. Approximately 10% of pregnant women suffer from severe fear of childbirth (FOC).[1-7] The etiology of FOC is likely to be multi-factorial and may be related to a more general proneness to anxiety, as well as to specific fears.[8-16] Women with severe FOC need special care because they and their newborns are at increased risk of various complications, such as pre-term delivery,[17, 18] gestational hypertension and pre-eclampsia,[19] emergency caesarean section,[20] extra use of pain medication during delivery,[21, 22] low birthweight,[23] prolonged delivery, increased risk of postpartum post-traumatic stress and depression,[24] and later-on emotional and behavioural problems of the child.[23]

Several studies have evaluated interventions designed to reduce FOC.[25] Saisto et al. studied group psycho-education consisting of information and discussion of previous obstetric experiences, current feelings, and misconceptions.[26] Rouhe et al. compared group psycho-education including relaxation exercises with conventional care.[27, 28] Toolhill et al. studied individual psycho-education by telephone in women with moderate to severe FOC.[29] Nieminen et al. performed a feasibility study for an Internet-delivered therapist-supported self-help program based on to cognitive behaviour therapy.[30] These studies all reported a decrease of FOC and showed a reduction in caesarean birth, interventions and psychosocial factors.

The present thesis comprises a review on FOC, the protocol and the results of a randomized controlled trial on the treatment of severe FOC with haptotherapy (HT), a study on the correlation between FOC and mother-child bonding (MCB), and a short research note about the effect of HT on MCB. The main research question was as follows: Do women with severe FOC who received HT have a lower FOC than women who received psycho-education via the Internet or care as usual, and do with HT treated women have fewer medical interventions during delivery? In addition, we evaluated the relationship between FOC and MCB, and the effects of HT on MCB.

1.2 Haptotherapy

In 1993, the profession of haptotherapy was formalized by the Dutch Association of Haptotherapists (Dutch: Vereniging van Haptotherapeuten).[31] The complete history of the haptotherapy profession is described in the book `In touch, a history of the haptotherapy profession in the Netherlands'.[32] (Dutch 'Werken met gevoel, de geschiedenis van het beroep haptotherapie in Nederland').[33] Nowadays, haptotherapists who are working in primary healthcare in the Netherlands are directly accessible to the public without the intervention of a GP or medical specialist, and HT is fully or partially reimbursed by all health insurers.
HT during pregnancy requires additional knowledge about pregnancy and birth, for which healthcare haptotherapists in the Netherlands – at least those who are specialized in the treatment of FOC – attend additional education and training.[34] This special education and training was taught in a separate training programme since 1993. The training includes special exercises to treat women with severe FOC. The exercises were designed to create a change in the woman's perception of her pregnancy and to promote a more positive attitude towards pregnancy and childbirth. In addition, through HT, the pregnant woman may improve her readiness for the upcoming labour process, which in turn, is expected to result in a decrease of her FOC.[35]

1.3 Structure of the thesis

Chapter 2 summarizes the relevant literature regarding FOC. The focus is on definition problems, and on the features, prevalence, assessment methods and measurements of FOC, as well as on determinants, consequences and treatment methods. Chapter 3 provides an overview of the protocol for a randomized controlled trial on the treatment of severe FOC with haptotherapy, i.e., methods/design, background of severe FOC, characteristics of women with severe FOC, consequences of severe FOC, and a detailed description of the haptotherapeutic intervention. Chapter 4 presents the results of the randomized controlled trial 'Treatment of severe FOC with HT'. Chapter 5 examines the associations between FOC and MCB, i.e. the correlation between antepartum FOC and antepartum MCB, and the correlation between antepartum FOC and postpartum MCB. Chapter 6 evaluates the effect of HT on MCB. Chapter 7 critically discusses the findings of the thesis and the possible working mechanisms of HT, evaluates the strengths and limitations and provides suggestions for future research. Finally, several appendices are included.

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2. SEVERE FEAR OF CHILDBIRTH: ITS FEATURES, ASSESSMENT, PREVALENCE, DETERMINANTS, CONSEQUENCES AND POSSIBLE TREATMENTS

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2.1 Abstract

The review summarizes the relevant literature regarding fear of childbirth. A substantial number of (pregnant) women are more or less afraid of childbirth and a significant minority report a severe fear of childbirth. The focus will be on definition problems, its features, prevalence, assessment methods and measurements, determinants, consequences and treatment methods. To date, there is still no consensus about the exact definition of severe fear of childbirth. However, there is agreement that women with severe fear of childbirth are concerned about the well-being of themselves and their infants, the labour process, and other personal and external conditions. In studies on prenatal anxiety and fear of childbirth, various kinds of diagnostic methods have been used in the past. Recently, there is a consensus to determine severe fear of childbirth by using the Wijma Delivery Expectancy/Experience Questionnaire. The aetiology of fear of childbirth is likely to be multi-factorial and may be related to more general anxiety proneness, as well as to very specific fears. Furthermore, pregnant women are influenced by many healthcare professionals, such as midwives, nurses, gynaecologists, therapists and pregnancy counselors and the interactions with them. Trying to design a universal treatment for fear of childbirth will not likely be the ultimate solution; therefore, future research is needed into multidisciplinary treatment and predictors to establish which therapies at the individual level are most effective and appropriate.

2.2 Introduction

Pregnancy and delivery are major and generally positive life experiences for most women. However, a substantial number of women are more or less afraid of childbirth,[1-3] and approximately 10% report a severe fear of childbirth (severe FOC).[4-9] Some of these women actively avoid becoming pregnant, seek termination of pregnancy or try to induce a miscarriage.[10] In addition, the condition of FOC may increase the risk of psychological problems,[11-13] and the risk of medically unnecessary caesarean section.[14] To date, there is not yet consensus regarding the definition and diagnosis of severe FOC. There are strong associations with previous stressful obstetric experiences, specific personality characteristics, fear of pain, and fear of becoming a parent. Nevertheless, severe FOC often goes unrecognised. The present article focuses on the definition of FOC, its features, prevalence, consequences, determinants, measurements and possible treatments.

2.3 Method

For this review, we searched and examined studies addressing FOC and its features, including prevalence, assessment methods or measurements, determinants, consequences and treatment methods. Electronic databases PubMed (until December 2015), PsycINFO (until December 2015) and Google Scholar were searched, using combinations of the following search terms: fear of pregnancy, fear of childbirth, tokophobia, definition, prevalence, treatment, W-DEQ. Additional publications were identified from the reference lists of the retrieved articles. All relevant papers have been published in English and report original data and/or theoretical perspectives related to (severe) FOC.

2.4 Definition and features

Some women dread and avoid childbirth despite desperately wanting a baby. Fear of parturition has been already known for ages since Marcé – a French psychiatrist – wrote in 1858: "If they are primiparous, the expectation of unknown pain preoccupies them beyond all measure and throws them into a state of inexpressible anxiety. If they are already mothers, they are terrified of the memory of the past and the prospect of the future" (cited in Hofberg & Brockington, 2000, p. 83[15]). Nowadays, a minority of these pregnant women still suffer from a variety of fears. When this specific anxiety or fear to die during parturition precedes pregnancy and becomes so overwhelming that childbirth ('tokos' in Greek) is avoided whenever possible, it is referred to as 'tokophobia'. Hofberg and Brockington (2000) introduced the term "tokophobia" to refer to this pathological FOC in the medical literature.[15] More often the general term pathological FOC is used. To date, there is still no consensus concerning the exact definition of severe FOC. On the other hand, there is agreement that women with severe FOC are concerned about the wellbeing of themselves and their infants,[11, 16] the labour process, e.g., pain, medical interventions, abnormal course of labour, death, re-experiencing a previous traumatic delivery,[12] personal conditions (lack of control, distrust in own abilities) and external conditions, like interaction with or the assistance of the staff.[13]

According to Hofberg and Brockington (2000),[15] and Hofberg and Ward (2003),[17] three types of severe FOC can be distinguished (1) Primary FOC: This condition is characterised by a dread of childbirth that pre-dates pregnancy. It often starts in adolescence or early adulthood; (2) Secondary FOC: This occurs after having experienced a traumatic or distressing delivery, such as instrumental or operative deliveries due to foetal distress or

severe pain and perineal tearing; and (3) FOC as a symptom of prenatal depression: Some women develop a phobic fear and avoidance of childbirth as a symptom of depression in the prenatal period. However, in all three types, the fear and avoidance of childbirth was typically characterised by a recurrent intrusive belief that one was unable to deliver the baby and that, if one had to, one would die.

Zar et al. (2002) and Wijma and Wijma (2017) proposed to consider FOC as an anxiety disorder or as a phobic fear, which may manifest itself in nightmares, difficulties in concentrating on work or on family activities, physical complaints, and often in an increased request for a caesarean section as the mode of delivery.[10, 18] These authors assessed the links between several anxiety concepts and FOC, with a focus on state and trait aspects of anxiety in FOC. State anxiety is the transient reaction, which comes and goes, whereas trait anxiety refers to the more stable tendency of the individual to react with fear. Women who reported a severe FOC expressed higher general trait anxiety than women with moderate FOC who, in turn, expressed higher levels of general anxiety than women who experience low levels of FOC. This observation suggests that FOC comprises a considerable amount of trait fear. These authors also found support for the idea that FOC has important aspects in common with phobias.[3] According to the Diagnostic and statistical manual of mental disorders (DSM-V) of the American Psychiatric Association (APA, 1994),[19] for a phobia the following features are essential: (1) marked and persistent fear of a specific object or situation that is excessive or unreasonable, lasting at least six months; (2) immediate anxiety usually produced by exposure to the object; (3) avoidance of the feared situation, and (4) significant distress or impairment. Although these phobic features apply to women with severe FOC, FOC remains a specific fear at the end of a continuum ranging from negligible to severe fear that needs to be distinguished from general phobias.

Klabbers, Wijma, Paarlberg, Emons, and Vingerhoets (2014) suggested that severe FOC is featured by the prevalence of "restrain internal sensitive participation" (RISP): For example, a pregnant woman who undergoes a vaginal examination by a midwife or gynaecologist may feel somewhat awkward although she might understand the necessity of such a physical examination.[20] This is a normal reaction because the area examined is considered as private by most women. The pregnant woman will let her body object be internally examined, trying not being sensitively involved. RISP can be functional to allow a stranger, such as a physician or midwife, access to one's most private body parts. However, during childbirth, it is not functional to isolate the feelings in the belly and pelvic area. A persistent

RISP reaction may even form a severe obstruction because the birth of a child requires sensitive involvement. This RISP reaction often occurs during a situation that is experienced as uncomfortable. Women with an almost permanently present RISP lack the capacity to feel connected with their belly and pelvic area.

2.5 Clinical criteria

Wijma and Wijma (2016),[18] who have introduced the term 'childbirth anxiety' (CA) as an alternative of 'fear of childbirth' (FOC), described the clinical criteria of CA as follows: (1) Low CA: the woman does not see any or almost no problems with and is not bothered about giving birth; (2) Moderate CA: the woman can imagine that problems may appear during labour and delivery but also feels that those can be dealt with in an adequate way and that there a woman always runs some risks when she is giving birth; (3) Severe CA: the fear is so intense that is makes the woman dysfunctional with serious possible consequences for her personal, social, and work life and for her willingness to become pregnant and/or ability to give birth; and (4) Phobic CA: the fear fulfils the criteria of a specific phobia according to DSM-V (APA, 1994).[19]

2.6 Assessment and measurement

In the past, various kinds of diagnostic methods have been used to identify high FOC women. The anxiety aspect of FOC has frequently been measured with questionnaires originally developed to measure general anxiety,[21, 22] or by self-constructed questionnaires or interviews focusing on childbirth-related fear or anxiety.[14, 15] Huizink, Mulder, Robles de Medina, Visser, and Buitelaar (2004) demonstrated that assessment of general anxiety during pregnancy may underestimate the fear specifically related to pregnancy.[23] In their study, pregnancy fear rather than general anxiety was found to predict birth outcome and neuroendocrine changes during pregnancy. They further found that only about 20-25% of pregnancy anxieties during early and late pregnancy could be explained by personal factors and, therefore, they concluded that pregnancy anxiety should be regarded as a relatively distinctive syndrome. Generally speaking, general anxiety scales are not designed and thus not fit to assess anxieties and worries related specifically to pregnancy. They lack the needed construct validity and fail to predict specific outcomes. Therefore, to measure FOC, specific scales are recommended. Areskog et al. (1981, 1982) conducted one of the first studies on FOC.[1, 24] They assessed FOC by interviewing 139 women during their third trimester of pregnancy about their experiences and expectations and

combined the results with a newly developed 19-items questionnaire addressing childbirth. These results have led to the development of a questionnaire that has been used in its original or in a revised form, in several countries.[24-26]

Another assessment instrument, which has been developed by Wijma, Wijma, and Zar (1998), is the Wijma Delivery Expectancy/Experience Questionnaire (W-DEQ).[27] The W-DEQ has been designed specially to measure FOC operationalised by the cognitive appraisal of the delivery. This 33-item rating scale has a 6-point Likert scale as a response format, ranging from 'not at all' (=0) to 'extremely' (=5), yielding a score-range between 0 and 165. Internal consistency and split-half reliability of the W-DEQ = .87. A W-DEQ score of ≥ 85 is considered to indicate severe FOC (Wijma et al., 1998).[27] The W-DEQ proved to be a useful diagnostic test for disabling FOC in Swedish late pregnant women (sensitivity 91%, specificity 96%).[28] Recently, there is consensus to determine severe FOC by using the Wijma Delivery Expectancy/Experience Questionnaire (W-DEQ). However, different cut-off scores have been applied to qualify women as high FOC women. For instance: W-DEQ A score ≥ 100,[29] W-DEQ A score ≥ 85,[5, 20] and W-DEQ A score ≥ 66.[30] This implies that the definition of high FOC differs considerably among studies.

2.7 Prevalence

Using the W-DEQ ≥ 85 criteria, the prevalences of high FOC pregnant vary between 7.5% and 8% in Norway,[4, 7, 9] 9.2% in Canada,[8] between 10.0% and 15.8% in Sweden.[3, 5, 6, 14] The prevalence rates thus vary among studies, depending, among others, on factors like timing of the assessment and the cultural context.[31] The finding in Sweden that also 13.0% of the expectant men reported severe FOC indicates that also among fathers-to-be childbirth-related fear is an important issue that deserves attention.[32]

2.8 Determinants

A previous negative experience of pregnancy and childbirth are the main determinants of secondary FOC in multiparous women.[3, 33] For example, an emergency caesarean section has often been experienced as a severe trauma.[34] Also fear of death is expressed by up to 41% of women with a previous experience of a complicated childbirth.[13] These women additionally often report a lack of trust in the obstetric team and fear of their own incompetence. From the general trauma literature, it is known that only a minority of people develop post-traumatic stress disorder (PTSD) after having experienced a shocking event. A larger number of individuals, however, may develop posttraumatic stress symptoms, which may be part of a normal response to highly stressful events.[35] PTSD or intrusive stress reactions following childbirth mainly result from intolerable pain during labour or from an unanticipated complication such as an emergency caesarean section.[36] Studies of determinants of severe primary FOC – other than secondary FOC which results from negative previous obstetric experiences – are scarce.[2] The aetiology of FOC is likely to be multi-factorial and may be related to more general anxiety proneness, as well as to very specific fears. In addition, person and situational factors may all exert their influence. In the following paragraphs, possible determinants of severe FOC are discussed.

2.8.1 Person characteristics

General anxiety, neuroticism, depression, physical complaints, vulnerability, low self-esteem, dissatisfaction with the partner and lack of social support, have been found to be related to fear of vaginal delivery and pregnancy-related anxiety.[25] Additionally, is has been suggested that a pregnant woman's expectation of the delivery is relevant to her experiences of and behaviour during delivery.[3] FOC has been associated with both anxiety proneness in general,[37, 38] and clinical anxiety disorders.[10] In a Swedish population-based study of pregnant women, the prevalence of general mood and anxiety disorders was found to be respectively 11.6% and 6.6%.[39] In women with a psychiatric diagnosis, FOC was twice as common. Psychological characteristics such as depression, may also affect the woman's attitude to her pregnancy and her forthcoming delivery. Negative feelings, thoughts and emotions in early pregnancy also affect later childbirth experiences. FOC could be a sign of hidden depression, the diagnosis of, and therapy for which, would most likely improve the quality of life of the patient and her partner and, consequently, also FOC.[25]

2.8.2 Fear of pain

Fear of pain and a self-suspected low pain tolerance are among the most common causes of FOC.[2] However, labour and birth related fear seems to be strongly related to the proneness to experience fear of pain in general, irrespective of parity.[33] Fear of pain is also one of the most common reasons for requesting a caesarean section, and can be seen as pain-avoiding behaviour.[2]

2.8.3 Fear of being incapable of giving birth

Fear of being incapable of giving birth is common as well. Approximately two-third of women with severe FOC reported that they felt incapable of giving birth.[13] Remarkably, this reported fear and felt incapacity were not related to previous birth experiences. In addition, fear of doing something wrong and harming the foetus by inappropriate behaviour during labour is highly connected to the fear of being incapable of giving birth.[33, 40] There is often a fear of losing one's mind, losing touch with reality, or various emotions expressing hopelessness and helplessness. These kinds of fear can result from actualization of some traumatic events from one's childhood (e.g., being abandoned or abused), or from previous experiences of being neglected when asking for help (e.g., during previous contacts with health care professionals).[33] Women with FOC who strongly desired a surgical delivery and were refused, suffered from greater psychological morbidity than those granted their chosen method of delivery.[15]

2.8.4 Fear of becoming a parent

Another common fear is the fear of becoming a parent. The birth of a child is one of the major events in their transition to adulthood for young couples.[41] The birth of a child implies new responsibilities and requires new skills. As pointed out by Saisto & Halmesmäki,[2] because of the cultural changes in western society, the significance and admiration of maternity have decreased at the expense of emancipation, work, and career. Also, the lack of role models of how to be a good mother or father in the modern times may increase doubts about one's capability to take care of the new-born. Postpartum, anxious and neurotic women feel less confident about parenting and have a low confidence in their capacity to deal adequately with the baby.[21]

2.8.5 Abuse and trauma

A history of sexual abuse may be associated with an aversion to Gynaecological examinations including routine Pap smears or obstetric care.[15] Also, the trauma of a vaginal delivery, or even thinking about it, may cause a resurgence of distressing memories of childhood sexual abuse.[15] Women who have already suffered during childbirth may be afraid of re-

traumatisation. This can contribute to secondary pathological FOC and thus to a dread and avoidance of childbirth, even when a woman wants a baby. In a study by Heimstad, Dahloe, Laache, Skogvoll, and Schei (2006), women with FOC who reported being exposed to physical or sexual abuse in childhood had a higher W-DEQ score than did the non-abused counterparts and only half of the women who were sexually or physically abused in childhood (54% and 57% respectively) had uncomplicated vaginal delivery at term versus 75% of the non-abused women with FOC.[42]

2.8.6 Socio-cultural factors

Regarding primary FOC, there is some evidence that previous psychological morbidity puts a woman particularly at increased risk, if she additionally lacks support from her social network.[43] Saisto, Salmelo-Aro, and Halmesmäk (2001) found a strong association between FOC and pregnancy-related anxieties, on the one hand, and specific personality characteristics and socio-economic factors, on the other.[44] FOC may also transmit over generations,[45] and this can produce a second-generation effect of a mother's own unresolved frightening experience. It has been suggested that a woman's reproductive adaptation is like her mother's, which suggests a psychological "heredity".[46] Furthermore, a low education or socio-economic level, are factors predisposing to anxiety during pregnancy or FOC.[47] Moreover, the partner's dissatisfaction with life and with the partnership may contribute to the development of the woman's pregnancy-related anxiety and FOC.[25] Also, unemployed women and women who are not cohabiting with the father of the child are more likely to report pregnancy-related anxiety and FOC than women with a stable partnership and employment.[25, 33]

2.9 Consequences

Severe FOC may have several more or less dramatic consequences. In some tragic cases, a woman may be so terrified of giving childbirth, that she will terminate a desired pregnancy, rather than go through childbirth. Additionally, some women will actively seek out an obstetrician who is willing to perform an elective CS, even before becoming pregnant for the first time.[17] Some women never overcome their severe FOC and remain childless, whereas others decide to adopt a child. In exceptional cases, women enter the menopause without having delivered a much-desired baby and grieve this loss into old age.[17] In the following paragraphs, further possible consequences of severe FOC are discussed.

2.9.1 Sterilization

Ekblad (1961) addressed the issue of fear of pregnancy as a reason for requesting sterilisation. Some childless women presenting for this permanent contraceptive method may pathologically fear childbirth.[48] Fones (1996) reports on a case study in which a woman, who severely suffered from PTSD-symptoms and experienced FOC, underwent a tubal ligation, after which her PTSD-symptoms diminished.[49] Ekblad (1961) suggested that women with serious FOC should be treated by a psychologist to learn to deal with the FOC rather than undergoing such irreversible and life changing medical interventions.[48]

2.9.2 Termination of pregnancy

Termination of pregnancy may be requested by women who suffer from extreme pathological FOC. They are willing to have a baby but consider themselves as being unable to cope with their aversion of parturition. Hofberg and Brockington (2000) reported on three women who terminated their pregnancy because they were too terrified to endure a delivery.[15] One woman began to exercise strenuously in the hope of inducing a miscarriage rather than to undergo a vaginal delivery. The other two also sought termination of pregnancy despite their planned delivery. In the absence of an empathic professional ear, their only choice was to discontinue their pregnancy. They subsequently had to live with the psychological impact of that decision.

2.9.3 Caesarean section

Studies in several countries have revealed a remarkable rise of the overall CS rate.[50-54] For example, in the Netherlands the CS rate rose from 8.1% to 13.6% in the period of 1993-2002,[52] to 17% in 2014.[55] It has been suggested that severe FOC during pregnancy may increase the risk of emergency CS.[14] Sjögren and Thomassen (1997) reported that the number of pregnant women requesting CS because of fear of vaginal delivery has increased markedly from 1989 to 1992.[43] Hildingsson, Rådestad, Rubertsson, and Waldenström (2002) found that in comparison to pregnant women who intend to deliver vaginally, women preferring CS are more depressed and worried, not only about giving birth but also about other things in life.[56] This study additionally identified three factors that were statistically associated with a wish for CS: (1) a previous CS, (2) fear of giving birth and (3) a previous negative birth experience. The main reason for a woman's request for a CS on non-medical grounds was severe FOC, a finding that is supported by other studies.[13] These findings are in contrast with previous research, conducted in Sweden, in which severe FOC was found to be associated with an increased risk of an emergency CS.[13] However, FOC during the third trimester was not associated with mode of

delivery in a UK sample.[57] In that study, emergency CS was connected with previous CS, parity, age and a score reflecting medical risk, but not FOC or anxiety measures. In sum, the literature is inconclusive regarding the possible relevance of severe FOC for CS rates, and more research is needed to obtain a decisive answer to this question and to identify the specific contributing factors. Of utmost importance is the question if the rise in CS rates can be fully or partially explained by severe FOC and whether this is due to a true rise, or if it is better recognized nowadays, or if it is maybe seen as a more valid reason for a CS.

2.9.4 PTSD

Above we already discussed that PTSD could be considered as a determinant of FOC in multiparous women. In this paragraph, however, the focus is on PTSD as a consequence of these fears, which is increasingly being recognised.[34] According to Ayers, Eagle, and Waring (2006), approximately 1-2% of women develop PTSD as a consequence of childbirth.[58] Olde, Van der Hart, Kleber, Van Son, Wijnen, & Pop (2005) estimate the prevalence of PTSD following childbirth at approximately 2.8-5.6% at six weeks postpartum, with a decrease to approximately 1.5% at six months postpartum.[59] Olde et al. (2005, 2006) identified the following risk factors for PTSD and PTSD symptoms relating to childbirth: specific personality traits, the level of obstetric intervention, intense perinatal emotional reactions, a history of psychological problems, certain obstetric procedures, negative staff-mother contact, and lack of social support.[59, 60] Some studies indicate that women can perceive labour as traumatic independent of the type of procedure, but there is also evidence that invasive procedures, such as emergency CS or instrumental delivery are more likely to be experienced as traumatic.[61] Fear is an important risk factor of all kind of later problems in women during labour.[12, 36, 62, 63] Wijma et al. (1997) found that a PTSD-diagnosis was associated with a fear of losing or severely injuring the child or themselves.[36] PTSD as a consequence of childbirth, in its turn, may have several wide-ranging effects on women, their relationships, and the mother-baby bond.[58, 64]

2.10 Treatment

Interventions for high FOC women aim to reduce their childbirth-related anxiety and to facilitate the acceptance of uncertainties associated with the future delivery.[18, 65] The effects of treating anxiety and FOC can be evaluated in many different ways, such as in terms of alleviation of perceived stress and better adjustment during pregnancy, withdrawal of the request for a CS, having better mother-child bonding during pregnancy and

postpartum, have fewer childbirth complications, having less postpartum problems. The first attempts to treat FOC date back to the 1920s.[17] Early intervention included, among others, psycho-prophylaxis [66], and hypnosis.[67] In addition, different kinds of counselling and short-term psychotherapy have been given to pregnant women demanding an elective CS.[12] Pharmacological treatment of women with FOC is exceptional, unless co-morbidity like clinical anxiety, depression, or panic disorder calls for it.[2] Some interventions to reduce FOC focus especially on the recovery of PTSD-symptoms following childbirth.

Until now, interventions focusing on the reduction of severe FOC have been evaluated in four randomized clinical trials (RCTs): three focused on psycho-education in a group,[26, 29, 68] and one on individual psycho-education by telephone.[30] In addition, there are currently three RCT's ongoing: Treatment of severe FOC with haptotherapy: a multicenter randomized controlled trial,[20] Treatment of severe FOC with cognitive behaviour therapy, comparison of Internet cognitive behaviour therapy with traditional live therapy (see U.S. clinical trial register NCT02266186),[69] and finally, Eye movement desensitization and reprocessing treatment in pregnant women with FOC (see Dutch trial register NTR3339).[70] In the following paragraphs, the most common current treatments of FOC are discussed.

2.10.1 Psychotherapeutic interventions

Saisto and Halmesmäki (2003) point out that different kinds of psychotherapeutic interventions can be helpful, although they may be emotionally exhaustive and expensive.[2] These psychotherapeutic interventions can be combined with either simple or specific counselling. The few studies on this issue have combined different kinds of support or short-term therapy.[12, 43] Treatment generally includes individual emotional support, provided by an obstetrician. This proved to be successful, as 56% of the 100 women with FOC withdrew their request of CS after receiving this type of intervention.[43] In a smaller study (N=33), 50% of women withdrew their request for CS after psychological support, counselling, crisis intervention, or short-term psychotherapy.[12] In a study by Sjögren (1998) (N=100), a quarter of the women in his study accepted conventional, eclectic psychotherapy, given by a trained obstetrician.[71] The goals of the treatment were to identify the different aspects of the anxiety, to reduce the anxiety itself, and to encourage the women to consider a vaginal delivery, if possible. Contrary to expectations, the women who received therapy remembered their pregnancy as a more distressing period than the controls. The delivery itself, however, was remembered similarly by both groups. Sandström, Wiberg, Wikman, Willman, and Högberg (2008) investigated the effects of eye-movement desensitization and reprocessing treatment

(EMDR) to treat women with PTSD-symptoms after childbirth.[72] The EMDR treatment consisted of a structured treatment of traumatic experiences, by alternating between stimulating and questioning until the level of discomfort for the patient was reduced to the lowest possible. This study treated four women with a PTSD diagnosis after childbirth, and all women reported a reduction of PTSD symptoms afterwards. At 1-3-year follow-up, this positive effect was maintained for three of the four women. Because of the intensity of emotions exacerbating during this therapy, it is recommended to use this intervention for non-pregnant women who have experienced a traumatic birth and are ready for reprocessing it.[69] It thus seems possible to prevent secondary FOC. Further research is required to evaluate the usefulness of this kind of therapy in treating secondary FOC. To date, there is one ongoing RCT study using EMDR treatment in pregnant women with FOC (see Dutch Trialregister NTR5122).[73]

2.10.2 Psycho-education

The first randomized controlled effect study on FOC has been conducted by Saisto et al. (2001).[26] This intervention in the intensive group consisted of information and discussion of previous obstetric experiences, feelings, and misconceptions. The appointments were planned during routine obstetric check-ups to assure the normal course of the pregnancy. According to Saisto and Halmesmäki (2003), the cognitive approach is well suited for the treatment of FOC, because of its short and changeable duration and its focus on one problem.[2] The main principle of psycho-education is to focus on one target problem and the reformulation of it in a limited time, with an active role of the therapist. Moreover, an appointment with the midwife and visits to the obstetric ward were recommended to obtain more practical information about pain relief and possible interventions (e.g., vacuum, scalp blood sample) during labour and delivery. Written information was given at the first session regarding the pros and cons of vaginal delivery versus a CS, as well as about alternative modes of pain relief available in the hospital. The intervention in the comparison group consisted of the provision of standard information and routine obstetric check-ups, as well as written information about the pros and cons of vaginal versus caesarean delivery, and about the pain relief that is offered at the hospital. The intensive therapy group comprised 85 pregnant women, the conventional therapy 91. Twenty women (23.5%) in the intensive therapy group requested a CS for psychological reasons and 26 women (28.6%) in the conventional therapy group. After intervention in both groups, 62% of all of those originally requesting a CS chose to deliver vaginally.[26] In women delivering vaginally, labour lasted 1.7-hour shorter in the intensive intervention group than in the conventional group. Positive effects have been reported for psycho-education in a group,[29, 68] and for individual psycho-education over

the telephone.[30] All these interventions resulted in lower rates of caesarean sections, more spontaneous vaginal deliveries, and more satisfactory delivery experiences. Moreover, better maternal adjustment, a less fearful childbirth experience, and fewer postnatal depressive symptoms were demonstrated compared to care as usual.

2.10.3 Briefing

In case of secondary FOC, proper feedback of what happened during the previous childbirth may prevent many misunderstandings and can help women to cope more effectively with a possible subsequent delivery.[26, 74] This intervention is in the tradition of Pennebaker's work, who has introduced the writing paradigm in the psychological literature.[75] After the women have written down their problems, the gynaecologist arranges a session to take away their uncertainties about the childbirth. In addition, every member of the medical team who is seen by the women fearing childbirth (e.g., obstetricians, midwives, gynaecologists) is knowledgeable and well-informed about their fears and uncertainties. They also obtain extra support in the delivery room. The first results of this intervention are very positive. The women feel that their problems are taken seriously and that the medical team is adequately prepared. Until now, 35 of them experienced the childbirth without problems or complications, and they are very satisfied with the delivery.

2.10.4 Counselling

Counselling provides helpful information to women with FOC and assists them with making informed choices regarding their delivery. There is a wide variability of approaches of counselling, ranging from simply unstructured 'listening' sessions to specific interventions requiring psychotherapeutic training.[76, 77] These authors proposed crisis-oriented counselling for women with FOC who requested CS. The theoretical framework of crisis-oriented counselling makes a distinction between pure crisis and over determined crisis. FOC is considered an over determined crisis.[77] Of the 86 included women, 86% changed their request for a CS and were willing to deliver vaginally. Long term satisfaction with this decision was found, and participants remained satisfied with counselling at a 2-4-year follow-up.

2.10.5 Treatment in Aurora clinics

In Sweden, nearly all obstetric departments have established 'Aurora clinics'. These are qualified teams consisting of midwives, an obstetrician, a psychologist, a social worker, and sometimes a psychiatrist, who support women with FOC.[31] Pregnant women are usually referred to these teams by a midwife or doctor at the antenatal clinic and are referred mostly during their third trimester. First, an assessment of the individual problem takes

place and plans are made for the following counselling. Counselling often includes a visit to the local delivery ward and the making of a birth plan as guidance for the delivery ward staff. Most women pay 2-4 visits to the Aurora-team, but this may vary between patients. The clinics have currently not yet been evaluated yet by randomised controlled trials because of ethical issues, but the study of Waldenström et al. (2006) suggests that it may help women with antenatal fear to have a more acceptable experience of the delivery.[31]

2.10.6 Haptotherapy

In the Netherlands, pregnant high FOC women would normally visit a psychologist or psychiatrist. However, these women can also directly contact a healthcare haptotherapist who is specialized in the treatment of pregnant high FOC women. Haptotherapy claims to facilitate the development of specific skills changing the cognitive appraisal of giving birth and labeling childbirth as a more normal and positive life event, which may ultimately lower FOC. The intervention comprises a combination of skills, taught in eight sessions of one hour between gestational week 20 and 36.[20] Preferably, the partner of the pregnant woman also attends every session and participates actively in several exercises. Klabbers et al. (2014) have described the intervention in detail.[20] To date, there is an ongoing RCT study evaluating haptotherapy treatment in pregnant women with severe FOC (see Dutch trial register NTR3339).

2.10.7 Treatment based on the PLISSIT model

Saisto & Halmesmäki (2003) introduced the 'PLISSIT' model (Permission / Limited Information / Specific Suggestions / Intensive Therapy) for the treatment of FOC.[2] This model implies and emphasizes that different health care professionals should contribute to the treatment of FOC women. The PLISSIT model distinguishes four different levels of confrontation, and it can be easily adapted to the treatment of FOC. This model implies a spirit of cooperation and knowledge sharing. According to this model, the training of pregnancy and childbirth professionals must include skills in recognizing women with FOC, depression, and PTSD after a previous childbirth or other traumatic events, lessons about psycho-education and possible therapies. The proponents further propose that treatment of women suffering from FOC should be tailored to the woman's specific situation and needs. As is the case for all interventions, the model should be first implemented into clinical practice before one can appropriately evaluate its effectiveness in treating FOC.

2.10.8 Negative outcomes

Although several treatments seem to diminish FOC, they occasionally also may have negative consequences. For example, Ryding, Persson, Onell, and Kvist (2003) studied birth experience, posttraumatic stress symptoms and satisfaction with care in new mothers who had consulted specially trained midwives because of FOC during pregnancy.[78] Contrary to expectations, women in the intervention group reported a more frightening experience of delivery and more frequent symptoms of post-traumatic stress related to delivery than did women in the comparison group. This finding emphasizes that women who seek help for FOC are a vulnerable group and that it cannot be taken for granted that interventions always have (only) positive effects. Adequate evaluation research is badly needed to obtain more insight into the specific benefits of an intervention.

2.11 Conclusion

FOC occurs in a significant minority of pregnant women. It may have serious negative effects on both the pregnant woman and birth outcome. There are many variables and circumstances influencing FOC. In addition, there is limited evidence that a variety of interventions may have positive effects. However, trying to design the universal treatment for FOC will not likely be the ultimate solution. Research is needed to obtain a better understanding of which person and context factors predict which therapies fit individual patients best.

2.12 References

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3. TREATMENT OF SEVERE FEAR OF CHILDBIRTH WITH HAPTOTHERAPY: DESIGN OF A MULTICENTER RANDOMIZED CONTROLLED TRIAL

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3.1 Abstract

3.1.1 Background
About six percent of pregnant women suffer from severe fear of childbirth. These women are at increased risk of obstetric labour and delivery interventions and pre- and postpartum complications, e.g., preterm delivery, emergency caesarean section, caesarean section at maternal request, severe postpartum fear of childbirth and trauma anxiety. During the last decade, there is increasing clinical evidence suggesting that haptotherapy might be an effective intervention to reduce fear of childbirth in pregnant women. The present study has been designed to evaluate the effects of such intervention.

3.1.2 Methods/Design
Included are singleton pregnant women with severe fear of childbirth, age ≥ 18 year, randomised into three arms: (1) treatment with haptotherapy, (2) Internet psycho-education or (3) care as usual. The main study outcome is fear of childbirth. Measurements are taken at baseline in gestation week 20–24, directly after the intervention is completed in gestation week 36, six weeks postpartum and six months postpartum. Secondary study outcomes are distress, general anxiety, depression, somatization, social support, mother-child bonding, pregnancy and delivery complications, traumatic anxiety symptoms, duration of delivery, birth weight, and care satisfaction.

3.1.3 Discussion
The treatment, a standard haptotherapeutical treatment for pregnant women with severe fear of childbirth, implies teaching a combination of skills in eight one-hour sessions. The Internet group follows an eight-week Internet course containing information about pregnancy and childbirth comparable to childbirth classes. The control group has care as usual according to the standards of the Royal Dutch Organisation of Midwives and the Dutch Organization of Obstetrics and Gynaecology.

3.1.4 Trial registration
This trial was entered in the Dutch Trial Register and registered under number NTR3339 on March 4th, 2012.

3.2 Background

Fear of childbirth (FOC) is a normally distributed phenomenon in the population of pregnant women. The level is slightly higher in primiparous women than in multiparous women.[1] A significant minority of pregnant women (6%) suffers from severe FOC, which negatively interferes with daily functioning.[2, 3] Zar et al. found that, according to DSM IV criteria,[4] 2.4% of pregnant women suffer from phobic FOC,[5] i.e. being so afraid of giving birth that they request a caesarean section in order to avoid vaginal birth. In the Netherlands, in 2012, 173.000 deliveries took place,[6] meaning that annually about ten thousand women suffer from severe FOC. Until now, as far as we know, only two randomized clinical trials have been published on interventions treating severe FOC.[7, 8] In these studies, positive effects have been reported of psycho-education in a group nulliparous women with FOC. In the most recent study, the intervention was associated with lower caesarean sections, more spontaneous vaginal deliveries and more satisfactory delivery experiences.[8] Haptotherapy (HT) has been applied in the clinical setting with promising results,[9] but without scientific confirmation. Therefore, the present study has been specially designed to evaluate the effect of haptotherapy as a model for treatment of severe FOC.

3.2.1 Characteristics of the women with fear of childbirth

Women with FOC are concerned about the well-being of themselves and of their infants,[10, 11] the labour process (pain, medical interventions, abnormal course of labour, death, re-experiencing a previous traumatic delivery),[12] personal conditions (lack of control, distrust in own abilities) and external conditions (interaction with or the assistance of the staff).[13] FOC is determined by the way a woman processes her sensations cognitively and emotionally. Her concerns about what may happen during an imminent or future delivery are crucial to this fear.[14] The event of childbirth is momentous for the woman giving birth, for the child being born, and for the woman's partner. Her accomplishments during the delivery have lifelong physical, social and existential consequences for herself and her loved ones.[1] A woman with FOC has a propensity to worry about her ability to deal with possible obstetric problems, her capacity to perform adequately and the health, or even survival, of herself and her child during and after the delivery. Therefore, women with severe FOC not only continuously and apprehensively are vigilant for signals of danger, they often feel to have their suspicions verified,[1] creating a vicious cycle of adverse expectations and negative experiences.[1] Some pregnant women with a strong inclination to worry about delivery, may even completely avoid childbirth information.[1] Towards the end of the pregnancy, some of these women may suddenly find

themselves caught in a situation that they were not even able to contemplate. In such a situation, the women's FOC may escalate to such high levels that their attention increasingly narrows and finally fully concentrates on fear related stimuli.[1]

3.2.2 State-and trait-anxiety

Severe FOC may be considered from both a state and a trait perspective. For most pregnant women, the prospect of labour and delivery evokes a certain degree of uncertainty, perhaps even worry or fear. This may be called `state-anxiety` (situational FOC). The degree of state anxiety during childbirth depends on how labour and delivery are progressing, the woman's interpretation of what is happening, her propensity to view situations as hazardous or threatening and, finally, her ability to cope with what she perceives as difficult and dangerous.[15, 16] FOC as a `state` condition is a short-term reaction that waxes and wanes. FOC as a 'trait' condition is, generally, more a characteristic of the woman, emphasizing her predisposition to react with fear to all kind of stimuli, including childbirth. FOC as a trait will influence fear levels both before and after the delivery. Individual differences in trait-anxiety may be the result of genetic factors as well as past experiences, such as the amount of negative information the expectant mother has received or collected about childbirth and her own life experiences. Women with high trait-anxiety levels show state-anxiety elevations more frequently than their low trait-anxiety counterparts.[5] Women with higher trait-anxiety further tend to regard a broader range of aspects of the delivery as dangerous or threatening.[1] For women less prone to FOC (low trait anxiety), childbirth may generate a low level of negative emotional arousal and rather produce alertness and interest in the ongoing process.[1] Emotions become more intense during labour and delivery, which – in FOC women – may disrupt perception and behaviour, which in turn may lead to more uncertainty, greater concern and more intense fear.[1]

3.2.3 Consequences of severe FOC

Previous studies suggest that women with severe FOC and their infants are at increased risk of several adverse conditions, including hypertension and pre-eclampsia,[17] pre-term birth,[18, 19] complications during delivery and emergency caesarean section,[20] extra use of pain medication during delivery,[21, 22] prolonged delivery and trauma anxiety,[23] whereas their infants may more likely suffer from low birth weight and emotional and behavioural problems.[24]

3.2.4 Haptotherapy

In the Netherlands HT is an officially acknowledged profession[25]. It is practiced by qualified healthcare haptotherapists who are members of and licensed by the Association of Haptotherapists.[26] Most haptotherapists have a basic education as a physical therapist. As will be explained below, healthcare haptotherapists differ from `haptonomic pregnancy counselors`, who are qualified for haptonomic counselling of healthy pregnant women not in need of therapeutic interventions.[27, 28] These pregnancy counselors are neither therapist nor do they perform any haptotherapeutic interventions. In the Netherlands, a patient with severe FOC can be referred to a specialized licensed healthcare haptotherapist. In practice some overlap exists between the domains of the healthcare haptotherapists and the haptonomic pregnancy counselors. The healthcare haptotherapists taking part in this study to accomplish the HT also perform haptonomic pregnancy counselling with pregnant women, not being part of the study.

The HT method concerns both the identified FOC and at full mental state of the pregnant woman.[29] The intervention focuses on the identified anxiety issues and, subsequently, on a change in mindset which is meant to reduce FOC. HT aims to influence both the trait- and the state-component of FOC. A common component of all HT treatments is to become more familiar with perceived and experienced physical sensations.[30] It has empirically established that HT results in fear reduction as soon as a person registers feelings in his/her body (in this article meaning awareness of corporeality as the lived experience of the subject body[31]), and more specifically for the pregnant woman, when she is able to have a perceptive participation for what is going on in her belly and pelvic area during pregnancy and childbirth. HT is claimed to facilitate the development of specific skills changing the cognitive appraisal of giving birth and labeling childbirth as a more normal and positive life event, which may ultimately lower FOC.[32]

The HT sessions focus on (1) the pregnant women’s ability to open and close in reaction to the awareness of perceived impressions, (2) the affective confirmation of the mother-foetus bonding by means of the exercise in which the woman’s belly is touched by the partner and the foetus reacts, (3) skills such as the correct use of abdominal pressure during pushing at the third stage of labour, learning skills to handle painful contractions and learning to deal with labour pain in general. These skills may help to lower state-anxiety, intending women to feel more competent and more in control. In this way, the delivery might be anticipated with more trust and confidence. The partner (if present) can play an important role in the therapy and in the continuity of the skill training exercises. The practice of skill exercises at home together with a partner increases the effect of the skills. If

the partner is not available, sometimes a mother, sister or (girl)friend can participate and provide social support, otherwise the pregnant woman will be guided on her own.

3.2.4.1 Changing the mindset

A further objective of HT is to make the individual aware of his/her capacity to allow feelings and to experience them. In other words, the person learns to consciously open and close oneself for these feelings.[33] HT distinguishes between the `body-object` and `body-subject`.[34] The term `body-object` refers to the body as an object that, for example, can be examined for medical purposes. The term `body-subject` refers to the way the body is subjectively experienced.[34, 35] HT tries to make the patient aware of the difference between the body-object and the body-subject. This can be achieved by verbal explanation and experiential exercises to create physical awareness. HT in pregnancy serves the same goals as HT in general. More specifically, the pregnant woman needs to acquire the skill of opening herself for sensory impressions, exercising practical techniques for handling labour pains, easing contractions and correctly utilizing abdominal pressure for pressing. She additionally creates a mindset that helps her to better cope with the delivery process. Furthermore, HT aims to gradually shape the mindset and to teach the pregnant woman to become more (self-) confident about her ability to deliver the baby spontaneously vaginally. It is thought that increasing the woman's self-reliance and self-confidence also results in FOC reduction.

3.2.4.2 Changing body-awareness and self-awareness

In women with FOC HT additionally focuses on becoming aware of or (re)discovering their own ability to experience feelings. The therapy is based on the dialogue between the haptotherapist and patient resulting in increased insight in the own capabilities of giving birth vaginally. Furthermore, skill developing exercises and direct touch by therapist and/or partner are applied, in order to promote body awareness and self-awareness. For example, a pregnant woman who undergoes a vaginal examination by a midwife or gynaecologist may feel somewhat awkward, although she might understand the necessity of such a physical examination. This is a normal reaction, because the area examined is considered as private by most women. The pregnant woman will let her body(−object) be internally examined, trying not being sensitively involved. The first author (GK) has labeled this mechanism: `restrain internal sensitive participation` (RISP), which can be functional to allow a stranger, such as a physician or midwife, access to one's most private body parts. However, during childbirth it is not functional to isolate the feelings in the belly and pelvic area. A persistent RISP reaction may even form a severe obstruction, because the birth of a child requires

sensitive involvement. This RISP reaction often occurs during a situation which is experienced as uncomfortable. Women with an almost permanently present RISP, lack the capacity to feel connected with their belly and pelvic area.

The emotional experience of the pregnant woman with severe FOC may not be directly observable and she will not always express her fear at her own initiative. However, if a pregnant woman touches her belly in an objectifying manner and speaks about her child in an objectifying way, this may – according to clinical observations of the first author (GK) – be an indication of severe FOC. In haptotherapeutic practice it has been observed that many pregnant women with severe FOC have an undesired objectified perception of both their (lower) body and their child. HT tries to familiarize pregnant women with their body and its functions and to teach specific skills that assist in creating a positive prospect on giving birth. These skills are meant to facilitate coping with uterine contractions, to handle the labour pain more adequately and to push more effectively in the third phase of the delivery. Additionally, application of these techniques is expected to create a change in the woman's perception of her pregnancy, which may reduce FOC. Subsequently, a reduction of FOC may lead to fewer complications during and after birth.

3.2.5 Aims

The main goal of this study is to evaluate the effectiveness of HT in reducing severe FOC, in comparison to (1) psycho education about pregnancy and childbirth, and (2) to care as usual. We also study how effectiveness is related to background variables including perceived distress, social support, and complications in pregnancy. The following research questions are addressed: 1. Do FOC women with severe FOC have lower FOC after HT treatment than women who receive psycho education about pregnancy and childbirth via the Internet or who have care as usual? 2. Do women with severe FOC after HT treatment (1) have a better emotional bonding with their child during pregnancy and postpartum and (2) have fewer complications requiring forceps, vacuum extraction, or caesarean delivery and less third-degree tears or episiotomy, (3) have lower levels of distress, depression, anxiety, PTSD symptoms and somatization, than women who receive psycho education about pregnancy and childbirth via the Internet or who have care as usual?

3.3 Methods/Design

3.3.1 Study participants

The study sample consists of pregnant women, age ≥ 18, with severe FOC. FOC is measured by the Wijma Delivery Expectancy/Experience Questionnaire (W-DEQ).[15] The participants with a W-DEQ score ≥ 85 are randomly assigned to one of the three arms: (1) HT (HT Group), (2) Internet psycho-education (Internet Group) or (3) care as usual (Care as usual Group). Women with a W-DEQ score < 85, and thus not classifying for any of the other three treatment arms, will be assigned to (4) the Comparison-group in which randomly one third of all participants with a W-DEQ score < 85 will be followed. Exclusion criteria are multiparity and a history of psychotic episodes.

3.2.3 Ethical approval

This trial has been approved by the Dutch Medical Ethics Review Committee and registered under number NL3490000811.

3.3.3 Randomisation

Randomisation is arranged by computer-generated numbers by means of the program RANDOM.ORG, that has provided a random list of thousand numbers 1, 2 and 3.[36] An eligible pregnant woman with a W-DEQ A score ≥ 85 gets a number of 1, 2 or 3 in the order of the list. Those with the numbers 1, 2, and 3 are assigned to the HT Group, the Internet Group and Care as usual Group respectively.

3.3.4 Procedure

Recruitment takes place on the project's Internet website www.bevallingsbeleving.nl and by participating midwives, obstetricians and gynaecologists. During the routine check-up of pregnant women in gestation weeks 20–24, participating midwives and gynaecologists offer potential participants an information letter and/or a flyer that refers to the project's Internet website for registration for the study. Pregnant women show their informed consent by sending the completed approval form to the coordinating investigator, who returns the URL and login code to the participants by email. For the project a special safe Internet environment has been developed, facilitating the completion of the online questionnaires. Inclusion of participants will take approximately three years, followed by one year to complete follow up measurements. The therapeutic intervention will be carried out by certified haptotherapists in various regions in the Netherlands. Admission in 20–24 weeks gestation will continue until at least 64 participants with a W-DEQ A score ≥ 85 have been included in each of

the three arms respectively. At that time recruitment for the Comparison Group also stops.

3.3.5 Measures

3.3.5.1 Background variables

General issues concerning the birth and background factors will be assessed using a questionnaire which has been especially designed for this study to collect information about demographic characteristics and the participants' perception on health care in connection to pregnancy and delivery.

3.3.5.2 Fear of childbirth

The W-DEQ has been designed to measure FOC operationalised by the cognitive appraisal of the delivery. This 33-item rating scale has a 6-point Likert scale as response format, ranging from `not at all` (=0) to `extremely` (=5), yielding a score-range between 0 and 165. Internal consistency and split-half reliability of the W-DEQ= 0.87. A W-DEQ score of ≥ 85 is considered to signify severe FOC.[15] The W-DEQ proved to be a useful diagnostic test for disabling fear of childbirth in Swedish late pregnant women (sensitivity 91%, specificity 96%).[37]

3.3.5.3 Distress, anxiety, depression, somatization

Distress, Anxiety, Depression and Somatization will all be measured with the `Four-Dimensional Symptom Questionnaire` (4DSQ).[38] The 4DSQ consists of a list of 50 symptoms of psychological and psychosomatic symptoms according to DSM IV.[4] The 4DSQ measures distress, depression, general anxiety and somatization as separate dimensions. The 4DSQ scales have a high internal consistency (Cronbach's alpha: 0.84 to 0.94).[39, 40]

3.3.5.4 Social support

Social support is measured by the Social Support Questionnaire (SSQ).[41] The SSQ is a valid instrument for measuring social support and has acceptable psychometric properties. The first part of each item assesses the number of available others the respondent feels (s)he can turn to in times of need in each of a variety of situations (Number of Perceived Availability score). The second part of each item measures the individual's degree of satisfaction with the social support (Satisfaction score). For the subscale `number of supporters` Cronbach's alpha is 0.90 and for the subscale `satisfaction of support` Cronbach´s alpha is 0.92.

3.3.5.5 Anxiety and depression

Anxiety and Depression are measured by the `Hospital Anxiety and Depression Scale (HADS).[42, 43] The HADS includes a depression and anxiety subscale, each composed of seven items. Each item is scored on a scale ranging from 0 to 3. The HADS is widely used in medical patients, because it does not contain items relating to physical symptoms (e.g., fatigue, sleep problems) that are connected with all kind of medical and physical conditions (including pregnancy) and related to serious mental disorders. The Cronbach's alpha is: 0.91 for total scale; 0.86 for the anxiety subscale, and 0.85 for the depression subscale.[42]

3.3.5.6 Emotional bonding

Emotional bonding is measured by the Pictorial Representation of Attachment Measure (PRAM).[44] The PRAM measures mother-child bonding in a quick and easy way,[44] see Figure 1. A pregnant woman is shown a white screen with a big circle which represents her life as it currently is. A yellow circle in the centre of the big circle represents the woman's 'Self'. She is handed a green circle and is instructed to imagine that the green circle represents the unborn baby. Subsequently she was asked: "where would you place the baby in your life at this moment?" For quantitative use, the outcome measure is the Self-Baby-Distance (SBD), i.e., the distance (in centimetres) between the centres of the 'Baby' and 'Self' circles.

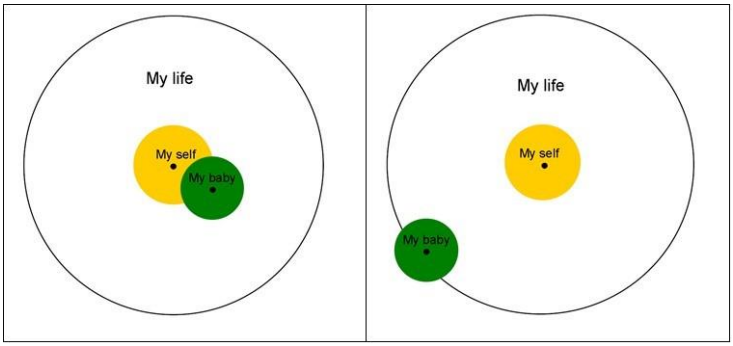

Figure 1: Two examples of the Pictorial Representation of Attachment Measure.

3.3.5.7 PTSD following childbirth

PTSD after childbirth is measured using the Traumatic Event Scale (TES).[23] The TES has been developed in accordance with DSM-IV criteria for the PTSD syndrome and comprises all the DSM-IV symptoms and criteria of PTSD.[4] Internal consistency for the TES = 0.87.

3.3.5.8 Birth complications

Birth complications and medical interventions, such as pain relief and instrumental delivery are recorded. For which has been designed a birth evaluation questionnaire.

3.3.6 Timing of measurement

All participants answer questionnaires by Internet at the following four moments, see Figure 2: T1: admission to the study in weeks 20–24 of gestation. Measures: W-WDEQ A, 4DKL, HADS, SSQ, PRAM, demographic characteristics. T2: week 36 of gestation. Measures: W-DEQ A, 4DKL, HADS, SSQ, PRAM. T3: 6 weeks postpartum. Measures: W-DEQ B, PRAM, TES, Birth evaluation questionnaire. T4: 6 months postpartum. Measures: W-WDEQ A, 4DKL, HADS, SSQ, PRAM, TES.

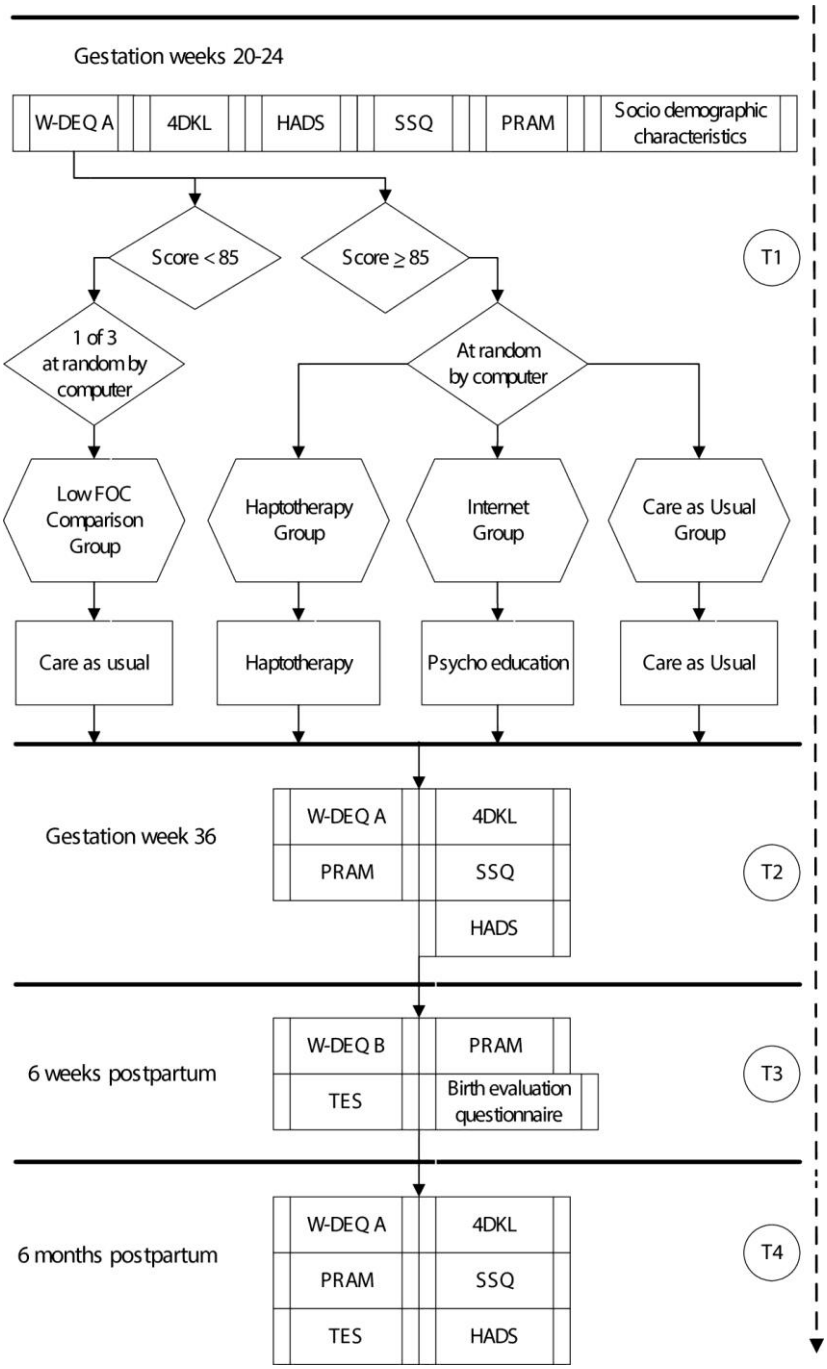

Figure 2: Schematic representation of the design and procedure of this study.

3.4 Discussion

3.4.1 The haptotherapeutic intervention

The structure of the standardized HT intervention has been developed by the first author (GK) in close collaboration with HT colleagues. The first three sessions contain simple exercises from everyday life that correspond with the pregnant woman's own experiences, to guide her towards her own ability to open up and close herself to the awareness of feelings. For instance, by simply shaking hands differently or handling daily items differently, the woman can discover that she can choose to perform these activities either with or without the awareness of sensate focus. Next, these skills are used to distinguish between having a body as an object and the conscious intrinsic experience of the body as a subject. In subsequent sessions, these skills that the pregnant woman is developing/has developed are repeatedly reaffirmed by the haptotherapist. Next, these skills are applied to learn the correct use of abdominal pressure during pushing and handling labour pains and uterine contractions. In the practice of counselling a pregnant woman with severe FOC, it frequently appears that, instead of feeling a joyful expectancy of the foetus in her, she is extremely negatively focused on the upcoming delivery which she severely fears. In contact with the pregnant woman, the therapist speaks about the `baby or child in your womb`, instead of `foetus`. The pregnant woman may have lost her own ability to open up or shut herself in reaction to the awareness of sensational impressions. The HT exercises are designed to create a change in the woman's perception of her pregnancy and to promote a more positive attitude.[45] Stimulating positive affective contact between both parents (if a partner is present) and the unborn child is affirmative for the woman as a mother to be. The effect is that she may feel more relaxed, more at ease, more secure and, as a consequence, the muscle tone of her uterus may decrease considerably. In addition, she may become more involved with the upcoming labour process, creating confidence which is expected to imply a decrease of her FOC. Usually it takes several weeks to help the mother develop and integrate these HT skills into daily live.[46]

3.4.1.1 The content of the sessions

HT for pregnant women with severe FOC in the present study comprises a combination of skills, taught in eight sessions of one hour between gestational week 16 and 36. Preferably, the partner of the pregnant woman also attends every session and participates actively in several exercises. If the partner, mostly the father, has the capacity for affirmative affective contact, in connection with his/her partner and their child, (s)he helps to create an atmosphere of safety, security and trust for the pregnant women. If the partner is not (yet) comfortable with this, the haptotherapist can guide

him/her in this with some simple exercises. Similarly, the affective affirming contact between partners can be just self-evident. The content of the separate sessions will be briefly described below.

Session 1: Intake
Introduction, getting to know each other, taking an anamnesis, and making an agreement on the working methods of HT as defined in a treatment guideline. The first session is mainly an informative and administrative meeting.

Session 2: Ability to open and close
Introduction into the human ability to open and close to the awareness of sense impressions and the experience of its physical consequences. After this, the pregnant woman and her partner are taught to feel the difference between emotionally (affective) turning towards and turning away from another person. Once this is clear, this skill is applied in an exercise for the parents directed to the foetus by invitingly touching the woman's belly. The foetus in the belly may respond by moving towards the touching hand. The confrontation with the ability to open up or to shut to the awareness of sensate impressions is the essence of the HT intervention which is the basis of the therapy.

Session 3: Further development of the ability to open and close
It is necessary to repeat the introductory exercises several times, because women with FOC, who are often blocked by their fear, may have difficulty to open up for sensate impressions. At the end of the session the exercise with invitingly touching the woman's belly and the reactions of the baby may be further explored. The movements of the baby can help the pregnant woman to get familiar with the sensations of her body, because the movements of the baby from the inside draw the woman's attention.

Session 4: Sensibilisation
HT stresses the importance of a sensitive interaction between the woman and her foetus and her (lower) body in order to facilitate the delivery process. Whereas the first three sessions can be seen as a preparation, in the fourth session the attention will be directed to the belly and pelvic area of the pregnant woman. New exercises are performed to sensitize this part of the body. At the end of the session, the exercise in which the woman's belly is touched and the reactions of the baby are further explored, which is meant to increase sensitivity of both parents gradually.

Session 5: Abdominal press
The aim of the fifth session is to practice the right use of abdominal pushing during childbirth. Therefore, all the aspects of opening for sensate impressions, interaction between the mother and her foetus, emotionally turning towards the childbirth process and emotional reactions in general will be paid attention to. At the end of the session, there again is a rehearsal of the belly touch exercise.

Session 6: Absorbing contractions and dealing with pain
The aim of this session is to practice coping with uterine contractions and dealing with pain during the delivery. Therefore, all aspects dealt with in previous sessions, will again be paid attention to and at the end of this sixth session, as a recurrent theme, the focus again will be on invitingly touching the woman's belly.

Session 7: Labour and delivery simulation
This seventh session consists of a training of labour by simulating all the aspects of labour as far as possible. Abdominal press and coping with contractions and dealing with pain in various positions are practiced. Attention is also paid to the role of the partner during labour and delivery.

Session 8: Evaluation and rehearsal
Evaluation of and, if necessary, rehearsal of exercises are the main components of this last session.

3.4.2 Psycho education via Internet condition

During gestation weeks 20–36, the Internet Group follows a course in eight modules via the Internet providing information about pregnancy and labour and delivery.[47] The entire process, from the beginning of the pregnancy to the delivery and postpartum period is described. In this way, the pregnant woman can increase her knowledge about the normal course of pregnancy and delivery. Each week, the participant has the opportunity to ask questions about her own situation. The program covers a period of 8 weeks. In the first week, there is information about the development of the embryo and changes in the mother's body in the first trimester. In the second week, the information addresses how these developments and processes continue during the second part of the pregnancy (the second trimester). The third week focuses on everything that happens in the final phase of the pregnancy (the third trimester). The fourth week begins with information on preparation for the delivery and important points to ponder in view of this major event. There is attention to what happens when labour begins. The fifth week is devoted to the options for pain management during labour and delivery, the various methods available and what the woman herself can do. In the sixth

week, the course continues focussing on labour and delivery, in particular on what happens during the second and third phase of labour. In the seventh week possible emergencies that can occur during the delivery are discussed, what can happen and what is done in such case, including emergency caesarean sections. Week eight, the closing session, focus on the final part of the delivery: birth of the placenta (third stage of labour) and on the first days postpartum.

3.4.3 Care as usual group

The Care as Usual Group receives care as usual according to the standards of the Royal Dutch Organisation of Midwives (Koninklijke Nederlandse Organisatie van Verloskundigen, KNOV) and the Dutch Organization of Obstetrics and Gynaecology (Nederlandse Vereniging voor Obstetrie en Gynaecologie, NVOG).

3.4.4 Low FOC comparison group

The low FOC Comparison Group receives care as usual.

3.5 Statistical analyses and power analysis

3.5.1 Statistical analyses

To answer the primary research questions, we will use descriptive statistics (M and SD), between-subjects analysis of variance (ANOVA), followed by two planned pair wise comparisons (HT treatment versus care as usual, and HT treatment versus Internet group). To maintain the experiment-wise Type I error rate at the 5% level, we use a Bonferroni corrected alpha of 0.05/2 = 0.025 for each single comparison. Clinical significance of the HT intervention will be tested both according to Jacobson and Truax's criteria of reliable and clinical change,[48] and by examination of the number of participants changing W-DEQ score from above to below a cut off score of 85. For the secondary research questions, we will use multiple regression, with `distress, depression, anxiety, somatization, PTSD symptoms, birth complications` as dependent variables, intervention (care as usual, psycho education via Internet, and haptotherapy) as independent variable, and `background variables, social support, FOC` as covariates.

3.5.2 Sample size calculation

The power analysis concerns the primary research question. All computations are performed using GPower3.0.[49] For the planned pair wise comparisons, to detect medium effects or larger (i.e., Cohen's $d \geq 0.5$[50]) with at least 80% power and a Bonferroni corrected alpha of 0.025, a minimal sample size of 64 in each group is needed. With three groups (one

experimental and two control groups) and 64 respondents per group, we also have at least 80% power to find effect sizes (n2) in excess of .05 (indicating a medium effect according to Cohen[50]) using ANOVA.

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4. HAPTOTHERAPY AS A NEW INTERVENTION FOR TREATING FEAR OF CHILDBIRTH: A RANDOMIZED CONTROLLED TRIAL

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4.1 Abstract

4.1.1 Objective
To evaluate the effect of haptotherapy on severe fear of childbirth in pregnant women.

4.1.2 Design
Randomized controlled trial.

4.1.3 Setting
Community midwifery practices and a teaching hospital in the Netherlands.

4.1.4 Population or Sample
Primi- and multigravida, suffering from severe fear of childbirth (N = 134).

4.1.5 Methods
Haptotherapy, psycho-education via Internet and care as usual were randomly assigned at 20-24 weeks of gestation and the effects were compared at 36 weeks of gestation and 6 weeks and 6 months postpartum. Repeated measurements ANOVA were carried out on the basis of intention to treat. Since there were crossovers from psycho-education via Internet or care as usual to haptotherapy, the analysis was repeated according to the as treated principle.

4.1.6 Main Outcome Measures
Fear of childbirth score at the Wijma Delivery Expectancy/Experience Questionnaire.

4.1.7 Results
In the intention to treat analysis, only the haptotherapy group showed a significant decrease of fear of childbirth, $F(2, 99) = 3.321, p = .040$. In the as treated analysis, the haptotherapy group showed a greater reduction in fear of childbirth than the other two groups, $F(3, 83) = 6.717, p < .001$.

4.1.8 Conclusion
Haptotherapy appears to be more effective in reducing fear of childbirth than psycho-education via Internet and care as usual.

4.1.9 Clinical trial registration
This trial has been approved by the Dutch Medical Ethics Review Committee and is registered under ABR number: NL34900.008.11. Clinical trial registration: Dutch Trial Register, NTR3339.

4.2 Introduction

Approximately ten percent of pregnant women suffer from severe fear of childbirth.[1-7] The etiology of fear of childbirth is likely to be multi-factorial and may be related to a more general anxiety proneness, as well as to specific fears.[8-16] Women with severe fear of childbirth and their newborns are at increased risk of various complications, such as pre-term birth,[17, 18] gestational hypertension and pre-eclampsia,[19] emergency caesarean section,[20] extra use of pain medication during birth,[21, 22] low birthweight,[23] prolonged birth and trauma anxiety,[24] increased risk of postpartum post-traumatic stress and depression,[24] and later-on, emotional and behavioural problems of the child.[23] Several studies have evaluated interventions designed to reduce fear of childbirth.[25] Saisto et al. studied group psycho-education consisting of information and discussion of previous obstetric experiences, current feelings, and misconceptions.[26] Salmelo-Aro studied group psycho-education consisting six sessions during pregnancy and one after childbirth.[27] Rouhe et al. compared group psycho-education including relaxation exercises with conventional care.[28, 29] Toolhill et al. and Fenwick et al. studied individual psycho-education by telephone in women with moderate to severe fear of childbirth.[30, 31] Nieminen et al. performed a feasibility study for an Internet-delivered therapist-supported self-help program according to cognitive behaviour therapy.[32] These studies all reported a decrease of fear of childbirth and showed a reduction in caesarean birth, interventions and psychosocial factors. However, they provide little information about long term clinically meaningful psychological health outcomes. Attempts to decrease fear of childbirth in pregnant women are not always successful. For instance, Ryding et al. found that new mothers who had consulted specially trained midwives because of fear of childbirth during pregnancy afterward reported a more frightening experience of birth and more frequent symptoms of post-traumatic stress related to birth than women in the comparison group.[33] Moreover, in a study among pregnant women with a DSM-IV anxiety diagnosis, Verbeek et al. found that the mean birth weight was over 275 grams lower and the mean gestational age almost a week shorter in a cognitive behavioural therapy group than in their care as usual group.[34] During the past decade, clinical experience has suggested that fear of childbirth might be effectively reduced by means of haptotherapy.[35] The haptotherapy exercises have been designed to create a change in the woman's perception of her pregnancy and to promote a more positive attitude towards pregnancy and childbirth. In addition, through haptotherapy, the pregnant woman may improve her readiness for the upcoming labour process, which in turn, is expected to result in a decrease of her fear of childbirth.[25, 35] To evaluate the effect of haptotherapy on fear of

childbirth, we compared haptotherapy with psycho-education via the Internet and care as usual as control conditions in a randomized controlled study. The main research question was as follows: (1) Do pregnant women with severe fear of childbirth after haptotherapy have a lower fear of childbirth than women who received psycho-education via Internet or care as usual? The secondary research questions were as follows: (2) Do women with severe fear of childbirth who received haptotherapy have a better mental wellbeing during pregnancy and postpartum than women who received Internet-psycho-education or care as usual, and (3) do they have fewer medical interventions during birth?

4.3 Method

4.3.1 Design

Between April 2012 and June 2015, pregnant women were recruited through 35 Dutch community midwifery practices, gynaecologists at a teaching hospital, and the project's website. Women who provided informed consent received a login code by email and were requested to digitally complete the Wijma Delivery Expectancy/Experience Questionnaire (W-DEQ). Inclusion criteria for the intervention study were singleton pregnancy, age ≥ 18 years and a W-DEQ score ≥ 85, i.e. suffering from severe fear of childbirth.[36] Exclusion criteria were multiple pregnancies and a history of psychotic episodes. The participants were randomly[37] assigned to (1) haptotherapy, (2) psycho-education via the Internet, or (3) care as usual.

4.3.2 Interventions

4.3.2.1 Haptotherapy

In the Netherlands, pregnant women recognized with severe fear of childbirth would ordinarily visit a psychologist or psychiatrist. However, these women can also directly contact a certified healthcare haptotherapist who is specialized in the treatment of pregnant women with severe fear of childbirth. Haptotherapy claims to facilitate the development of specific skills changing the cognitive appraisal of giving birth and labelling childbirth as a more normal and positive life event, which may ultimately lower fear of childbirth. This intervention, described in detail by Klabbers et al. (2014), consists of training participants in a combination of skills, which are taught in eight one-hour sessions between gestational week 20 and 36.[35] Preferably, the partner of the pregnant woman also attends every session and participates actively in several exercises.[38]

4.3.2.2 Psycho-education via the Internet
Psycho-education via the Internet consisted of eight modules (and a brief test) during a period of eight weeks between gestational week 20 and 36, providing information about the normal course of pregnancy, labour, and birth.[39] Participants also could ask questions about their own situation.

4.3.2.3 Care as usual
Care as usual was conducted according to the standards of the Royal Dutch Organization of Midwives (KNOV),[40] and the Dutch Organization of Obstetrics and Gynaecology (NVOG).[41] In the Netherlands, the obstetric health care is comprised by an echelon system. All healthy women with uncomplicated medical and obstetrical histories enter the primary care system, where pregnancy and delivery are monitored by independent community midwives. Only in case of (increased) risk for complications or interventions during pregnancy or delivery, women are referred to an obstetrician in a general hospital (secondary care) or university referral center (tertiary care). In primary obstetric care, according to the national guidelines, women are seen on average between 12 to 16 times during pregnancy for individual consultations by a midwife. Next to that, there are two optional group counselling's.[42] In secondary and tertiary care this schedule is similar, although, dependent of the medical condition, the number of consultations can be increased. In secondary and tertiary care, the woman may be seen by obstetricians, residents, clinical midwifes and/or nurses.[43] Although healthcare-haptotherapists who are working in primary healthcare in the Netherlands are directly accessible to the public without the necessary intervention of a GP or specialist, haptotherapy was not available as part of care as usual. Some of the participants, who had been allocated to the psycho-education via Internet group or the care as usual group, however, were aware of the other treatment arms and violated the protocol by switching to haptotherapy. These participants were considered as crossovers.

4.3.3 Measures
Fear of childbirth was measured using the W-DEQ,[9, 36] with 33 items on a 6-point Likert scale ranging from `not at all` (= 0) to `extremely` (= 5). Internal consistency and split-half reliability of the W-DEQ is 0.87. A W-DEQ score of ≥ 85 is considered to signify severe fear of childbirth.[36] In the current study, at T1, the Cronbach's α was .95. Distress, anxiety, depression and somatization were assessed using the Four-Dimensional Symptom Questionnaire (4DSQ).[44] This measure contains 50 psychological and psychosomatic symptoms according to DSM-IV.[45] In the present study, at T1, Cronbach's α was .94. Social support – as a potential confounder – was measured by the Social Support Questionnaire (SSQ),[46] with a Cronbach's α of .92. Post-Traumatic Stress Disorder (PTSD) following childbirth was

measured by the Traumatic Event Scale (TES).[24] This measure comprises all the DSM-IV symptoms and criteria of PTSD,[45] (Cronbach's α = .88). We additionally collected information about baseline characteristics, birth complications and medical interventions.[35]

4.3.4 Procedure

The questionnaires were sent by e-mail on four occasions: admission to the study at 20–24 weeks of gestation (T1); 36 weeks of gestation (T2); 6 weeks postpartum (T3), and six months postpartum (T4). The project had a secured Internet environment to facilitate the completion of the online questionnaires. After the approval of the Dutch Medical Ethics Review Committee (ABR number: NL34900.008.11), the original protocol was modified as follows: (1) Pregnant women initially received the information letter, in which they were asked to participate, in week 8-12 of gestation. Given the low response rates, following the recommendation of the participating midwives: (1) the baseline was brought forward to week 20-24 of gestation; (2) after eight months, the inclusion criterion `primigravida` was expanded with `multigravida`; (3) after eight months of study, we started a special research website through which pregnant women could also sign up directly to participate in our study.

4.3.5 Statistical Analyses

4.3.5.1 Intention to treat analyses

To evaluate the effects of haptotherapy on fear of childbirth, we compared the W-DEQ means of the haptotherapy group at T2 with the means of the psycho-education via Internet- and care as usual groups, using repeated measures analysis of variance (ANOVA), followed by two planned pair-wise comparisons to test pair-wise group mean differences (i.e., haptotherapy treatment versus care as usual, and haptotherapy versus psycho-education via Internet). The experiment-wise Type I error rate was set at 5% level. For the post-hoc comparisons, we used a Bonferroni-corrected alpha of .05/2 = .025 for each single comparison. To exclude the influence of birth, we focused on the first two measurements, i.e., (T1) at 20 weeks of gestation, and (T2) 36 weeks of gestation, directly after the intervention. Applying Jacobson and Truax's criteria, we defined a decrease of a W-DEQ score of minimally 16 points to < 85 as a clinically significant change.[47] For the secondary research questions, we ran a series of multiple regression analyses with the predictors W-DEQ and Social Support at T1. As dependent variables, we used the changes in distress, depression, somatization and anxiety between T1 and T2, and postpartum PTSD symptoms at T3. The kind of intervention (haptotherapy, psycho-education via Internet or care s usual) was also used as a predictor.

4.3.5.2 Power analysis
Concerning the primary research question, we performed an a-priori power analysis with GPower3.0.[48] For the planned pair-wise comparisons, to detect medium or larger effects (i.e., Cohen's $d \geq 0.5$[49]) with at least 80% power and a Bonferroni corrected alpha of 0.025, a minimal sample size of 64 in each group was needed.

4.3.5.3 Effect of treatment as received
In case of non-adherence to assigned treatment and crossing over between treatments, we additionally compared W-DEQ scores, at post-test, using groups defined by the treatment as received, (`as treated analysis`).[50] To gauge possible confounding, we compared the baseline characteristics of the as treated groups.

4.4 Results

4.4.1 Sample Characteristics
After three years, recruitment numbers showed a sharp decline and we decided to end the data collection. Consequently, we did not reach the predetermined number of inclusions. At T1, data were obtained from 555 respondents, see Figure 1 for the full details. The inclusion criterion of severe fear of childbirth was met by 134 women (24.2 %), who were randomized (haptotherapy: $n = 51$; psycho-education via Internet: $n = 39$; care as usual: $n = 44$). Not all participants adhered to the intervention to which they were assigned. Eleven assigned to the psycho-education via Internet group switched to the haptotherapy group on their own initiative, as did 14 who had been assigned to the care as usual group. Also, 32 participants dropped out (haptotherapy: $n = 9$; psycho-education via Internet: $n = 14$, care as usual: $n = 9$; see Figure 1).

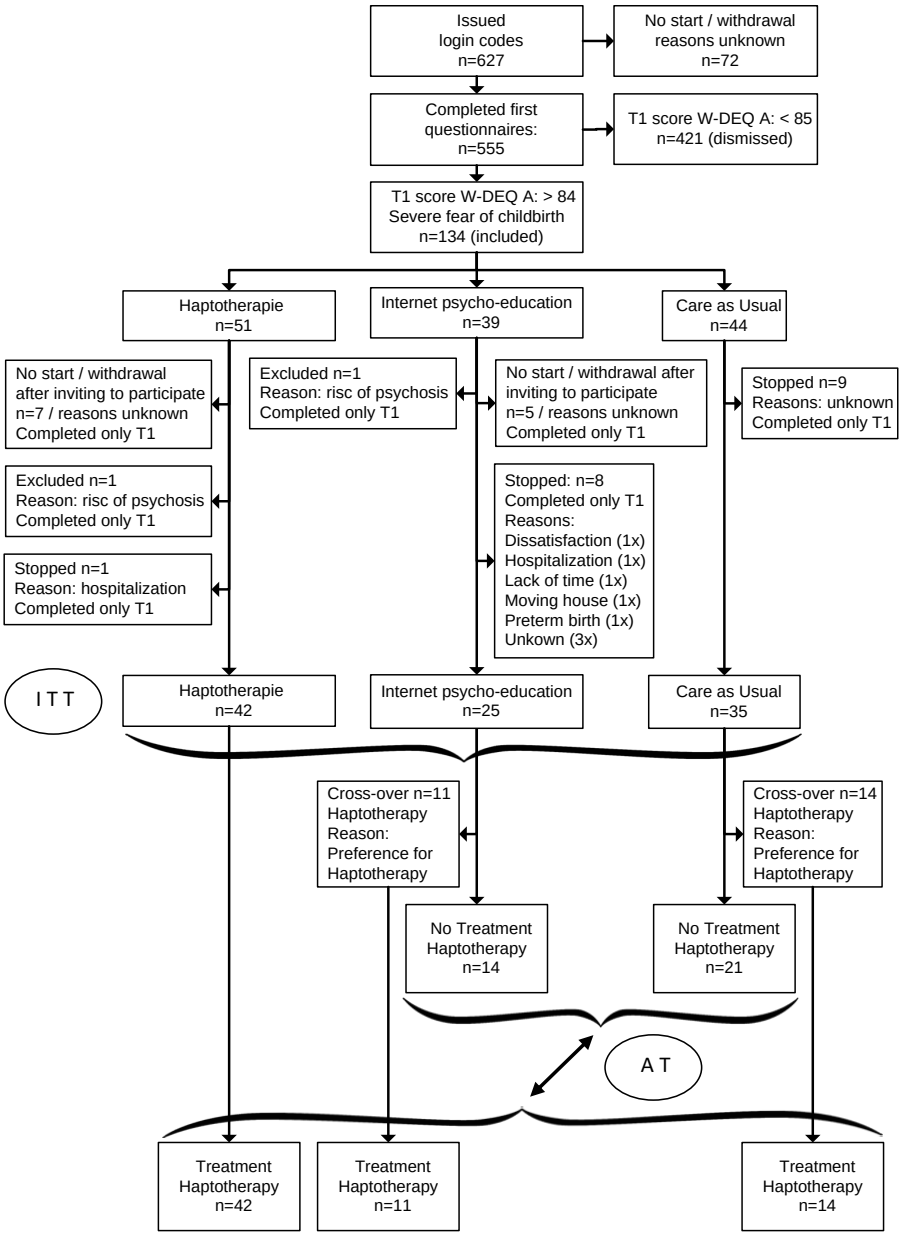

Figure 1: Allocation overview. ITT: Intention to treat analysis. AT: As treated analysis.

4.4.2 Baseline characteristics

Table 1 shows the baseline characteristics and measurements of the three groups haptotherapy, psycho-education via Internet and care as usual as assigned intention to treat and as treated. Baseline levels of W-DEQ, 4DSQ and social support did not statistically differ between the groups.

Table 1: Baseline Characteristics and Measurements

	Intention to treat analysis (ITT)						As treated analysis (AT)			
	HT (*n*=51)		INT (*n*=39)		CAU (*n*=44)		HT (*n*=67)		no-HT (*n*=35)	
	N	%	N	%	N	%	N	%	N	%
Primigravida	32	(62.7)	17	(43.6)	25	(56.8)	37	(55.2)	16	(45.7)
Multipara	19	(37.3)	22	(56.4)	19	(43.2)	30	(44.8)	19	(54.3)
High educational level	36	(70.5)	21	(53.8)	27	(61.4)	49	(73.1)	19	(54.3)
Medium educational level	14	(27.5)	18	(46.2)	15	(34.1)	18	(26.9)	14	(40.0)
Low educational level	1	(2.0)	0	(0.0)	2	(4.5)	0	(0.0)	2	(5.7)
Partner	49	(96.1)	39	(100)	41	(93.2)	66	(98.5)	33	(94.3)
	M	Sd	M	Sd	M	Sd	M	Sd	M	Sd
Age (years)	32.8	(4.6)	31.8	(3.9)	32.6	(5.3)	33.2	(4.1)	32.3	(4.7)
Gestational age (wks)	20.6	(4.4)	20.1	(4.1)	20.5	(4.6)	19.9	(4.4)	20.3	(4.9)
4DSQ Anxiety (range: 24)	4.5	(4.4)	4.6	(5.3)	4.7	(5.1)	4.4	(4.4)	3.2	(3.5)
4DSQ Depression (range: 12)	1.2	(2.4)	1.1	(1.7)	1.2	(2.4)	1.1	(2.4)	0.5	(0.8)
4DSQ Distress (range: 32)	14.0	(8.6)	15.1	(7.2)	14.3	(7.8)	13.7	(8.6)	13.7	(6.1)
4DSQ Somatization (range: 29)	11.1	(7.0)	11.5	(5.6)	11.9	(6.1)	10.1	(7.0)	12.1	(5.4)
SSQ (range: 22)	23.6	(5.0)	22.2	(5.0)	23.1	(5.5)	24.1	(5.0)	22.1	(5.7)
W-DEQ (range: 141)	101.1	(13.8)	104.5	(17.5)	98.6	(15.4)	101.4	(13.8)	97.5	(13.3)

HT = Haptotherapy. INT = Psycho-education via Internet. CAU = Care as usual. 4DSQ = Four Dimensional Symptom Questionaire. SSQ = Social Support Questionaire. W-DEQ = Wijma Delivery Expectancy/Experience Questionnaire.

4.4.3 Effect of haptotherapy

4.4.3.1 Intention to treat analysis

Repeated measures ANOVA showed a significant interaction effect of fear of childbirth for T1 and T2 in the three groups, $F(2, 99) = 3.321, p = .040$, implying that the average change between T1 and T2 differs among groups. Post-hoc comparisons revealed a larger decrease of fear of childbirth for the haptotherapy group than for the other two groups: haptotherapy versus psycho-education via Internet (mean difference in change -8.75: $p = .250$) and haptotherapy versus care as usual (mean difference in change -11.09, $p = .049$). A repeated measures ANOVA without the crossovers also showed a significant change of fear of childbirth from T1 to T2 in the three groups, $F(2, 74) = 9.255, p < .001$ and post-hoc comparisons demonstrated a larger decrease of fear of childbirth for those who were assigned to the haptotherapy condition than for the other two groups; haptotherapy versus psycho-education via Internet (mean difference in change -17.07: $p = .016$) and haptotherapy versus care as usual (mean difference in change -20.0, $p = .001$).

Figure 2a displays the profiles of fear of childbirth scores across T1-T4 for the three groups. In all three groups, from pre- to postpartum, the fear of childbirth further decreased to T3 and did not change from T3 to T4. The mean fear of childbirth score of the haptotherapy group shows a (non-significant) trend to remain the lowest in comparison to psycho-education via Internet and care as usual ($F(6, 164) = 1.616, p = .146$; see Figure 2a).

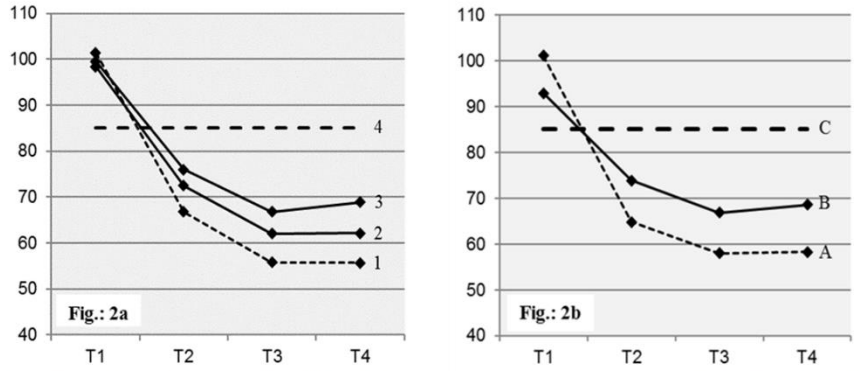

Figure 2: Means of fear of childbirth (W-DEQ score) across four measurement occasions. T1: 20-24 weeks of gestation, T2: 36 weeks of gestation, T3: 6 weeks postpartum, T4: 6 months postpartum. **2a**: Intention to treat analysis (ITT). 1: Haptotherapy (HT), 2: Psycho-education via the Internet (INT), 3: Care as usual (CAU), 4: Cut off score 85. **2b**: As treated analysis (AT). A: Haptotherapy including Cross-overs (HT+CRO), B: Combined no-HT groups (INT + CAU), C: Cut off score 85.

4.4.3.2 As-treated analysis

Figure 2b shows the profiles of fear of childbirth across T1-T4 in an as treated analysis of women who actually obtained haptotherapy and those who obtained either psycho-education via Internet or care as usual. At T2, average fear of childbirth was lower in the haptotherapy group than in the combined no-haptotherapy groups (psycho-education via Internet and care as usual). Repeated measures ANOVA showed an interaction effect across all four measurement occasions, $F(3, 83) = 6.717, p < .001$ and on fear of childbirth for T1 and T2, $F(1, 100) = 27.092, p < .001$ (haptotherapy group mean W-DEQ score -35.49, no-haptotherapy -15.89, haptotherapy versus no-haptotherapy mean difference in change score -19.6, $p < 0.01$). Cohens *d*: haptotherapy = 2.4 and no-haptotherapy = 0.8, meaning haptotherapy more effectively reduced fear of childbirth than no-haptotherapy, see Figure 2b.

According to as treated analysis, the percentages of women with a reliable and clinically significant change of fear of childbirth between T1 and T2 (i.e., a decrease of the W-DEQ score $\geq$ 16 + a W-DEQ score < 85 at T2), in the haptotherapy group (haptotherapy + crossovers) versus the no-haptotherapy groups together (psycho-education via Internet + care as usual) were 75% and 51% respectively ($Z = 2.36, p < .01$).

4.4.4 Secondary data analyses

Regression analysis revealed no significant differences in the adjusted means of the TES-scores at T3 between the intention to treat groups when controlling for fear of childbirth and social support at T1, $F(2,88) = 2.945, p = .058$. Intention to treat uniquely accounted for 5.9% of the total variance. However, post-hoc comparisons of the adjusted means suggested a significant difference between haptotherapy and care as usual, $t(88) = -2.257, p = .026$. We may notice that in the case of three groups, no Bonferroni correction is needed to maintain the experiment-wise alpha at the 5% level.[50] We should also notice that caution should be exercised with interpretation of the post-hoc test because the assumption of homogeneity did not hold. As the smallest within-group variance was for the largest group, the *p*-values tend to be little too low (i.e., the test is too liberal). But given that the *p*-value of .026 is considerably smaller than the nominal level of .05, the conclusion that the effect exist seems robust even though the test is liberal.

Regarding the as treated analysis, Table 2 shows the results of the regression analysis for the secondary outcomes (4DSQ). The dependent variables are the changes between T1 and T2 (i.e., T2-T1), with negative change scores reflecting improvement. The intervention had a significant effect on changes in 4DSQ-scores, controlled for fear of childbirth and social support at T1. The haptotherapy group showed a larger improvement on average than the no-haptotherapy groups. The haptotherapeutic intervention uniquely accounted for 4.9% to 9.8% of the variance in change scores. Social support also was significantly associated with change in depression, see Table 2, meaning that more social support results in fewer depression symptoms. No statistically significant correlation was found between social support and change in fear of childbirth for the haptotherapy group (r = .024, n = 67, p = .844); nor for the no-haptotherapy group (r = .244, n = 35, p = .200). Applying the cut-off values of the 4DSQ,[51] in the haptotherapy group ($n = 67$) the percentages of women with high distress and depression 4DSQ-scores decreased, between T1 and T2, from 22.4% to 3.0% ($p = .001$) and from 16.4% to 6.0% ($p = .039$), respectively. In contrast, in the combined no-haptotherapy groups (psycho-education via Internet + care as usual), ($n = 35$), the percentages of pregnant women with severe distress

symptoms (14.3%) and depression symptoms (5.7%) did not change significantly. No significant differences between intervention groups were observed concerning somatization, medical interventions, duration of pregnancy, or birthweight.

Table 2: Results of multiple regressions using AT analyses with FOC and social support at T1 and the intervention as predictors, and the 4DSQ-scale T1-T2 change scores as dependent variables. (significant values printed in boldface).

Predictor	Dependent variable							
	Δ Distress		Δ Depression		Δ Somatization		Δ Anxiety	
	B	r^2_{pr}	B	r^2_{pr}	B	r^2_{pr}	B	r^2_{pr}
W-DEQ T1	0.057	1.6%	0.000	0%	-0.036	1.0%	-0.015	0.5%
SSQ T1	0.211	2.5%	**0.098**	**5.0%**	0.119	1.3%	0.083	1.8%
Intervention		**4.9%**		**8.4%**		0.2%		**9.8%**
HT	**-2.997**		**-1.288**		0.452		**-1.982**	
No-HT	---		---		---		---	
R-square		**10.6%**		**12.1%**		3.7%		**12.7%**
N	102		102		102		102	

Note. r^2_{pr} is the squared semi-partial correlation, which reflects the proportion of the total variance in the dependent variable (in percentage) that is uniquely explained by the predictor. AT = As treated. FOC = Fear of childbirth. HT = Haptotherapy. SSQ = Social support questionnaire. T1: 20-24 weeks of gestation. T2: week 36 of gestation. AT = As treated.

4.5 Discussion

The aim of this study was to evaluate the effect of haptotherapy on fear of childbirth by comparing haptotherapy with psycho-education via Internet and care as usual as control conditions in a randomized controlled study. In comparison to psycho-education via Internet and care as usual, haptotherapy had a stronger positive effect on the mental wellbeing of the mother. During pregnancy, prenatal distress symptoms and prenatal depressive symptoms were lower in the haptotherapy group, and postpartum participants in the haptotherapy group also had less fear of childbirth and fewer PTSD symptoms. Fewer PTSD symptoms postpartum suggest that women in the haptotherapy group experienced childbirth as less traumatic than the women in the no-haptotherapy groups, perhaps because they were better able to mentally handle birth. In contrast, no differences were observed concerning somatization, medical interventions, duration of pregnancy, birthweight and gestational age. This indicates that haptotherapy had no negative side effects on birthweight or gestational age. A considerable number of participants switched from a no-haptotherapy treatment to the treatment condition haptotherapy. According to Marcus and Gibson (2001), such switching can cause intention to treat results to poorly indicate the efficacy of the treatment.[53] Therefore, we carried out an additional as treated analysis, which revealed a more pronounced decrease of fear of childbirth in the

haptotherapy group as compared with the psycho-education via Internet- and care as usual groups. This analysis also revealed a substantially higher percentage of women showing a clinically significant change in the haptotherapy group than in the two no-haptotherapy groups combined. This is the first study to examine haptotherapy as treatment for severe fear of childbirth, which precludes a comparison with previous studies.
Comparisons with other studies are also problematic because of the use of different W-DEQ cut-off scores to define fear of childbirth and differences in population groups.[25] For example, Rouhe et al.[28, 29] used a W-DEQ score $\geq$ 100, whereas Toolhill et al.[30] used a W-DEQ score $\geq$ 66. Only Nieminen et al.[32] also used a W-DEQ score $\geq$ 85, as was recommended by the developers of the W-DEQ.[54] International consensus about the cut-off score to define severe fear of childbirth, would make it much easier to compare outcomes of RCT's. In the present study, the percentage of pregnant women with a W-DEQ score $\geq$ 85 was 24.2%. A recent systematic review,[55] has shown the worldwide prevalence in developed countries is 14%. However, there might be populations with significantly higher prevalences of fear of childbirth, and Dutch women may be one of those populations. An alternative obvious explanation may be that this study in particular attracted the attention of high fear women.
According to Ugarriza et al.[56] and Chojenta et al.[57], a lack of social support is associated with postpartum depression, which is consistent with our findings that more social support results in fewer antepartum- and postpartum depression symptoms. However, in the haptotherapy group and the no-haptotherapy group as well, we found no association between social support and fear of childbirth. One may argue, that the haptotherapeutic sessions, comprising of eight episodes together with the partner, may well lead to experience of additional attention and feelings of support by both the therapist and the woman's partner. This experience might add to feelings of being socially supported and may be of influence in the results. However, although perceived social support decreases feelings of depression, it did not show to reduce fear of childbirth.

4.5.1 Proposed mechanism

HT has been designed to gradually shape the mind-set and teach the pregnant woman to become more confident about her ability to deliver the baby vaginally. It is plausible that increasing the woman's self-reliance and self-confidence results in reduction of fear of childbirth.[35]

4.5.2 Limitations

Based on power analysis, we had fewer participants than planned due to difficulty with recruitment and amended the protocol to improve this. We also had a considerable number of crossovers: 11 participants in the 'psycho-education via Internet' group and 14 participants in the 'care as usual' group chose to switch to haptotherapy, which impacted our planned analysis. Nevertheless, we were able to demonstrate statistically and clinically significant differences in favor of haptotherapy. One of the reasons for the many crossovers might have been that the participants knew about the possibility of haptotherapy and actively opted for it. The participating midwifery practices did not adequately represent practices in general but were more motivated than others to improve the care for women with severe fear of childbirth. Therefore, their care as usual might have been more supportive than in the average midwifery practices, which have less experience in dealing with women with severe fear of childbirth. Consequently, they likely also attract more pregnant women with special needs, as was reflected in the high percentage of women with severe fear of childbirth.

4.5.3 Strengths

The crossovers were not planned by protocol, but were also followed in our study. Whereas the crossovers in some way must be regarded as a major weakness of the study, this particular characteristic simultaneously renders the study less artificial and gives it a high ecological validity. Apparently, both the psycho-education via Internet group and the care as usual group comprised many pregnant women with strong views about the treatment they wanted. Currently, in clinical practice, empowerment is a hot issue and patients increasingly make their own choices and select the specific treatment they feel most comfortable with, rather than passively accepting whatever treatment the health provider proposes. Furthermore, we respected the women's choice for specific antenatal guidance, which also contributed to the high ecological validity.

4.5.4 Recommendations for future research

One of the reasons why it might have been difficult to recruit enough women might be that the WDEQ comprises of 33 items, which is rather lengthy. In order to compare the outcomes to previous studies – for future research on interventions which aim to decrease fear of childbirth – we recommend, that everyone uses the same questionnaire, such as the WDEQ. For clinical use however, there is need for a shortened questionnaire. In this respect, the two-item Fear of Birth Scale (FOBS) has been tested against the WDEQ as a 'gold standard' and seems to be promising for clinical use.[58] Therefore, in future research it is recommended to use both questionnaires: WDEQ for

comparison with other studies and FOBS for validation in clinical settings. Furthermore, further research is needed to explore the proposed working mechanism of haptotherapy in reducing fear of childbirth.

4.6 Conclusion

We demonstrated positive effects of haptotherapy on fear of childbirth, both in comparison to care as usual and psycho-education via Internet. Haptotherapy additionally improved several aspects of the wellbeing of the mother, such as prenatal distress- and depressive symptoms, as well as postpartum fear of childbirth and PTSD symptoms. No differential effects were observed in somatization, medical interventions, or duration of pregnancy. Haptotherapy seems a promising intervention for pregnant women suffering from fear of childbirth.

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5. RESISTANCE TO FEAR OF CHILDBIRTH AND STABILITY OF MOTHER-CHILD BOND

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5.1 Abstract

In order to examine (1) the stability of the mother-child-bond and (2) associations between mother-child-bonding and aspects of maternal-well-being, pregnant women (N = 170) completed measures on well-being and mother-child-bonding at two antepartum and two postpartum time points. We found relatively weak associations between mother-child-bonding at 20 weeks of gestation and mother-child-bonding at 6 months postpartum. Fear of childbirth was weakly, but statistically significantly associated with mother-child-bonding at 6 weeks (but not at 6 months) postpartum. Correlations between antepartum general well-being and social support, on the one hand, and mother-child-bonding, on the other, failed to reach statistical significance. Women with a partner had a better mother-child-bonding at 36 weeks of gestation and 6 months postpartum, than women without a partner, and older women had better mother-child-bonding at 20 weeks of gestation, than younger women. Our findings thus suggest that mother-child-bonding is not a very stable phenomenon, but it is quite robust against potential negative influences of poor maternal mental health.

5.2 Background

Mother-child-bonding (MCB) refers to thoughts and feelings of the mother towards her child and has been found to be related to maternal well-being and positive child development outcomes.[1, 2] This bond between mother and child is hypothesized to start to develop early during pregnancy and to continue its development during pregnancy and beyond.[3] According to theories about antepartum bonding, the importance of positive thoughts and feelings about the relationship with the unborn baby is that they promote antepartum and postpartum maternal behaviour and caregiving.[3] Feelings of bonding occur in parallel with the physical development of the foetus and psychological adjustments accompanying the upcoming motherhood.[4]

Optimal MCB facilitates the mother's nurturing behaviour and supports her role to protect the child. MCB also positively influences maternal health practices during pregnancy and postpartum period, such as choosing a healthy diet and drinking no alcohol.[5] Research also found that a compromised antepartum MCB may be predictive of a future lack of MCB,[6] and the development of psychopathology in the child.[7] Remarkably, until now studies failed to explore the course of its precise development during pregnancy, and post-partum and how mother characteristics are associated with this factor is also still largely unexplored.

Whereas previous studies showed that maternal general anxiety might affect MCB,[8] to our knowledge, few studies have examined mothers' feelings and thoughts about the unborn baby in women experiencing severe fear of childbirth (FOC). Approximately ten percent of pregnant women suffer from severe FOC,[9] which means that the fear of giving birth is so intense that it makes the woman dysfunctional with severe consequences for her personal, social, and work life and for her willingness to become pregnant and/or ability to give birth.

When the fear fulfils the criteria for a phobia according to DSM-5, women often may want to avoid delivery or the delivery is endured with intense anxiety.[10] Studies have also demonstrated that women with high levels of antepartum childbirth anxiety are concerned about the well-being of themselves and their infants,[11] the labour process (pain, medical interventions, abnormal course of labour, death, re-experiencing a previous traumatic delivery),[12] personal conditions (lack of control, distrust in own abilities), and external conditions (interaction with or the assistance of the staff).[13]

In addition, associations between FOC and several possible health indicators have been reported, such as hypertension and pre-eclampsia,[14] preterm birth;[15, 16] complications during delivery and emergency caesarean section;[17, 18] more frequent use of analgesia during delivery,[19] and prolonged delivery and trauma anxiety.[20]

In a clinical observation, Klabbers, Wijma, Paarlberg, Emons and Vingerhoets (2014) observed that high FOC women often touch their belly in an objectifying manner and speak about their unborn child in an objectifying way, which might be an indication of a compromised MCB.[21] Previously, Hofberg and Ward (2003) suggested that bonding problems with the infant might be associated with FOC due to previous traumatic deliveries.[22]

The present study has two principal objectives. The focus is, first, on the stability of MCB over time (both antepartum and postpartum) and, second, on associations between MCB and aspects of maternal well-being, i.e., maternal symptoms of distress, depression, general anxiety and somatization, as measured with the four-dimensional symptoms questionnaire (4DSQ).[23]

5.3 Methods

5.3.1 Design and procedure

Between April 2012 and June 2015, women with a singleton pregnancy, age 18 or older, were recruited in 35 Dutch community midwifery practices, by gynaecologists at a department for Obstetrics and Gynaecology at a teaching hospital, or via the project's website.[21] Women were invited to complete an informed consent form, after which they received a login code by email and were asked to digitally complete the project measures. A secured Internet environment was designed for the project, facilitating the completion of the online questionnaires. The questionnaires were sent by e-mail at four-time points: at 20 to 24 weeks of gestation (T1), when the movements of the baby can usually be felt for the first time; at 36 weeks of gestation (T2), i.e., a few weeks before delivery, when usually the upcoming birth is becoming actual for pregnant women; at 6 weeks postpartum, at the end of postpartum maternity leave (T3); and at 6 months postpartum, to measure longer-term psychological health outcomes (T4).

5.3.2 Study participants

The study sample consisted of 555 pregnant women aged $\geq$ 18 who had filled out the questionnaires. Exclusion criteria were a multiple pregnancy and a history of psychotic episodes.

5.4 Measures

5.4.1. Pictorial Representation of Attachment Measure

MCB was measured using the Pictorial Representation of Attachment Measure (PRAM),[24] see Figure 1.

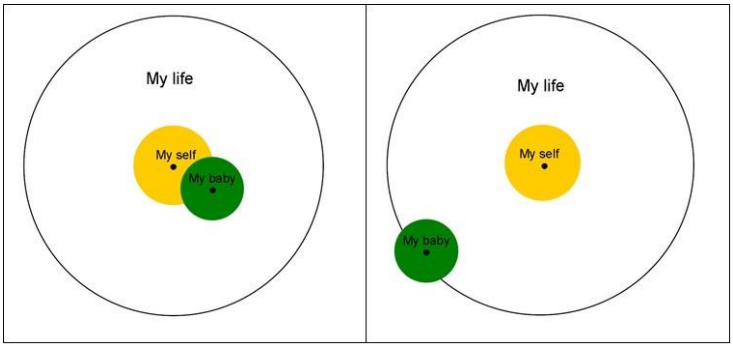

Figure 1: Two examples of the Pictorial Representation of Attachment Measure (PRAM).

The PRAM was recently introduced as a potential valid, quick, and easy-to-administer instrument of parent-infant bonding (see Figure 1) which showed meaningful associations with validated questionnaires measuring mother and father bonding.[8, 25, 26] The original paper version of the PRAM has been validated.[26] In the current study, a digital version was used, not yet validated in this form. The measure is represented by a white screen with a big circle, which represents the pregnant mother's current life. A yellow circle in the center of the big circle represents the woman's 'Self'. Next to the big circle, a green circle represents the foetus/infant at that very moment. The mother's task is to move the foetus/infant circle to a certain place in the circle representing her current life. The outcome measure is the Self-Baby-Distance (SBD), i.e., the distance (in millimeters) between the centers of the 'Baby' and 'Self' circles. The score on the PRAM is inversely related to MCB, i.e. a higher PRAM score indicates lower MCB.

5.4.2 Wijma Delivery Expectancy/Experience Questionnaire

FOC was measured using the 33-item Wijma Delivery Expectancy/ Experience Questionnaire (W-DEQ),[27] with a 6-point Likert scale ranging from `not at all` (=0) to `extremely` (=5), yielding total scores ranging from 0 to 165. We used a cut-off score of 85, i.e., a W-DEQ score ≥ 85 indicating that the mother suffers from severe FOC, in agreement with recommendations of the author of the W-DEQ.[10, 27] In the current study, at T1, the Cronbach's α was .95.

5.4.3 Four-Dimensional Symptom Questionnaire

Distress, anxiety, depression, and somatization were assessed using the Four-Dimensional Symptom Questionnaire (4DSQ).[28] The 4DSQ comprises a list of 50 symptoms according to DSM-IV (American Psychiatric Association, 1994). The 4DSQ measures distress, depression, general anxiety and somatization as separate dimensions, with a 6-point Likert scale ranging from `no` (=0) to `very often or constantly` (=5). In the present study, at T1, the Cronbach's α was .94.

5.4.4. Social Support Questionnaire

Social support was measured using the Social Support Questionnaire (SSQ),[29] in which a 5-point Likert scale, ranging from 'not applicable' (=0) to `very applicable` (=5), yields total scores ranging from 0 to 30. In the present study, at T1, the SSQ Cronbach's α was .92.

5.4.5. Biographic characteristics

We additionally collected information about the participants' biographic characteristics such as age, relationship status, parity, and educational level with questions especially designed for this study.[21]

5.5 Statistical Analyses

Descriptive statistics (M and SD) were calculated for all measures. Pearson product-moment correlations were calculated to determine the associations among MCB measures at 20 weeks of gestation, 36 weeks of gestation, 6 weeks postpartum, 6 months postpartum, and between FOC, MCB, social support, and well-being of the mother (i.e., maternal distress, somatization, depression, measured at T1) and MCB (measured at T1-T4). Additionally, two repeated ANOVAs across two antepartum (T1 and T2) and two postpartum measurement occasions (T3 and T4) were performed to test stability and to compare group means of PRAM scores over time in women with a W-DEQ score < 85 and in those with a W-DEQ score $\geq$ 85.

5.6 Results

The sample consisted of 555 pregnant respondents, of whom 332 (59.8%) were primigravida, see Table 1. At T1, data were obtained from all 555 respondents [1]. There was an outflow at T2 due to technical problems with the digital application of the PRAM and several additional dropouts at T2, T3, and T4. For the exact details, see Figure 2. For biographic characteristics, see Table 1.

Table 1: Biographic Characteristics at T1.

Age (M-years, SD)	31.9	(4.5)
	n	%
Primigravida	332	(59.8)
Multigravida	223	(40.2)
High educational level	372	(67.7)
Medium educational level	166	(30.2)
Low educational level	17	(3.1)
Partner	543	(97.8)

T1: 20-24 weeks of gestation.

[1] Unfortunately, due to software problems, PRAM data of 71 respondents at T1 were not registered. The mean W-DEQ score of those 71 respondents did not significantly differ from the scores of the other 484 respondents: $F(1, 553) = .023$, $p = .880$.

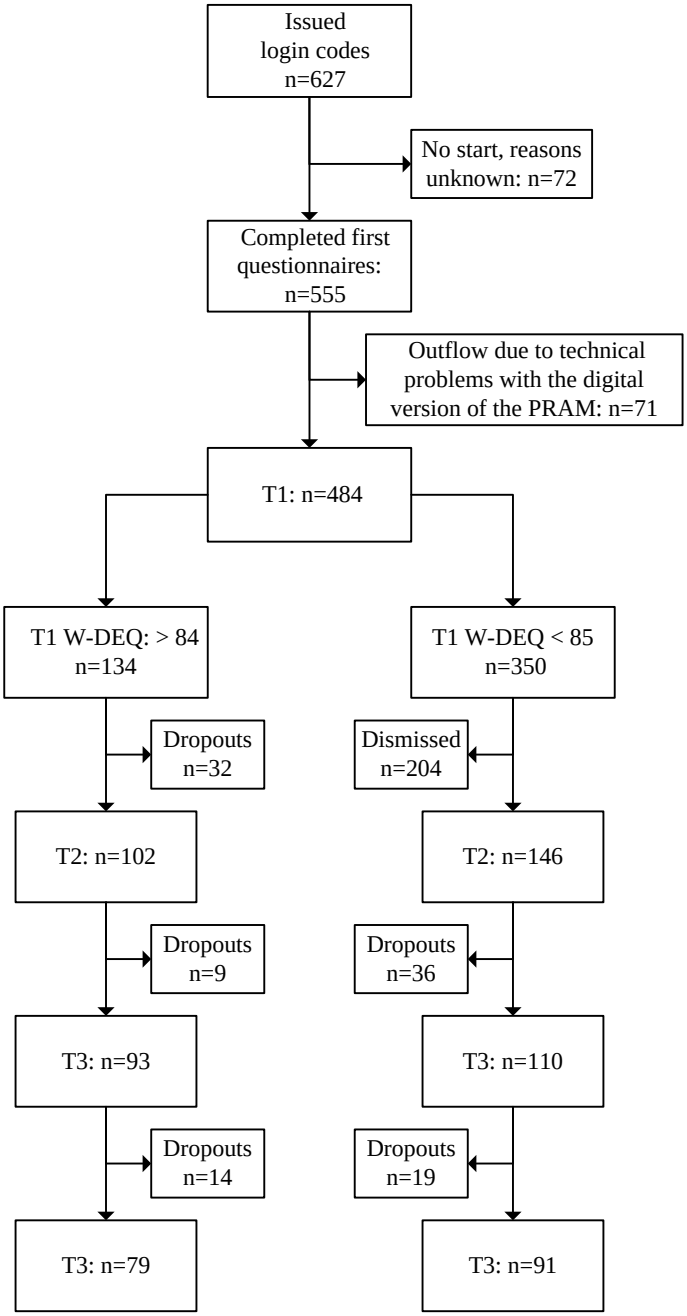

Figure 2: Flowchart. T1: 20-24 weeks of gestation. T2: gestation week 36. T3: 6 weeks postpartum. T4: 6 months postpartum.

Regarding the development of MCB over time, two results are apparent, see Table 2. First, the mean values were not significantly different between the time points and the correlations between the PRAM scores were all significant (varying between .223 and .386, p's < .05).

Table 2: Pearson's correlations between the PRAM scores at T1-T4.

	T1-PRAM	T2-PRAM	T3-PRAM	T4-PRAM
M	70.4	69.9	70.0	69.9
SD	9.3	8.7	6.7	7.8
N	484	248	203	170
T1-PRAM	1	.264 **	.223 **	.311 **
T2-PRAM		1	.386 **	.282 **
T3-PRAM			1	.296 **
T4-PRAM				1

** Correlation is significant at the 0.01 level (2-tailed). PRAM: Pictorial Representation of Attachment Measure. T1: 20-24 weeks of gestation. T2: 36 weeks of gestation. T3: 6 weeks postpartum. T4: 6 months postpartum.

Concerning the second research question, the correlations among antepartum depression, distress, somatization, social support and antepartum and postpartum MCB varied from -.114 to .087 and none reached statistical significance, see Table 3. Having a partner was found to be statistically significantly positively correlated to MCB at T4 (r = .198, n = 170, p = .010). We further found relatively weak associations between mother-child-bonding at 20 weeks of gestation and mother-child-bonding at 6 months, ($r = .311\, n = \ 160, p < .001$.

To test whether PRAM scores of the group of women with severe FOC, i.e., W-DEQ-score $\geq$ 85 differed from the scores of the group of women with a W-DEQ score < 85, a repeated measures ANOVA across four measurement occasions (T1-T4) was carried out. No significant mean group differences in MCB (PRAM scores) between pregnant women with a W-DEQ score < 85 and those with a W-DEQ score $\geq$ 85 were found: $F(3, 142) = .288, p = .834$.

Table 3: Pearson's product-moment correlations between fear of childbirth, biographic characteristics, social support and wellbeing of the mother (i.e, maternal depression, distress, somatization) on the one hand and mother-child bonding at T1-T4 on the other.

			T1-PRAM n = 484	T2-PRAM n = 248	T3-PRAM n = 203	T4-PRAM n = 170
T1	W-DEQ:	Fear of childbirth	-.071	-.050	-.145 *	.041
	4DSQ:	Distress	-.063	-.059	-.110	.064
		Depression	-.051	-.060	-.030	.027
		Somatization	-.030	-.084	-.114	.045
	SSQ:	Social Support	.087	.065	.077	.020
	BC:	Age	-.104 *	.066	-.123	-.137
		Education	-.007	-.030	-.030	-.123
		Partner	-.080	.144 *	.101	.198 **
		Primi-/multigravida	.036	-.059	.011	-.047

* Correlation is significant at the 0.05 level (2-tailed). ** Correlation is significant at the 0.01 level (2-tailed). T1: 20-24 weeks of gestation. T2: 36 weeks of gestation. T3: 6 weeks postpartum. T4: 6 months postpartum.W-DEQ: Wijma Delivery/Expectancy Questionnaire. 4DSQ: Four Dimensional Symptom Questionnaire. PRAM: Pictorial Representation of Attachment Measure. SSQ: Social Support Questionnaire. BC: Biopraphiccharacteristics.

PRAM scores at T1 and the W-DEQ scores at T1 were both normally distributed, with a skewness of -.278 (SE = .111) and a kurtosis of .577 (SE = .222) for the PRAM, and a skewness of .430 (SE = .104) and a kurtosis of .254 (SE = .207) for the W-DEQ.

Between FOC at T1 and MCB at T3, a statistically significant negative correlation was found ($r = -.145, n = 203, p = .038$). Between FOC and MCB at T1 no statistically significant correlation was found ($r = -.071, n = 484, p = .117$); nor between FOC at T1 and MCB at T4 ($r = .041, n = 170, p = .598$), see Table 3.

5.7 Discussion

The primary objectives of the present study were to learn more about the stability of MCB over time, both antepartum and postpartum and, second, to investigate the possible association between background variables and the general well-being of the mother, operationalized in terms of FOC and 4DSQ scores, and antepartum and postpartum MCB. Regarding the first aim of the study, the MCB was stable over a 9 month period and did not change from pregnancy to 6 weeks and 6 months postpartum findings failed to reveal a systematic and substantial change over time.

Concerning the second issue, contrary to expectations, the results also did not show substantial relations between FOC and postpartum MCB, suggesting that FOC may not have a significant impact on MCB or that that influence might be either positive or negative, depending on yet to determine factors, e.g., the attachment style of the mother. We only found a statistically significant negative correlation between antepartum FOC and MCB at 6 weeks postpartum. Between antepartum FOC and postpartum MCB at 6 months postpartum also no statistically significant association was found. When MCB was compared between high and low to moderate FOC women, also no significant mean group differences were observed. Therefore, although previous studies demonstrated that high FOC was associated with several adverse consequences for both mother and infant,[2, 12, 14-17, 30] our study did not find an overall negative impact of severe FOC on MCB.

Previous studies used different measuring tools to assess MCB at different measurement points. This may have caused differences in results between the current and previous studies. For example, De Cock et al. (2016) used the Maternal Antenatal Attachment Scale (MAAS) at three-time points:[8] 26 weeks of gestation, 6 months postpartum, and 24 months postpartum, whereas Ossa et al. (2012),[31] between 25 and 40 weeks of gestation, used the Condon's Antenatal Emotional Attachment Questionnaire.[32] Moreover, the percentage of pregnant women with a W-DEQ score $\geq$ 85 was considerably higher (24.2%) in our study than the 10% mentioned in previous research reports (see for an overview Klabbers, Van Bakel, Van den Heuvel & Vingerhoets, 2016).[33] This may imply a selection bias because this study seemed to attract the attention of high FOC women in particular.

From the biographic characteristics (i.e., age, parity, education, relationship status) and all psychological factors (fear of childbirth, depression, distress, somatization, social support), at 6 months postpartum, only ‘having a partner’ was weakly positively associated with postpartum maternal feelings of bonding with the baby. This failure to find meaningful association is in accordance with other studies, such as those by Cranley (1981),[34] which also did not show a relationship between prenatal attachment and parity and Armstrong (2002),[35] who demonstrated that depressive symptoms and pregnancy-specific anxiety do not seem to affect subsequent parent-infant attachment in a pregnancy after a previous perinatal loss. However, on the other hand, Ferketich and Mercer (1995),[36] and Van Bussel, Spitz, and Demyttenaere (2010) found that multiparous women had lower attachment scores than primiparous women,[37] Sorensen and Schuelke (1999) demonstrated that prenatal fantasies about the unborn child were more prevalent in primigravida than in multipara,[38] and A. Yarcheski, Mahon, Yarcheski, Hanks and Canella (2009) found that social support is a predictor of MCB.[39] The reasons for these inconsistent results might be the fact that MCB was measured during different time periods of pregnancy and with different kinds of instruments in these various studies.

The lack of an association between MCB, FOC, and indices of the mother’s well-being in our study might be explained in several ways. First, although a significantly high percentage of women in the present study reported suffering from FOC, high levels of FOC did not negatively affect the levels of bonding with their child. Levels of fear thus might not be high enough to influence their feelings of bonding or, as said before, might change bonding in opposite ways. Mothers may feel very fearful about giving birth but, nevertheless, will be able to feel firmly connected to their unborn child, but the fear that the infant is at serious risk may also dampen this bond, in an attempt to reduce the suffering associated with the loss of the infant. Second, it can be argued that MCB is not readily compromised by the mother’s symptoms of distress, or depressive or anxious feelings. For example, the stability of MCB might be comparable to the robustness of the Baby Schema Effect (BSE).[40] The BSE refers to the phenomenon that a set of specific infantile physical features, such as the large head, round face, and big eyes, are automatically perceived as cute and motivates caretaking behaviour in adults. Lehmann et al. (2013) demonstrated that BSE is insensitive to a possible negative influence of person factors such as narcissism and insecure attachment.[40]

The authors suggest that such an essential biological phenomenon, which might facilitate MCB, should be rather robust and not too easily be affected by non-optimal person factors in order to guarantee an optimal caregiving

process. The same line of reasoning may apply to the findings in the current study, i.e., MCB might also be such a crucial biological phenomenon for the mother and the survival of the child that it is plausible that it is quite resistant to the possible negative influences of high levels of maternal fear and anxiety. Note that the used instrument (4DSQ) must be considered a screening tool and is not able to diagnose reliably a major depression or any other serious psychopathology. Therefore, it cannot be concluded on the basis of the current finding that MCB is not affected by severe psychopathology.

5.7.1 Limitations

First of all, the percentage of high FOC pregnant women was considerably higher (24.2%) in our study than the 10% mentioned in the literature,[33] which suggests a selection bias. Women experiencing FOC may have been more willing to participate in the study and complete the initial questionnaire. Second, when women were invited via Internet advertising, women suffering from FOC might have been more inclined to participate. Further, we had lost data due to software problems with the digital version of the PRAM, causing extra outflow (n = 71). Finally, it is not clear to what extent the current digital PRAM may have yielded different findings than the original paper version.

5.7.2 Recommendations

Further research is needed to confirm and extend the present findings. In order to facilitate the comparison with results of previous studies, we recommend using validated measures and tuning the timing of the measurements in future studies better, i.e., using the same questionnaires at the same time points. Moreover, additional research is needed to evaluate the comparability of the paper version of the PRAM and the here used online version (cf. Noyesa & Garland, 2008). Finally, the notion that fear that the infant will not survive delivery may delay the bonding process as a preventive coping mechanism needs further appropriate consideration.

5.8 Conclusion

MCB seems not to be negatively affected by maternal depression, distress, somatization, and lack of social support. Antepartum MCB and having a partner are positively associated with postpartum MCB. In women with severe FOC, MCB does not seem to be negatively affected. Antepartum FOC is weakly negatively associated with an impaired MCB at 6 weeks postpartum, but not with MCB at 6 months postpartum, nor is antepartum FOC related to antepartum MCB.

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6. DOES HAPTOTHERAPY BENEFIT MOTHER-CHILD BONDING?

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6.1 Abstract

6.1.1 Objective
To evaluate the effect of haptotherapy during pregnancy on mother-child bonding (MCB).

6.1.2 Population or Sample
Primigravida and multigravida (N = 73).

6.1.3 Methods
Data were obtained from a randomized controlled trial study on treatment for severe fear of childbirth with haptotherapy. Fear of Childbirth (FOC) was evaluated using the Wijma Delivery Expectancy/Experience Questionnaire (W-DEQ) and mother-child bonding (MCB) by an online version of the Pictorial Representation of Attachment Measure (PRAM). Screen-positive women for severe FOC were randomly assigned either to a haptotherapy (HT) arm or a no-haptotherapy (No-HT) arm (psycho-education via Internet or care as usual). In this group, a median split was carried out on the PRAM to allow focusing on the women with the 50% poorest MCB levels. Measurements were on four occasions: (T1) 20-24 weeks of gestation, (T2) 36 weeks of gestation, (T3) 6 weeks postpartum, and (T4) 6 months postpartum. Repeated measurements ANOVA was carried out on the basis of the as-treated principle.

Main Outcome Measures
MCB measured with the PRAM across two measurement occasions T1 and T4.

6.1.4 Results
In the group of women with high MCB, we found no statistically significant difference in the mean PRAM change scores between the HT arm and the no HT-arm, $F(3, 69) = 2.009$, $p = .121$. However, in the group of women with low MCB, women in the HT arm showed a statistically significant greater improvement of mother-child bonding than in the no-HT, $F(3, 69) = 2.877$, $p = .042$.

6.1.5 Conclusion
Haptotherapy during pregnancy can statistically significantly increase mother-child bonding in women with a high fear of childbirth and a poor MCB as compared with psycho-education via internet or care as usual.

6.2 Introduction

Mother-child bonding (MCB) can be considered as positive thoughts and feelings of the mother towards her child.[1] Ideally, these thoughts and feelings develop in pregnancy several months before a child is born, and, according to prenatal attachment theories, they will facilitate ante- and postpartum maternal behaviour and caregiving.[1] The development of feelings of bonding is facilitated by the physical development of the foetus and by psychological adjustments accompanying the upcoming motherhood.[2] MCB has the function of securing the nurturing and protection of the child and positively influences maternal health practices during pregnancy and postpartum.[3, 4] Because of the importance of MCB, we wondered whether haptotherapy (HT) positively influences MCB in women with severe FOC. To evaluate the effect of HT on MCB, we were interested whether there was a difference in MCB throughout pregnancy and postpartum between women who obtained HT as compared with women who obtained a no-haptotherapy (no-HT) intervention: psycho-education via the Internet (INT) or care as usual (CAU). Since the results are most clinically relevant for women with low MCB, we focused on the women in the lowest half of MCB scores on the PRAM.

Haptotherapeutic treatment has shown to be an effective intervention to reduce severe fear FOC in pregnant women, as compared with two control conditions (psycho-education via Internet and care as usual).[5] HT makes pregnant women more familiar with perceived and experienced physical sensations.[5] Moreover, HT facilitates the development of specific skills influencing the cognitive appraisal of contact with the foetus, giving birth and labeling childbirth as a more normal and positive life event.[5] Therefore, one might expect that HT also has a positive influence on MCB bonding. In the current research report, we evaluate the effect of HT on MCB as compared with women in the control conditions in a group of women with severe FOC.

6.3 Method

6.3.1 Design

Design of the original research protocol

Between April 2012 and June 2015, 555 pregnant women were recruited through 35 Dutch community midwifery practices, gynaecologists at a teaching hospital, or the project's website. Women who provided informed consent received a login code by email and were requested to digitally complete the Wijma Delivery Expectancy/Experience Questionnaire (W-

DEQ).[6] Inclusion criteria for the intervention study were singleton pregnancy, age ≥ 18 years, and a W-DEQ score ≥ 85, i.e., suffering from severe fear of childbirth.[7] Exclusion criteria were multiple pregnancies and a history of psychotic episodes. The participants with a high WDEQ-score were randomly[8] assigned to (1) HT, (2) INT, or (3) CAU.[5]

Design of this study

The MCB scores were assessed at four occasions. Questionnaires were sent by e-mail: admission to the study at 20–24 weeks of gestation (T1); 36 weeks of gestation (T2); 6 weeks postpartum (T3), and six months postpartum (T4). The project had a secured internet environment to facilitate the completion of the online questionnaires. For our analysis, we used the data from those participants who completed the questionnaires at all four measurements occasions (T1, T2, T3, T4). We performed a median split on the PRAM scores and analysed the whole group, the groups with the lowest half and the highest half PRAM scores respectively, see Figure 1. Since we assumed that social support might positively influence MCB, we controlled for it in the analysis.

6.3.2 Measures

MCB was measured using an online version of the Pictorial Representation of Attachment Measure (PRAM).[9] The PRAM was recently introduced as a potential valid, quick, and easy-to-administer instrument of parent-infant bonding,[9] see Figure 1.

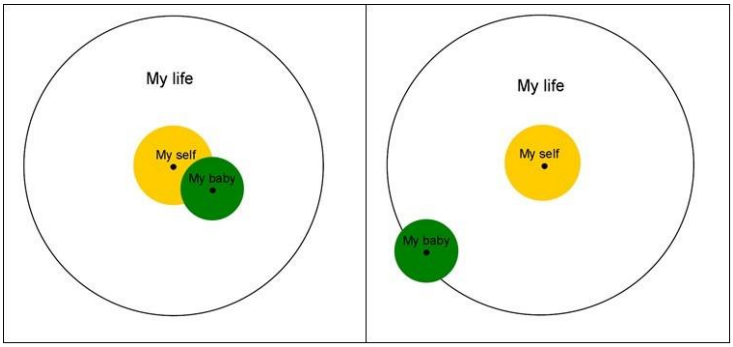

Figure 1: Two examples of the Pictorial Representation of Attachment Measure (PRAM).

Research findings revealed that, as was also found with other MCB measures,[10] the PRAM showed meaningful associations with a validated questionnaire measuring mother and father bonding. Since all questionnaires were being sent by email, we used a digital version in this study, similar to the paper one, but not yet validated in digital format. Participating pregnant women were shown a white screen with a big circle, which represents her

life as it currently is. A yellow circle in the center of the big circle represents the woman's 'Self'. Next to the big circle, a green circle represents the foetus/infant at a certain moment, in our study the moments T1-T4. The mother's task was to move the infant circle to a certain place in the circle representing her life at this moment. The outcome measure was the Self-Baby-Distance (SBD), i.e., the distance (in millimetres) between the centres of the 'Baby' and the mother's 'Self' circles. The score on the PRAM is inversely related to MCB, i.e. a higher PRAM score indicates lower MCB.

FOC was measured using the 33-item W-DEQ,[6] with a 6-point Likert scale ranging from `not at all` (= 0) to `extremely` (= 5), yielding total scores ranging from 0 to 165. Internal consistency and split-half reliability of the W-DEQ is 0.87.[6] We used a cut-off score of 85, i.e., a W-DEQ score ≥ 85 indicating that the mother suffers from severe FOC, in agreement with the author of the W-DEQ.[11] In the current study, at T1, the Cronbach's α was .95. Social support – as a potential confounder – was measured by the Social Support Questionnaire (SSQ).[12] The SSQ is a valid instrument for measuring social support and has good psychometric properties (a Cronbach's α of .92). With questions especially designed for this study, information was collected about the participants' biographic characteristics, such as age, education, partner, and primi-/multigravida.[5]

6.3.3 Interventions

1. Haptotherapy was applied according to the guideline developed for this purpose.[13] HT aims to facilitate the development of changes in the pregnant mother's appraisal of giving birth and labeling childbirth as a more normal and positive life event, which may ultimately lower fear of childbirth. This intervention, described in detail by Klabbers et al. (2014),[5] consisted of training participants in a combination of skills, which are taught in eight one-hour sessions between gestational week 20 and 36. Preferably, the partner of the pregnant woman also attends every session and actively participates in the exercises.[14]
2. Psycho-education via the Internet consisted of eight modules (and a brief test) during eight weeks between gestational week 20 and 36, providing information about the ordinary course of pregnancy, labour, and birth.[15] Participants also could ask questions about their own situation.
3. Care as usual was conducted according to the standards of the Royal Dutch Organization of Midwives (KNOV),[16] and the Dutch Organization of Obstetrics and Gynaecology (NVOG).[17]

6.3.4 Statistical Analyses

To evaluate the effects of HT on MCB, repeated measurements ANOVA were carried out across four measurement occasions: (T1) 20-24 weeks of gestation, (T2) 36 weeks of pregnancy, (T3) 6 weeks postpartum, and (T4) 6 months postpartum. We compared PRAM scores, using groups defined by the treatment as received (`as treated analysis`).[18] The experiment-wise Type I error rate was set at 5% level. Additionally, we performed a multiple regression analysis with the type of intervention (HT, no-HT), social support and parity at T1 as predictors. As dependent variable, we used the change in MCB between T1 and T4.

6.4 Results

At T1, PRAM scores were obtained from 484 respondents, of whom 146 completed the PRAM at all four measurement occasions (T1, T2, T3, and T4). In this group a median split was carried out, i.e., 50% lower half PRAM scores at T1 (*n*=73) and 50% higher half PRAM scores at T1 (*n*=73), see Figure 2.

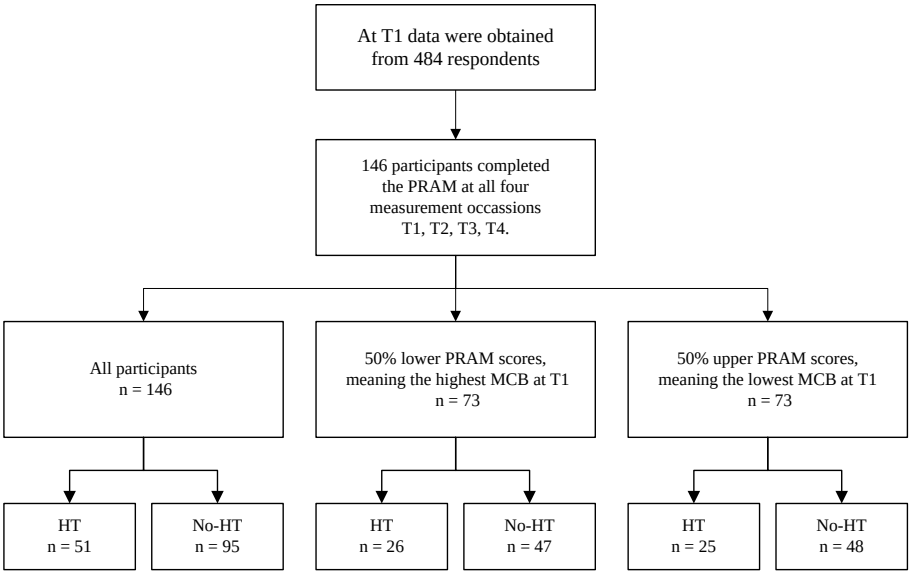

Figure 2: Allocation overview. T1: 20-24 weeks of gestation. T2: 36 weeks of gestation. T3, 6 weeks postpartum. T4: 6 months postpartum. PRAM: Pictorial Representation of Attachment Measure; MCB: mother-child bonding. HT: haptotherapy. No-HT: combined groups (Psycho-education via Internet + care as usual).

See Table 1, for all baseline characteristics. Repeated measurements ANOVA for the total group and the low PRAM (high MCB) group revealed no significant difference in the mean PRAM change score between T1 and T4, respectively, $F(3, 142) = 2.193$, $p = .092$ and $F(3, 69) = 2.009$, $p = .121$.

For clinical reasons, we focused in particular on the group with poorest MCB, i.e. those women with the highest PRAM scores, in which at 20-24 weeks of gestation (T1) the average PRAM score was significantly higher in the HT group than in the combined no-HT groups (psycho-education via Internet and care as usual), $F(1,71) = 5.735$, $p = .019$, see Table 1. At 36 weeks of gestation (T2), the average PRAM score was significantly lower (meaning MCB was higher) in the HT group than in the combined no-HT, see Table 1.

Table 1: Sample characteristics and PRAM measurements T1-T4

PRAM scores		All (n=146)				Lower half (n=73)				Upper half (n=73)			
Intervention		HT		No-HT		HT		No-HT		HT		No-HT	
N		51		95		26		47		25		48	
Age (M years)		33.3		31.7		34.0		32.4		32.5		31.0	
		n	%	n	%	n	%	n	%	n	%	n	%
Primigravida		25	49.0	61	64.2	14	53.8	31	66.0	11	44.0	30	62.5
Multigravida		26	51.0	23	35.8	12	46.2	16	34.0	14	56.0	18	37.5
High educational level		41	80.4	65	68.4	23	88.5	30	63.8	18	72.0	35	72.9
Medium educational level		10	19.6	29	30.5	3	11.5	16	34.0	7	28.0	13	27.1
Low educational level		0	0	1	1.1	0	0	1	2.2	0	0	0	0
Partner		50	98.0	93	97.9	26	100	46	97.9	24	96.0	47	97.9
		M	SD	M	SD	M	SD	M	SD	M	SD	M	SD
T1	PRAM (mm.)	71.3	11.5	69.7	8.9	62.9	7.2	62.8	6.3	80.1	7.9	76.5	4.9
	SSQ	24.1	4.8	25.4	4.2	24.0	5.3	24.4	4.8	24.2	4.4	26.3	6.2
T2	PRAM (mm.)	70.9	10.3	70.4	7.8	69.8	10.8	67.6	8.3	72.0	9.8	73.1	6.2
	SSQ	25.6	4.0	25.7	3.9	25.6	4.1	24.4	4.4	25.5	3.9	26.9	3.0
T3	PRAM (mm.)	68.9	6.6	70.8	7.0	68.0	6.4	68.8	7.7	69.9	6.7	72.7	5.8
	SSQ	-	-	-	-	-	-	-	-	-	-	-	-
T4	PRAM (mm.)	70.9	7.0	69.6	7.9	70.9	7.9	66.2	7.9	71.0	7.3	72.8	5.8
	SSQ	24.6	4.6	25.2	4.4	23.7	5.0	24.0	4.4	25.5	4.0	26.4	4.1

T1: 20-24 weeks of gestation. T2: 36 weeks of gestation. T3: 6 weeks postpartum. T4: 6 months postpartum PRAM: Pictorial Representation of Attachment Measure. Lower half PRAM scores: upper half mother-child bonding. Upper half PRAM scores: lower half mother-child bonding. HT: Haptotherapy. No-Haptotherapy: (psycho-education via internet + care as usual). SSQ: Social Support Questionnaire (not measured at T3).

The HT group showed a significantly greater increase of MCB as represented in the PRAM scores than the no-HT groups together (psycho-education via Internet + care as usual) by repeated measures ANOVA, $F(3,69) = 2.877$, $p = .042$, suggesting that in the HT group MCB was more increased than in the no-HT, see Figure 3. In the no-HT group no statistically significant difference in mean PRAM change score between INT and CAU was found.

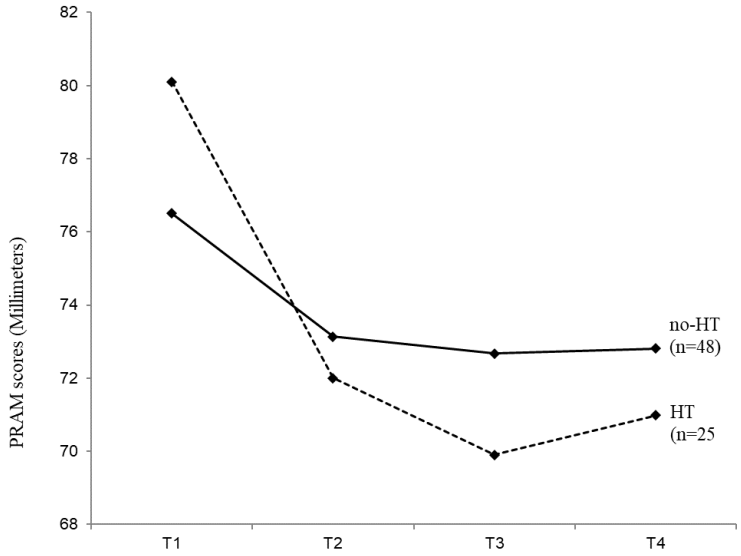

Figure 3: Means of MCB (PRAM score) across four measurement occasions. T1: 20-24 weeks of gestation. T2: 36 weeks of gestation. T3, 6 weeks postpartum. T4: 6 months postpartum. HT: haptotherapy. No-HT: combined groups (Psycho-education via Internet + care as usual). PRAM: Pictorial Representation of Attachment Measure; high PRAM score means low MCB. MCB: mother-child bonding.

Table 2 shows the results of the regression analysis using AT analysis with parity and social support at T1 and the interventions as predictors. The dependent variable was the PRAM-scale change scores between T1 and T4 (i.e., T4-T1), with positive scores reflecting improvement of MCB. The intervention had a statistically significant positive effect on PRAM scores, controlled for parity and social support at T1. The HT group showed a more substantial decrease in average PRAM scores than the no-HT groups. When controlled for parity and social support, the haptotherapeutic intervention uniquely accounted for 5.5% of the variance in change score, see Table 2.

Table 2: Results of multiple regressions using AT analysis with parity and social support at T1 and the interventions as predictors, and the PRAM-scale change scores T1 - T4 as dependant variable. (significant values printed in boldface).

	Δ PRAM T4-T1	
	B	r_{pr}^2
Parity at T1	-.360	0.0%
Social Support Questionnaire at T1	.318	1.5%
Intervention		**5.5%**
Haptotherapy	**4.742**	
No-Haptotherapy	---	
R-square		**9.8%**
N	73	

Note. r_{pr}^2 is the squared semi-partial correlation, which reflects the proportion of the totaal variance in the dependent variable (in %) that is uniquely explained by the predictor. AT: As treated. PRAM: Pictorial Representation of Attachment Measure. T1: 20-24 weeks of gestation. T4: 6 months postpartum.

6.5 Discussion

The objective of this study was to evaluate whether HT would have a positive influence on MCB. In comparison to the control conditions INT and CAU, HT seems to have a positive effect on MCB in the group representing the 50% lowest MCB on the PRAM. Whereas we already demonstrated that HT can reduce feelings of fear of childbirth, the current results additionally yielded evidence that this intervention has the potential to improve MCB in women who report low MCB at the beginning of pregnancy. However, caution should be exercised with the interpretation of our results, since at T1 there were some notable differences between the intervention and the control group. Firstly, there was a statistically significant difference in the mean PRAM score of the HT group and the no-HT group, and, secondly, the HT group consisted of fewer primiparous women and thus more multiparous women than de no-HT group.

Nevertheless, at T1 the PRAM score was higher in the HT group which suggests that in the intervention group suffered from poorer MCB and this group had the steepest, statistically significant decline in PRAM scores, reflecting an improvement in MBC. This strongly suggests a positive effect of the intervention in this particular group. We may carefully state that HT likely improves MCB in a group of pregnant women with high FOC and low MCB. However, it is too early to conclude whether this finding also has clinical relevance.

A subsequent logical question is what possible mechanism may underlie the MCB improvement. We propose that the haptotherapeutical intervention in the pregnant woman might stimulate affective thoughts and feelings of the mother towards her child. Further research is needed to explore the possible working mechanism of HT in encouraging MCB.

However, the study also suffers from some limitations. First, we opted for the ‘as-treated design.' In the randomized controlled trial, 25 women who were allocated to the control arm chose to follow haptotherapy by themselves. This thus resulted in a selection bias, since when one has the conviction that HT will be more effective to reduce FOC than the control condition, this might influence the results. Second, the HT group contained more multiparous women than de no-HT group. This also might reflect a certain selection bias, since these women might have known from a previous pregnancy what HT might do to them. Thirdly, the study participants who received HT all were women with an initial score of 85 or higher on the WDEQ, indicating severe fear of childbirth, which also may result in a selection bias. Fourthly, we chose to consider the 50% pregnant women with the lowest level of MCB as the clinically relevant group. But in this study, this PRAM cut-off score has been used for the first time. In future studies it would be interesting to compare prenatal PRAM scores with postnatal PRAM scores and mother-infant attachment scores, assessing the best cut-off score in ROC-curves.

We recommend further research on this topic. Since MCB and active mother-infant interaction is thought to prevent insecure attachment in the child,[1, 19, 20] for indicated prevention it is essential to design interventions that can already be applied during pregnancy. A logical next step is to study haptotherapy on MCB in an unselected group of pregnant women since in this study- only women with high FOC participated. Furthermore, since the PRAM is a rather new instrument for determining prenatal MCB, more evidence is needed to determine a clinically relevant cut-off score of the PRAM and to test whether this outcome is associated to postnatal mother-baby attachment.

6.6 Conclusion

In the group of the 50% pregnant women with high FOC and with the lowest MCB, we demonstrated positive effects of HT on MCB, as compared with psycho-education via Internet and care as usual. In the group of women with the highest MCB, we found no statistically significant difference.
HT seems a promising intervention in improving MCB during pregnancy in women with severe FOC and low MCB. However, it is too early to conclude whether this finding also has clinical relevance.

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7. GENERAL DISCUSSION

7 General Discussion

This study is the first randomized controlled trial that evaluated haptotherapy (HT) as an intervention for reducing severe fear of childbirth (FOC). We compared HT with (1) Internet psycho-education about pregnancy and childbirth, and (2) care as usual (CAU). We further explored the influence of HT in relation to background variables (e.g., distress, social support, perinatal complications) and mother-child bonding (MCB).

7.1 Research questions

The research questions were the following: (1) Do women with severe FOC have lower FOC after HT than women in the comparison groups who do not receive HT? (2) Do women with severe FOC after HT, compared with women in comparisons groups, (a) have a better emotional bonding with their child during pregnancy post therapy and postpartum than before therapy; (b) have fewer perinatal interventions (e.g., instrumental delivery, caesarean section, and episiotomy), and fewer complications such as severe perineal tears; (c) have fewer symptoms of distress, depression, somatization and PTSD?

7.2 Discussion of the results

Our results showed that after the intervention at T2 (20-24 weeks of gestation), women in the HT group demonstrated lower FOC as measured by the Wijma Delivery/Expectancy Questionnaire (W-DEQ) than the women in the INT and CAU groups. Moreover, in the HT group several aspects of the mothers' wellbeing had improved after the intervention: a decrease of antepartum distress and antepartum depressive symptoms at T2, less postpartum FOC and less postpartum PTSD symptoms at T3 (6 weeks postpartum) and T4 (6 months postpartum) than the women in the INT and CAU groups. Additionally, in women with low MCB, at T4 HT improved MCB more than INT and CAU. No differences between the groups were found for somatization, perinatal interventions and -complications, infants' birthweight and gestational age at any timepoints. As this is the first study to examine HT for severe FOC, a comparison with previous studies is not possible. Until now, only four randomized clinical trials (RCT's) on interventions aimed at reducing FOC have been reported. However, they used different inclusion criteria, different kinds of intervention and different types of outcome evaluation: (1) In the study of Saisto et al. (2001), the inclusion criterion was five or more affirmative answers to ten screening

questions for a maternal request for cesarean section.[1] The intervention was cognitive behavioural therapy. Fewer requests for cesarean section were seen in the intervention group. (2) Rouhe et al. (2012) studied in women with severe FOC whether psychoeducation would result in a reduced cesarean section rate as compared with care as usual.[2] As a cut-off score of severe FOC, a score $\geq$ 100 on the Wijma Delivery/Expectancy Questionnaire (W-DEQ) was used as inclusion criterion for participation in the study. Here also a lower cesarean section rate was seen in the intervention group as compared with the controls. (3) In another study of Rouhe et al. (2014) also a score $\geq$ 100 on the W-DEQ was used to meet the inclusion criteria.[3] Similarly, in this study, the intervention group had psycho-education, whereas the controls received care as usual. Better postpartum maternal adjustment and lower postpartum depressive symptoms were found in the intervention group as compared with the controls. (4) Studying the effects of their intervention on FOC, confidence to deliver, decisional conflict and depressive symptoms, Toohill et al. (2014) applied individual psycho-education by telephone as intervention and compared this with care as usual in the control group.[4] In this study, a considerably lower W-DEQ score ($\geq$ 66) for inclusion was used than in the studies mentioned previously. The intervention group, as compared with the control group, showed lower FOC and higher confidence to deliver as compared with the control group. The effect on decisional conflicts and depressive symptoms was not significant. As said before, the differences in inclusion criteria, in interventions and outcome evaluations, hardly allow meaningful comparisons of these studies with the present study.

Currently, two additional RCT's on interventions aimed to reduce FOC are in progress, i.e.: (1) treatment of severe FOC with cognitive behavioural therapy - a comparison of Internet cognitive behaviour therapy with traditional live therapy (see U.S. clinical trial register NCT02266186), and (2) eye movement desensitization and reprocessing treatment in pregnant women with FOC in comparison to care as usual (see Dutch trial register NTR5122).

Attempts to decrease FOC in pregnant women have not always been successful. For instance, Ryding et al. (2003) found that new mothers with high FOC scores, who had received counseling by trained midwives because of FOC during pregnancy, postpartum reported a more frightening experience of the delivery and more frequent symptoms of delivery-related post-traumatic stress than women in the comparison group.[5] As a possible explanation for this finding, the authors suggest that women who fear childbirth and already suffer from posttraumatic stress related to previous childbirth and/or sexual abuse or domestic violence may be extra sensitive for new mentally burdening events.[5] In another study among pregnant

women with a DSM-IV anxiety diagnosis, Verbeek et al. (2015) found that the mean infants' birth weight was on average 275 g lower and the mean gestational age almost a week shorter in the cognitive behavioural therapy group than in the control group that had received care as usual.[6] In our study, no significant negative effects were observed concerning somatization, perinatal interventions and complications, infants' birthweight and gestational age. HT thus seems to have no negative side effects, on the one hand, but also no positive effects in this respect.

7.3 Proposed working mechanism in HT

FOC is influenced by various factors, and the course of the therapeutic process can be affected by the woman's personal history,[7] as well as by contextual aspects.[7] For example, (1) if the woman suffers from Restrain Internal Sensitive Participation (RISP),[8, 9] customization to the physical perception of her abdominal and pelvic area is most important, and (2) if the woman fears painful contractions during delivery, it is more important to teach her how to handle those painful contractions. In relation to women's personal history, further research is needed to figure out on which kind of HT treatment should be focused on. In order to be able to offer a more tailor-made HT, more research is needed to identify the therapy-specific factors of HT. This might be analogous to the ideas of Bleijenberg (2009) about the specific treatment of 'permanent fatigue after cancer'.[10] This author suggested that one should first determine which of several possible determinants are etiologically relevant by using valid diagnostic methods. More precisely, in the case of permanent fatigue after cancer, factors like coping problems, fear of recurrence, dysfunctional cognitions, irregular sleep-wake rhythm, over- or under-activity and unrealistic expectations of the environment all might play a role, but often only one or two might be problematic.[10] Therefore, after the identification of the problematic factor(s), the intervention can be tailored explicitly to these issues, leaving the others unaddressed. Since HT is a relatively new intervention, research should focus both on (1) the active ingredients of HT and (2) the exact consequences of the different components of the HT when used in the case of FOC. Furthermore, it is essential to know if the different elements possibly reinforce, or maybe even extinguish each other's effectiveness. Currently, the discussion about the possible working mechanisms of all kind of interventions in psychological therapies focuses on both unspecific and specific factors.[11] More than anything else, a new type of intervention needs to be explicit about the assumed specific working mechanisms.

7.3.1 Specific factors in HT

HT during pregnancy has been developed to teach pregnant women to become more confident about their ability to deliver the baby vaginally ("changing the mind-set"[12-14]). It is plausible that increased self-reliance and self-confidence in women may result in reduced FOC. The HT sessions focus on (1) the pregnant woman's ability to 'open' and 'close' her body and mind in reaction to perceived impressions, (2) the affective confirmations of mother-foetus bonding by exercises in which the woman's belly is touched by her partner and the foetus reacts, (3) skills such as training the correct use of abdominal pressure, e.g. pushing downwards instead of mainly pushing with the head, during pushing in the third phase of labour, learning skills to handle painful contractions and learning to deal with labour pain in general. The main reason for therapeutic touching in HT in pregnant women is to make pregnant women familiar with the mechanism of 'sensitive participation,' meaning that women have learned to follow the processes going on in their body. This skill usually helps them discovering their capability to 'open' and 'close' to the awareness of sensitive impressions and the experience of the physical and mental consequences of these impressions.[8] The use of therapeutic touch is a central feature of HT, for which healthcare haptotherapists are specially educated and trained.[12] However, touching within the context of a (psycho)therapy is a subject of debate among supporters and opponents.[15-17] For instance, Kertay and Reverie (1993) noticed that touch in psychotherapy could become counter-therapeutic if it is employed as a technique or is in-authentic in its use by the therapist.[18] Therefore, Bonitz (2005) argued that a therapist should have adequate training in the way the touching takes place.[16] That raises the question about when a training might be considered as adequate and what precisely should be trained? Between parents and their children or within the intimacy of a partner relationship, touching each other is mostly a normal part of everyday life. At the same time, in a therapeutic relationship, it is not common. Therefore, for the sake of clarity in the relationship with their clients, haptotherapists are trained in therapeutic touching. Therapeutic touching in HT means that the client is respectfully touched, respecting maximum approach while professional distance is maintained.[19] In this way, it is clear, for both client and therapist, what the meaning of touching is within the framework of the treatment.

7.3.2 Non-specific factors in HT

Well-known unspecified factors for all kinds of therapies are therapeutic alliance, empathy, goal consensus, and collaboration between therapist and patient, as well as a sense of cohesion between patient and therapist.[20, 21] HT with pregnant women is only possible when the pregnant woman consents to the intervention. There can be little doubt that intrinsic

motivation and a positive attitude for this kind of treatment may add to the therapeutic effect, whereas women who are not open for an intervention less likely may experience an effect or even an adverse effect.[22] In the current study, these aspects, unfortunately, were not evaluated.

7.3.3 Non-specific factors that are regarded as specific in HT

Touching can be subdivided into, on the one hand, the non-specific effect of being touched affectively, which may have a reassuring effect,[23] and on the other hand, the specific effect of becoming aware of one's ability to 'open' and 'close' in reaction to perceived impressions, i.e. to turn towards or away from something or somebody.[24] Interestingly, Gray et al. (2000) demonstrated that the right kind of touch soothes,[25] and Main et al. (1990) showed that an important function of touch is to signal safety,[26] by which infants know whether the environment is safe, on the basis of information from their parent's touch. In HT, it is assumed that these effects of 'touch' remain similar in adulthood. One could argue that these findings of Gray et al. (2000),[25] and Main et al. (1990),[26] confirm the observation in HT that therapeutic touch of the haptotherapist and stimulating affective contact between both parents (if a partner is present) and the unborn child are affirmative for the woman as a mother-to-be, whereby she may feel more relaxed, more at ease and more secure.

7.4 Strengths and limitations

Our study has several strengths. We designed an RCT with three arms, and we had explicitly described the details in haptotherapeutic intervention and the psycho-education. Furthermore, the PEDRo score of our research is 6/10, meaning that the methodological quality is good.[27] On the other hand, the study also has limitations, some of which are characteristic of all psychotherapy evaluations. (1) Due to the nature of the study therapist blinding was not possible. (2) Likewise, we were not able to realize study participant blinding. (3) Concealed allocation and assessor blinding were also not realized. These latter aspects should be taken into account in future research. (4) We had fewer participants than planned according to our power-analysis. This was due to difficulty with recruitment, and although we amended the protocol to improve participation, after three years, recruitment numbers showed a sharp decline, resulting in the decision to discontinue the intake. Consequently, we did not reach the predetermined number of inclusions. Nevertheless, we were able to demonstrate statistically and clinically significant effects. (5) A substantial number of pregnant women immediately broke the randomization by switching from the control groups to the HT group, as soon as the classification was announced. This may have

led to selection bias in the 'as treated' comparisons, although we did not find a significant difference in mean W-DEQ change score between the randomized HT group and the cross-overs. (6) In all three groups there were withdrawals without explanation, respectively 13.7% in the HT-group, 12.8% in the INT-group and 20.5% in the CAU group. This also might have led to selection bias. However, no selective withdrawals were observed. (7) In the Netherlands, midwives are responsible for initial antenatal care in 85% of the pregnant women, where only about 15% of women with high initial risk primarily attend the gynaecologist. The participating community midwifery practices did not adequately represent midwifery practices in general. They were known to be motivated to improve the care for women with severe FOC. Therefore, their care as usual might have been more supportive than in the average midwifery practices that have less experience in dealing with women with severe FOC. Consequently, the participating community midwifery practices might also attract more pregnant women with special needs, probably reflected in the high percentage of women with severe fear of childbirth.

7.5 Suggestions for future research

Our experience with this research project was helpful to formulate recommendations for future research. In a future study design cross-over should be minimized as much as possible and it should comprise more participants. Using a more advanced design, experimenting with exclusive treatment ingredients of HT like merely touch, only verbal explanation and/or education, in- or excluding the partner, etc. would offer more detailed information about the therapeutic influence of the various elements. Finally, the participants should be asked about their specific treatment preferences.

7.6 Conclusion

HT seems a promising therapy for women with severe FOC. However, more methodologically sound research is needed to confirm and extend the present findings. In addition, active mechanisms of HT and the role of individual components of HT need to be investigated, in order to further optimize this intervention for this specific group of women with high FOC.

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APPENDICES

A: Summary in English 133
B: Summary in Dutch (Nederlandse samenvatting) 137
C: List of abbreviations 141
D: Co-authors and their affiliations 143
E: List of publications 145
F: Guideline haptotherapy in women with severe fear of childbirth in Dutch (Richtlijn haptotherapie bij bevallingsangst) 147
G: Acknowledgements in Dutch (Dankwoord) 155
H: About the author in Dutch (Over de auteur) 159
I: About the author in English 161

Appendix A: Summary in English

This thesis contains a review of the literature on fear of childbirth, the protocol and the results of a randomized controlled study on the effect of haptotherapy on severe fear of childbirth, a study on the correlation between severe fear of childbirth and mother-child bonding, and a short research note about the effect of haptotherapy on mother-child bonding. The main research question was: What is the effect of haptotherapy on fear of childbirth in women with excessive fear of childbirth, compared with psycho-education via the Internet and care as usual? The secondary research questions were: Do pregnant women with severe fear of childbirth who received haptotherapy during their pregnancy have better mental health during their pregnancy and postpartum compared to those who received psycho-education via the Internet or care as usual, and do they undergo fewer medical interventions during childbirth? In addition, we investigated the relationship between fear of childbirth and mother-child bonding, and the effects of haptotherapy on mother-child bonding.

Severe fear of childbirth
In Chapter 2, 'Severe Fear of Childbirth: Its Features, Assessment, Prevalence, Determinants, Consequences and Possible Treatments', a summary is given of the relevant literature on childbirth anxiety. The focus was on the definition problems, the characteristics of pregnancy with fear of childbirth, the prevalence, the assessment methods and the measurements, the determinants, possible consequences and treatment methods. The review leads to the conclusion that more scientific research is needed to establish which kind of treatment is most effective for individual pregnant women with fear of childbirth.

Research Protocol
The research protocol is described in Chapter 3, 'Treatment of severe fear of childbirth with haptotherapy: design of a multicenter randomized controlled trial'. This chapter explains the methods used, the design of the research, the backgrounds of childbirth anxiety, the characteristics of women with fear of childbirth and the consequences of fear of childbirth. Further, it provides a detailed description of the haptotherapeutic intervention (for the guideline Haptotherapy for fear of childbirth, see Appendix F). The participants were randomized into three treatment groups: (1) one group receiving eight treatments of haptotherapy, (2) one group receiving online psycho-education for eight weeks, and (3) a care as usual group. As primary outcome measure, we evaluated fear of childbirth, but attention was also paid attention to other

aspects of maternal well-being, including somatization, and the application of medical interventions.

Effect of haptotherapy in pregnant women with fear of childbirth
The research results of the randomized controlled study on the effect of haptotherapy in pregnant women with fear of childbirth are presented in Chapter 4: 'Haptotherapy as a new intervention for treating fear of childbirth: a randomized controlled trial'. The effectiveness of eight sessions of haptotherapy was studied in comparison with two control groups: (1) a group receiving psycho-education via the Internet and (2) a group receiving care as usual. To evaluate the effect of haptotherapy on fear of childbirth we used the 'intention to treat' analysis. However, a substantial number of pregnant women immediately broke the randomization by switching from the control groups to the haptotherapy group as soon as the classification was announced. Therefore, we additionally used the 'as treated' analysis.

The results show that the haptotherapeutic intervention reduces fear of childbirth more than care as usual and psycho-education via the Internet. Haptotherapy also improved several aspects of the mother's wellbeing, such as prenatal distress and depressive symptoms, as well as postpartum PTSD symptoms. No effects of haptotherapy were observed on somatization and medical interventions. The latter is surprising because various studies have shown that fear of childbirth increases the risk of medical interventions. Therefore, it was expected that when fear of childbirth is reduced the number of medical interventions also would decrease, but this expectation is not support by this study. Possibly other factors played a more significant role during childbirth.

Childbirth and mother-child attachment
Chapter 5, 'Resistance to fear of child birth and stability of mother-child bond' describes that, although excessive labour anxiety is associated with many consequences for both the mother's antepartum and postpartum well-being, there seems to be no effect of excessive fear of childbirth on mother-child bonding. Mother-child bonding, as measured using a digital version of the Pictorial Representation of Attachment Measure (PRAM), showed no significant correlation with maternal antepartum and postpartum well-being. In conclusion, it was suggested that mother-child bonding, may be such an essential biological survival process that it is very robust and resistant to a less optimal psychological state of the mother.

Effect of haptotherapy on mother-child bonding

A short research note ‘Does haptotherapy benefit mother-child bonding in women with severe fear of childbirth’, is presented in Chapter 6. In the group of the 50% pregnant women with the lowest mother-child bonding, hhaptotherapy showed to have a significant positive effect on mother-child bonding, compared to care as usual and psycho-education via the Internet, whereby social support seemed to not affect mother-child bonding.

General Discussion

In Chapter 7, we discuss the results of this study, the proposed working mechanism of haptotherapy in pregnant women with severe fear of childbirth, the strengths and limitations of this study, and we conclude that haptotherapy seems a promising therapy for women with severe fear of childbirth. Additionally, we provide suggestions for future research.

Appendix B: Nederlandse samenvatting

Dit proefschrift bevat het protocol en de resultaten van een gerandomiseerde gecontroleerde studie naar het effect van haptotherapie bij ernstige bevallingsangst, een review over bevallingangst en een studie naar de correlatie tussen bevallingsangst en moeder-kind hechting. De belangrijkste onderzoeksvraag was: Wat is het effect van haptotherapie op bevallingangst bij zwangeren met bovenmatige angst voor de bevalling, in vergelijk met psycho-education via Internet en care as usual? De secundaire onderzoeksvragen waren: (1) Hebben zwangeren met ernstige bevallingsangst die tijdens hun zwangerschap haptotherapie hebben ontvangen een beter welbevinden tijdens hun zwangerschap en daarna, dan diegenen die psycho-education via Internet of gangbare verloskundige zorg hebben ontvangen? (2) Ondergaan zwangeren met ernstige bevallingsangst die tijdens hun zwangerschap haptotherapie hebben ontvangen, minder medische interventies tijdens de bevalling, dan diegenen die psycho-educatie via Internet of gangbare verloskundige zorg hebben ontvangen? Aanvullend hebben we de relatie van bevallingsangst en moeder-kind hechting onderzocht, en het effect van haptotherapie op moeder-kind hechting.

Bevallingsangst
In Hoofdstuk twee: ‘Severe Fear of Childbirth: Its Features, Assessment, Prevalence, Determinants, Consequences and Possible Treatments’, wordt een samenvatting gegeven van de relevante literatuur over bevallingsangst. De focus lag op de definitieproblemen, de eigenschappen van zwangeren met bevallingsangst, de prevalentie, de beoordelingsmethoden en de metingen, determinanten, mogelijke gevolgen en behandelingsmethoden. Er wordt concluderend gesteld dat meer wetenschappelijk onderzoek nodig is, om te kunnen voorspellen welke behandeling het meest effectief is voor zwangeren met bevallingsangst.

Onderzoeksprotocol
Het onderzoeksprotocol wordt beschreven in hoofdstuk drie. Dit hoofdstuk gaat over de behandeling van ernstige angst voor de bevalling met haptotherapie en beschrijft het ontwerp van een gerandomiseerd gecontroleerd onderzoek in meerdere centra. In dit hoofdstuk wordt uitleg gegeven over de gebruikte methoden, het ontwerp van het onderzoek, de achtergronden van bevallingsangst, de kenmerken van vrouwen met bevallingsangst en de gevolgen van bevallingsangst. Verder wordt de haptotherapeutische interventie in detail beschreven (zie bijlage F: voor de richtlijn haptotherapie bij bevallingsangst). De deelnemers werden gerandomiseerd ingedeeld in drie behandelgroepen: acht behandelingen

haptotherapie, online psycho-educatie gedurende acht weken en een care as usual groep. De primaire uitkomstmaat was bevallingsangst, maar er werd secundair ook gekeken naar het algemeen welzijn van de moeder, inclusief somatisatie en medische interventies/

Effect van haptotherapie bij zwangeren met bevallingsangst
De onderzoeksresultaten van de gerandomiseerde gecontroleerde studie naar het effect van haptotherapie bij zwangeren met bevallingsangst, worden gepresenteerd in Hoofdstuk vier: 'Haptotherapie als nieuwe interventie om angst voor de bevalling te behandelen: een gerandomiseerd gecontroleerd onderzoek'. Onderzocht werd wat de effectiviteit is van acht sessies haptotherapie in vergelijking met twee controlegroepen: psycho-educatie via Internet en gangbare verloskundige zorg. De resulaten laten zien dat vrouwen die in de haptotherapie arm zaten, een sterkere daling van bevallingsangst laten zien dan de vrouwen die psycho-educatie via Internet of gangbare verloskundige zorg kregen. Haptotherapie verbeterde bovendien verscheidene aspecten van het welzijn van de moeder, zoals antenatale distress- en depressieve symptomen, evenals postpartum posttraumatische stress-symptomen. Er werden geen effecten waargenomen op somatisatie en medische interventies. Dat laatste is verassend, omdat diverse onderzoeken hebben aangetoond dat door bevallingsangst het risico op medische interventies doet toenemen en dan zou je mogen verwachten dat bij vermindering van bevallingsangst, dientengevolge het aantal medische interventies zou afnemen, maar dat kon met dit onderzoek niet aangetoond worden. Mogelijk dat andere factoren tijdens de bevalling een grotere rol speelden.

Bevallingsangst en moeder-kind hechting
In Hoofdstuk vijf: 'Resistance to fear of child birth and stability of mother-child bond', wordt beschreven dat alhoewel bovenmatige bevallingsangst verband houdt met veel gevolgen voor zowel het antepartum- als het postpartum welzijn van de moeder, er geen effect lijkt te zijn van bovenmatige bevallingsangst op moeder-kind hechting. Moeder-kind hechting vertoonde geen significante correlatie met antepartum- en het postpartum welzijn van de moeder. Concluderend werd gesuggereerd dat moeder-kind hechting, zoals gemeten met een digitale versie van de Pictorial Representation of Attachment Measure (PRAM) wellicht zo'n belangrijk biologische overlevingsproces is, dat het bestand is tegen een niet optimale psychologische toestand van de moeder.

Effect van Haptotherapie op moeder-kind hechting
Een korte bespreking van het effect van haptotherapie op moeder-kind hechting wordt gepresenteerd in Hoofdstuk 6. Haptotherapie blijkt een significant positief effect te hebben op moeder-kind hechting. Hierbij lijkt de mate van sociale ondersteuning geen effect te hebben.

Algemene discussie
In Hoofdstuk 7 worden de resultaten van deze studie besproken, het veronderstelde werkingsmechanisme van haptotherapie bij zwangere vrouwen met ernstige angst voor de bevalling, de sterke- en zwakke punten van deze studie, en de conclusie dat haptotherapie een veelbelovende therapie lijkt te zijn voor vrouwen met ernstige angst voor de bevalling. Aanvullend worden suggesties gedaan voor toekomstig onderzoek.

Appendix C: List of abbreviations

ANOVA: Analysis of variance
CA: Childbirth anxiety
CAU: Care as usual
CS: Caesarean section
DSM-IV: Diagnostic and statistical manual of mental disorders IV
EMDR: Eye Movement Desensitization and Reprocessing
FOBS: Fear of birth scale
FOC: Fear of childbirth (as measured by the W-DEQ)
HT: Haptotherapy
INT: Psycho-education via Internet
KNOV: Koninklijke Nederlandse Organisatie van Verloskundigen
MCB: Mother-child bonding
NVOG: Nederlandse Vereniging voor Obstetrie en Gynaecologie
PLISSIT: Permission / Limited Information / Specific Suggestions / Intensive Therapy
PRAM: Pictorial representation of attachment measure
PTSD: Post Traumatic Stress Disorder
PTSS: Post Traumatic Stress Stoornis
RCT: Randomized Controlled Trial
ROC: receiver operating characteristics
Severe FOC: W-DEQ score ≥ 85
SSQ: Social support questionnaire
T1: 20-24 weeks of gestation
T2: 36 weeks of gestation
T3: 6 weeks postpartum
T4: 6 months postpartum
State-Anxiety related to childbirth: situational fear of childbirth
Trait-Anxiety related to childbirth: disposition to react with fear of childbirth
TES: Traumatic Event Scale
VVH: Vereniging van Haptotherapeuten
W-DEQ: Wijma Delivery Expectancy/Experience questionnaire
W-DEQ A: W-DEQ, Version A measures antepartum fear of delivery
W-DEQ B: W-DEQ, Version B measures postpartum fear of delivery
WPOG: Werkgroep Psychosomatische Obstetrie en Gynaecologie
4DSQ: Four-dimensional Symptom Questionnaire

Appendix D: Co-authors and their affiliations

Prof. dr. Hedwig J. A. van Bakel
Tilburg School of Social and Behavioural Sciences, Department of Tranzo, Tilburg University, Tilburg, the Netherlands.

Dr. Wilco H. M. Emons
Department of Methodology and Statistics,
Tilburg University, Tilburg, the Netherlands.

Marit M. A. van den Heuvel MA
Institute for Mental Health Care,
Mentaal Beter Tilburg, Tilburg, the Netherlands.

Dr. K. Marieke Paarlberg MD PhD
Department of Obstetrics and Gynaecology,
Gelre Hospitals, Apeldoorn location, Apeldoorn, the Netherlands.

Prof. dr. Ad J. J. M. Vingerhoets
Department of Medical and Clinical Psychology
Tilburg University, Tilburg, the Netherlands.

Prof. dr. Klaas Wijma
Unit of Medical Psychology, Department of Clinical and Experimental Medicine, Linköping University, Linköping, Sweden.

Appendix E: List of publications

Treatment of severe fear of childbirth with haptotherapy: design of a multicenter randomized controlled trial.
***Gert A. Klabbers**, Klaas Wijma, K. Marieke Paarlberg, Wilco H. M. Emons and Ad J. J. M. Vingerhoets.*
BMC Complementary and Alternative Medicine (2014), 14: 385.
DOI: https://doi.org/10.1186/1472-6882-14-385

Severe fear of childbirth: Its features, assessment, prevalence, determinants, consequences and possible treatments.
***Gert A. Klabbers**, Hedwig J. A. van Bakel, Marit M. A. van den Heuvel and Ad J. J. M. Vingerhoets.*
Psychological Topics 25 (2016), 1: 107-127.
http://pt.ffri.hr/index.php/pt/article/view/321

Haptotherapy as a new intervention for treating fear of childbirth: a randomized controlled trial.
***Gert A. Klabbers**, Klaas Wijma, K. Marieke Paarlberg, Wilco H. M. Emons and Ad J. J. M. Vingerhoets.*
Journal of Psychosomatic Obstetrics & Gynaecology (2017),
DOI: https://doi.org/10.1080/0167482X.2017.1398230

Does haptotherapy benefit mother-child bonding?
***Gert A. Klabbers**, K. Marieke Paarlberg, Ad J. J. M. Vingerhoets.*
International Journal of Haptonomy and Haptotherapy (2018), 3(1): 1-7
http://www.ijhh.org/userfiles/1515836314.pdf

Resistance to fear of child birth and stability of mother-child bonding.
***Gert A. Klabbers**, Klaas Wijma, Hedwig J. A. van Bakel, K. Marieke Paarlberg and Ad J. J. M. Vingerhoets.*
Early Child Development and Care (2018).
DOI: https://doi.org/10.1080/03004430.2018.1461093

Appendix F:
Richtlijn haptotherapie bij bevallingsangst

Gebruik van deze richtlijn/ waar de richtlijn voor bedoeld is
De richtlijn dient als ondersteuning voor gz-haptotherapeuten die zich gespecialiseerd hebben in de therapeutische begeleiding van zwangeren met angst voor de bevalling en biedt informatie aan collega's die zich willen specialiseren. Voor verloskundigen en gynaecologen en alle andere zorgprofessionals rondom zwangerschap en geboorte verschaft deze richtlijn informatie die van belang kan zijn bij een mogelijke verwijzing.

Doelstelling haptotherapie/ waar de interventie zich op richt
Haptotherapie richt zich op het verbeteren van het (zelf)vertrouwen van de zwangere vrouw in haar eigen vermogen om haar kindje via een natuurlijke vaginale bevalling geboren te laten worden, vermindering van angst voor de bevalling, afname van prenatale distress symptomen, afname van prenatale depressie symptomen, het verkleinen van het risico op mogelijke posttraumatische stress symptomen en het bevorderen van de postpartum moeder-kind hechting.

Doelgroep
Vrouwen met angst voor de bevalling, waarbij de bevallingsangst wordt vastgesteld middels een anamnese, waarneming en een score $\geq$ 85 op de Wijma Delivery Expectancy/ Experience Questionnaire (W-DEQ).

Kenmerken doelgroep
Vrouwen met bevallingsangst maken zich doorgaans zorgen over de gezondheid van zichzelf en hun kind, verwonding en beschadiging van hun lichaam, zich te misdragen of in paniek te raken tijdens de bevalling, ongewenste inmenging van de verloskundig zorgverleners, alleen gelaten te worden zonder adequate hulp, verlies van controle, medische interventies zoals episiotomie, vacuümextractie of een keizersnede, een niet vorderend geboorteproces, gebrek aan vertrouwen in de verloskundig zorgverleners en hun eigen kunnen, sterven tijdens de bevalling, ondraaglijke pijn, en bij multipara vrouwen, herhaling van een eerdere traumatische bevalling. Kortom, de angst van vrouwen voor de bevalling bestaat uit bezorgdheid voor het welzijn van zichzelf en van hun kind, angst voor het verloop van het geboorteproces (pijn, medische interventies, abnormale voortgang van het geboorteproces, de dood), persoonlijke factoren zoals verlies van controle en gebrek aan vertrouwen in eigen mogelijkheden, en externe omstandigheden (interacties met assisterend personeel).

Haptodiagnostiek
In de praktijk is gebleken dat zwangeren met bevallingsangst een objectiverende beleving kunnen hebben van hun (onder)lichaam en in plaats van een (liefdevolle) toewending naar het kindje, is er dan sprake van een (angstige) afwending. De angstige zwangere kijkt wel naar haar buik, maar is er innerlijk gevoelsmatig niet bij betrokken.
Echter, de gemoedsbeleving van de zwangere vrouw met bevallingsangst is niet altijd direct waarneembaar en zij zal er ook niet altijd uit zichzelf over beginnen, maar als een zwangere vrouw – ondanks een empathische benadering van de zorgverlener – zelf objectiverend haar buik aanraakt en objectiverend over haar kindje spreekt en het empathische contact van haar uit met de zorgverlener (volledig) ontbreekt, kan dat een aanwijzing zijn voor bevallingsangst.

Multidisciplinaire samenwerking
De bevallingsangst zal over het algemeen aan het licht komen in het contact met verloskundige of gynaecoloog. Het kan echter ook door de huisarts of andere zorgverleners worden gesignaleerd, waarna het afnemen van de specifieke vragenlijst voor bevallingsangst (W-DEQ) geïndiceerd is, bij voorkeur rondom de 20ste week van de zwangerschap. Indien uit de anamnese of onderzoek met de ‘Traumatic Event Scale (TES)’, (tevens) symptomen blijken die wijzen op een mogelijke Post Traumatische Stress Stoornis (PTSS), kan multidisciplinaire samenwerking en/of verwijzing gewenst zijn. Verwijzing en/of multidisciplinaire samenwerking geschiedt in overleg met de zwangere.

Vanwege de directe toegankelijkheid van haptotherapie wordt door de gz-haptotherapeut bij zwangeren met bevallingsangst de vierdimensionale klachtenlijst (4DKL) afgenomen om te screenen op verhoogde symptomen van distress, angst, depressie en somatisatie. De uitkomst van deze screening kan aanleiding zijn tot multidisciplinaire samenwerking en/of verwijzing. Bovendien kan de 4DKL ingezet worden als meetinstrument om de effectiviteit van de behandeling te monitoren, terugkoppeling aan de cliënt te geven en desgewenst – in overleg met de cliënt – de behandeling op onderdelen bij te sturen.

Contra-indicaties
Er is sprake van een contra-indicatie bij ernstige psychiatrische symptomen die niet- of onvoldoende onder controle zijn, zodat zelfs met ondersteuning van psychiatrische medebehandeling, een werkzame behandelrelatie niet mogelijk is en/of er taal- of communicatieproblemen zijn, die het volgen van haptotherapie onmogelijk maken.

Structuur van de interventie
Het verwerven van kennis, inzicht en vaardigheden gedurende acht haptotherapie-sessies van een uur. De sessies vinden bij voorkeur plaats in de periode tussen de 16e en 36e week van de zwangerschap.

Inhoud/ wat er concreet gebeurt
Haptotherapie bestaat - binnen het kader van behandeling van zwangeren met bevallingsangst - uit een verzameling van specifieke vaardigheden die worden geleerd in acht sessies (begeleidingen) van een uur tussen de 16de en 36ste week van de zwangerschap. Bij voorkeur is de partner van de zwangere vrouw (actief participerend) bij het merendeel van de sessies aanwezig. Als de partner, meestal de vader, in staat is tot affectieve betrokkenheid in relatie tot zijn/haar partner en hun kind, dan creëert hij/zij daarmee een klimaat van veiligheid en vertrouwen voor de zwangere vrouw. Als de partner hiermee nog niet vertrouwd is, dan kan de haptotherapeut hem/haar eenvoudige oefeningen aanreiken om daarmee te oefenen.

Sessie 1: Intake
Kennismaking, anamnese, afspraken maken over de werkwijze van haptotherapie en vastlegging daarvan in een behandelplan. De eerste sessie is vooral een informatieve en administratieve bijeenkomst.

Sessie 2: Vermogen tot openen en sluiten voor gevoelsindrukken
Introductie van het menselijk vermogen om zich te kunnen openen en sluiten voor gevoelsindrukken, almede het ervaren daarvan. Hierna kunnen de zwangere vrouw en haar partner leren om het verschil tussen toewending en afwending te ervaren en te beleven. Zodra dit duidelijk is, wordt deze vaardigheid gebruikt in een oefening voor de ouders om zich te richten op het kindje door de buik van de zwangere vrouw uitnodigend aan te raken. De baby in de buik reageert dan meestal door zich in de richting van de uitnodigende hand te bewegen. De confrontatie met het vermogen om zich te kunnen openen en sluiten voor gevoelsindrukken is de essentie van de haptotherapeutische interventie en vormt de rode draad in de begeleiding.

Sessie 3: Verdere ontwikkeling van het vermogen tot openen en sluiten
Het is noodzakelijk om de introductie uit sessie 2, meerdere malen te herhalen, omdat de meeste vrouwen met bevallingsangst moeite hebben om zich te kunnen openen en sluiten voor gevoelsindrukken. Aan het einde van deze sessie kan het uitnodigend aanraken van de buik van de zwangere vrouw en de reacties van de baby verder worden geëxploreerd en geoefend. De bewegingen van het kindje trekken van binnenuit de aandacht van de zwangere vrouw en kunnen haar zo helpen om vertrouwd te raken met haar (gevoelde) lichamelijkheid.

Sessie 4: Sensibilisatie
Voor een bevalling is een gevoelsmatige interactie van de vrouw met haar kind en haar (onder)lichaam noodzakelijk. De eerste drie sessies kunnen worden gezien als voorbereiding. In sessie 4 zal met nieuwe oefeningen de aandacht specifiek worden gericht op het (onder)lichaam van de zwangere vrouw en worden er oefeningen gedaan om het (onderste deel van) het lichaam te sensibiliseren, i.e., om het doorvoelen naar het bekkengebied te stimuleren. Aan het eind van deze sessie wordt de oefening herhaald waarbij de buik van de zwangere vrouw door de partner wordt aangeraakt en de reacties van de baby verder worden verkend om de gevoeligheid van beide ouders geleidelijk te vergroten.

Sessie 5: Abdominale druk
Het doel van deze sessie is om op de juiste manier gebruik te maken van de abdominale druk tijdens de bevalling. Daarom wordt aandacht besteed aan alle aspecten van het openen voor gevoelsindrukken, interactie van de moeder met haar kind, toewending naar en afwending van het bevallingsproces en aan de emotionele reacties. Aan het einde van deze sessie, kan de oefening met het uitnodigend aanraken van de buik van de zwangere vrouw opnieuw worden herhaald.

Sessie 6: Opvangen van de weeën en omgaan met pijn
Het doel van deze sessie is te leren om weeën op te kunnen vangen en te kunnen omgaan met pijn tijdens de bevalling. Hierbij komen in een aantal praktische oefeningen alle aspecten van de vorige sessies weer aan bod. Als terugkerend thema is er ook weer aandacht voor het kindje met het uitnodigend aanraken van de buik van de zwangere vrouw.

Sessie 7: Voorbereiding op de bevalling
Voorbereiding op de geboorte van het kindje, door het oefenen van (voor zover mogelijk) alle aspecten van de bevalling. In verschillende baringshoudingen wordt in deze sessie het omgaan met de pijn, het persen en het opvangen van de weeën geoefend.

Sessie 8: Evaluatie en herhaling
Evaluatie en - waar nodig - herhaling van oefeningen, alsmede uitleg over nog bestaande onduidelijkheden vormen de belangrijkste componenten van deze laatste sessie.

Werkzame factoren/ mechanismen
De kern van de haptotherapie is de zwangere bewust te maken van haar vermogen om zich te openen (toelaten en gewaarworden) en te sluiten voor gevoelsindrukken. Dit vormt de rode draad door de hele behandeling. In de haptotherapie wordt verschil gemaakt tussen het 'object-lichaam' en 'subject-lichaam'. Onder het object-lichaam verstaan we het lichaam dat wij hebben en dat bijvoorbeeld onderzocht kan worden voor medische doeleinden. Met het subject-lichaam wordt het lichaam bedoeld dat wij zijn en beleven. Dit verschil wordt aan de cliënt duidelijk gemaakt, gedeeltelijk door het uit te leggen, maar vooral door het de cliënt lijfelijk herkenbaar en bewust te maken. Voor zwangeren betekent dit het oefenen van het juiste gebruik van de abdominale druk bij het persen, het omgaan met pijn en het opvangen van de weeën. Daarmee ontstaat een andere mindset bij de zwangere vrouw. Een zwangere vrouw met sterke angst voor de bevalling wil de bevalling het liefst overslaan en verlost worden (desnoods door middel van een keizersnede). Tijdens de haptotherapie kan deze mindset geleidelijk veranderen en neemt met het aanleren van de specifieke vaardigheden gaandeweg het (zelf)vertrouwen toe van de zwangere vrouw in haar eigen vermogen om haar kindje via een natuurlijke vaginale bevalling geboren te laten worden.

Affectiviteit
De oefening die bij herhaling wordt aangeboden en wordt omschreven als "het uitnodigend aanraken van de buik van de zwangere vrouw", brengt meestal een gemoedsbeweging van de zwangere vrouw teweeg en een reactie van de baby in haar buik, namelijk een bewegen van de baby in de richting van de uitnodigende hand. Deze oefening is gebaseerd op de fenomenologie van het affectief bevestigend contact en de daaraan verbonden menselijke vermogens tot gewaarworden en gewaarzijn. Hierbij mag worden verondersteld, dat het niet sec de aanrakende hand is, maar (de intentie van) het liefdevolle gebaar dat daaraan ten grondslag ligt, dat de reacties oproept. Het liefdevolle gebaar van de partner dat zorgt voor een gevoel van veiligheid, vertrouwen en innerlijke gemoedsrust bij de moeder.

Kwaliteitswaarborg haptotherapie bij bevallingsangst
Opleiding en (na)scholing
De kwaliteit van de behandeling haptotherapie die door gz-haptotherapeuten wordt aangeboden aan Cliënten met Bevallingsangst, wordt o.a. gegarandeerd door vijf cumulatieve voorwaarden waaraan ten minste voldaan dient te worden, namelijk:
(1) De gz-haptotherapeut heeft een (para)medische- of psychosociale HBO/WO vooropleiding (NVAO-geaccrediteerd en door OCW-erkend);
(2) Heeft een erkend diploma haptotherapie (SPHBO-getoetst);

(3) Heeft aantoonbare HBO medische basiskennis, op basis van een separaat diploma, als onderdeel van de vooropleiding of als onderdeel van de opleiding haptotherapie;
(4) Als garantstelling voor o.a. het opleidingsniveau en het onderhouden van de kwaliteit van de beroepsuitoefening via periodieke nascholing op het gebied van kennis, inzicht, vaardigheden en attitude, dient de haptotherapeut, die werkzaam is binnen de gezondheidszorg, geregistreerd te staan in het landelijk register van gz-haptotherapeuten dat wordt beheerd door de Vereniging van Haptotherapeuten (VVH) en daarmee te voldoen aan alle eisen betreffende o.a. opleiding, (na)scholing, beroepscode en praktijkinrichtingseisen;
(5) Heeft een aanvullende haptonomische nascholing gevolgd betreffende kennis en vaardigheden rondom zwangerschap en geboorte.

Bevallingsangst-specifieke nascholing voor gz-haptotherapeuten
De gz-haptotherapeuten die gespecialiseerd zijn in haptotherapie bij bevallingsangst zijn tevens gekwalificeerd tot het verstrekken van haptonomische zwangerschapsbegeleiding. Zij functioneren in een regionaal interdisciplinair samenwerkingsverband, waarin naast de reguliere nascholing haptotherapie, ook periodiek specifieke vaardigheidstraining en intervisie worden georganiseerd. Bovendien is een richtlijn afgesproken voor haptotherapie bij bevallingsangst. Deze richtlijn wordt door de samenwerkende collega’s periodiek geëvalueerd en bijgesteld.

Samenstelling

Auteur

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Mw. P. M. (Petra) Bouwman MSc, Weesp
Mw. A. M. T. (Anna Marie) Buwalda, Groningen
Mw. R. R. (Renske) Harte-Sluman, Weesp
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Mw. S. P. (Sylvia) Nauta-Verhoef, Baarn en Utrecht

Cliëntenadviesraad

Mw. L. F. (Lindsey) Jacobsen
Mw. V. F. M. (Vera) Tomassen
Mw. J. S. (Jacqueline) Vergouwe
Dhr. G. J. (Arjan) Groeneveld

Appendix G: Dankwoord

Zonder de betrokkenheid, inzet en enthousiasme van een grote groep mensen was dit proefschrift er niet gekomen.

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En tot slot zijn er natuurlijk mijn lieve vrouw Ans Brinks, mijn kinderen en hun partners (Bas, Karin, Max, Suzanne en Lotte) en al onze vrienden en familie, die mij gedurende het hele onderzoeksproces zijn blijven steunen, terwijl ik voor hen minder tijd had. Dankjewel allemaal, voor jullie geduld.

Lieve Ans, zonder jou was het niet gelukt.

Appendix H: Over de auteur

Gert A. Klabbers werd geboren op 21-01-1958 te Apeldoorn en studeerde in 1982 af als fysiotherapeut, waarna hij op 24-jarige leeftijd startte met de basisopleiding Haptonomie te Rotterdam in de periode 1982-1984. Destijds heeft Gert een beroep gedaan op de wet gewetensbezwaren militaire dienst en werd hij dientengevolge ter vervanging van de militaire dienstplicht tewerkgesteld. Eerst als fysiotherapeut in verpleeghuis de Cromhoff te Enschede waar hij zijn vrouw Ans Brinks leerde kennen. Later als groepsleider in orthopedagogisch Instituut, Groot Emaus te Ermelo, waar hij vervolgens een aantal jaren parttime bleef werken. Tevens was hij in die periode werkzaam als fysiotherapeut in een eerstelijns praktijk fysiotherapie te Lelystad. In 1989 behaalde hij zijn diploma haptotherapie aan het Instituut voor Toegepaste Haptonomie te Berg en Dal, dat tegenwoordig gevestigd is in Nijmegen. Onderwijl had Gert zich in Apeldoorn gevestigd met een eerstelijns haptotherapie praktijk. Dat werk combineerde hij met tal van andere functies: lid Adviesraad van de stichting Algemeen Maatschappelijke Dienstverlening te Apeldoorn (1990-1992), coördinator mantelzorgproject ‘Thuishulp voor Ouders van Gehandicapten’ in Apeldoorn e.o. (1990-1999), landelijk beleidsmedewerker van de stichting Dienstverleners Gehandicapten (sDG) te Utrecht (1997-1998), Projectmanager Gespecialiseerde Gezinsverzorging voor thuiswonende gehandicapten bij de stichting Thuiszorg Oost-Veluwe (1999-2001). Vanaf 2002 richtte Gert zich meer en meer op de haptotherapie. In 2004 behaalde hij het diploma Haptonomische Zwangerschapsbegeleiding aan de Academie voor Haptonomie te Doorn en tijdens zijn opleiding heeft hij in 2003 initiatief genomen tot de oprichting van de vereniging van Haptonomische Zwangerschapsbegeleiders, waarvan hij bestuurslid bleef t/m 2006. Naast zijn therapeutische werkzaamheden was Gert bestuurlijk actief als Bestuurslid van het Regionaal Genootschap Fysiotherapie (RGF) Twente en IJsselzoom (2008-2009) en als Secretaris/Penningmeester van de Vereniging van Haptotherapeuten VVH (2006-2010). In 2006 was hij initiatiefnemer en organisator van het landelijk Symposium Haptonomie Nederland 2006 te Utrecht. In 2007 nam hij initiatief tot de oprichting van de werkgroep ‘Ketenzorg voor zwangeren met bevallingsangst in Apeldoorn’. Gert was initiatiefnemer en medeorganisator van het Wetenschappelijk Congres Haptotherapie in Amsterdam 2013. In 2012 is Gert gestart met zijn promotieonderzoek en anno 2018 werkt hij inmiddels fulltime in zijn praktijk Haptotherapie, Fysiotherapie en Haptonomische Zwangerschapsbegeleiding te Apeldoorn.

Appendix I: About the author

Gert A. Klabbers was born on 21 January 1958 in Apeldoorn and graduated in 1982 as a physiotherapist, after which he started at the age of 24 with the basic training Haptonomy in Rotterdam in the period 1982-1984. At the time, as a conscientious objector to military service, Gert was first employed as a physiotherapist in nursing home de Cromhoff in Enschede, where he met his future wife, Ans Brinks, and later as a group leader in an orthopedagogical institute, Groot Emaus in Ermelo, where he continued to work part-time for a number of years. In that period he also worked as a physiotherapist in a primary physiotherapy practice in Lelystad. In 1989 Gert obtained his haptotherapy degree at the Institute for Applied Haptonomy in Berg en Dal, nowadays located in Nijmegen. Meanwhile he had settled in Apeldoorn, where he opened a first-line haptotherapy practice. He combined this work with numerous other functions: member of the Advisory Board of the General Social Services Foundation in Apeldoorn (1990-1992), coordinator of the informal care project 'Home Help for Parents of Disabled People' in Apeldoorn e.o. (1990-1999), national policy officer of the Stichting Dienstverleners Gehandicapten (sDG) in Utrecht (1997-1998), and Project Manager Specialized Family Care for people living at home with the Stichting Thuiszorg Oost-Veluwe (1999-2001). From 2002 onwards, Gert focused more and more on haptotherapy. In 2004 he obtained the diploma Haptonomic Pregnancy Counselling at the Academy for Haptonomy in Doorn, and during this training he had taken the initiative in 2003 to establish the association of Haptonomic Pregnancy Counsellors, of which he remained a board member until 2006. In addition to his therapeutic activities, Gert was a Board Member of the Regional Society for Physical Therapy (RGF) Twente and IJsselzoom (2008-2009) and the Secretary / Treasurer of the Association of Haptotherapists VVH (2006-2010). In 2006 he was the initiator and organizer of the national Haptonomy Netherlands 2006 Symposium in Utrecht. In 2007 he took the initiative to set up the working group 'Chain care for pregnant women with childbirth anxiety in Apeldoorn'. Gert was the initiator and co-organizer of the Scientific Conference Haptotherapy that took place in Amsterdam in 2013. In 2012 Gert started his doctoral research. At present, in 2018, he is working full-time in his practice Haptotherapy, Physiotherapy and Haptonomic Pregnancy Counselling in Apeldoorn.


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