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Treatment of nulliparous women with severe fear of childbirth via the Internet: a feasibility study

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Abstract

Objective: The aim of the present study was to test the feasibility of Internet interventions among nulliparous women suffering from severe fear of childbirth (FOC) by means of an Internet-delivered therapist-supported self-help program based on cognitive behavioral therapy (ICBT).

Design: Prospective, longitudinal cohort study.

Setting: A feasibility study of an ICBT program for treatment of severe FOC in pregnant women.

Sample: 28 Swedish-speaking nulliparous women with severe FOC recruited via a project home page from January 2012 to December 2013.

Methods: The main components of the ICBT program for treatment of severe FOC comprised psycho-education, breathing retraining, cognitive restructuring, imaginary exposure, in-vivo exposure and relapse prevention. The study participants were anonymously self-recruited over the Internet, interviewed by telephone and then enrolled. All participants were offered eight weeks of treatment via the Internet. Participants reported their homework weekly, submitted measurements of their fear, and received feedback from a therapist via a secure online contact management system.

Main Outcome Measures: Level of FOC measured with the Wijma Delivery Expectancy/Experience Questionnaire (W-DEQ A) during screening at enrolment and weekly during the treatment (W-DEQ version A), and after the delivery (W-DEQ version B).

Results A statistically significant ($p<0.0005$) decrease of FOC (W-DEQ sum score decreased pre- to post-therapy, with a large effect size (Cohens' $d = 0.95$)).

Conclusions: The results of this feasibility study suggest that ICBT has potential in the treatment of severe FOC during pregnancy in motivated nulliparous women. The results need to be confirmed by randomized controlled studies.

The main text

Introduction

Severe fear of childbirth (FOC) is considered to significantly interfere with pregnant women's daily routines, professional life, social activities and relationships [1]. The level of FOC is determined by the way a woman processes her sensations cognitively and emotionally; this is why her concerns about what may happen during a future delivery are crucial to her fear. Women with severe FOC are often vigilant for signals of danger, and often find that their suspicions are verified, creating a vicious cycle of adverse expectations and negative experiences [2-4]. FOC is thought to explain, to some extent, the increasing number of caesarean sections (CS) based on maternal requests during the last decade [5-8].

When reporting and comparing FOC results in the present paper, we refer to the participants' sum score on the Wijma Delivery Expectancy/Experience Questionnaire (W-DEQ) version A (before delivery) and version B (postpartum). In the population of pregnant women, the level of FOC, as measured by the W-DEQ [9,10], is normally distributed [11,12]. Little is known about the normal course of FOC as measured with the W-DEQ in unselected samples of nulliparous pregnant women. Rouhe et al. [11] report that the level of FOC was lower before than after 20 weeks of pregnancy in nulliparous women. Zar et al. [3] report lower FOC levels postpartum than during pregnancy, but with a correspondence between high levels during pregnancy and high levels postpartum, as well as low levels at both times.

Several studies show that 20-25% of pregnant women have worrying thoughts about their imminent delivery [12-15], and that 6-11% suffer from severe FOC [5,16]. For some women (2.5%) [17], this fear is so intense that it meets the criteria for a specific phobia according to the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) [18].

The point prevalence of psychiatric disorders according to DSM-IV, in general, during pregnancy is 14.1% [19], while for anxiety disorders this is 10.5%[17].

Several trials on the treatment of anxiety disorders show strong evidence of the effectiveness of cognitive behavioral therapy (CBT) [20-22]. Internet-delivered CBT (ICBT) is widely studied and has been shown to be highly effective in the treatment of various psychological problems, especially of anxiety disorders [23-25]. Until now, no controlled studies on the treatment of FOC as such have been published.

The aim of this feasibility study was, after developing an ICBT self-help program with limited therapist support for women with severe FOC, to evaluate how the therapy would influence the level of FOC, as measured with W-DEQ, in nulliparous Swedish-speaking pregnant women.

Methods

Self-help manual: A self-help manual, based on CBT principles, was developed for the treatment of severe FOC by two of the authors (KW and KN), and presented to the participants via the Internet. The manual had eight modules, each module containing three parts: 1) An information track comprised the physiology of normal pregnancy, labor and delivery, as well as possible complications and treatments. 2) A therapy track included psycho-education, breathing retraining, cognitive restructuring, exposure in vitro and in vivo, assertiveness training, and relapse

prevention (for details see Table 1). 3) Each module included questions about the information track and the homework tasks for the current week, in order to assess whether the participants had assimilated the material.

Besides the aforementioned weekly tasks, the participants were, pre- and post-treatment, asked to do a homework task with open-ended questions, where they were requested to imagine themselves in five different delivery situations and spontaneously offer their descriptions. These narratives were separately analyzed in a qualitative study [26].

The participants were presented with one module per week. Short, individual feedback (mostly containing validation and motivating techniques) was given every week by a personal therapist, using the project's secure contact management system. The therapist was available for the participants to contact whenever they needed. The therapists were four MSc psychology students in their final term of a five-year clinical program, and the obstetrician in the research team (with basic education in CBT). All had been specially trained in diagnostics and had continuous clinical supervision by one of the senior authors.

As the recruitment process took more time than planned (probably because the treatment concept was unknown to the pregnant women and their midwives), and after the first six months, the obstetrician served as the only therapist.

Measures: On the application form applicants supplied biographical data, and completed assessments concerning FOC (W-DEQ A), as well as anxiety and depression (Hospital Anxiety and Depression Scale, HADS) [27]. They were also asked about their motivation to deal with their FOC.

The W-DEQ was used as a screening tool, as well as for weekly- and follow-up

measurements of the level of FOC [9,10]. The W-DEQ is a self-assessment questionnaire to measure FOC, validated for Swedish-speaking nulliparous women [9]. The scale includes 33 statements about childbirth; each statement is rated from “not at all” (zero) to “extremely” (five). The sum of scores can vary 0-165. The higher the score, the more severe the FOC. W-DEQ version A measures FOC before and during pregnancy, W-DEQ version B measures postpartum FOC and is used after the delivery. A W-DEQ sum score ≥ 85 is applied as a cut-off for severe FOC [9], and a sum score ≥ 100 for phobic fear [9,10]. Cronbach’s alpha for nulliparous women was previously shown to be 0.89 [9].

The HADS [27] is a self-report questionnaire with 14 items, designed for patients in somatic medical care. The subscales have been shown to be valid measures of severity of depression and anxiety. Cronbach’s alpha in previous studies has been 0.89 – 0.93 [27].

Recruitment and selection: A home page was created for the study (www.kbt.info/Frida) including general information about CBT, experiences from previous Internet-based studies, an outline of the study and an application form. The participants were self-recruited directly via the project home page.

To be included in the study the participants had to be nulliparous and have a W-DEQ sum score ≥ 85. They were not eligible if they suffered from a serious psychiatric problem such as psychosis or being suicidal. The participants needed to be 18-30 weeks pregnant at enrolment, at least 18 years of age, with Swedish speaking and writing ability, and access to the Internet. They were not to have an on-going psychological treatment specific to FOC. To check the participants’ mental wellbeing, all applicants were briefly interviewed by telephone by a therapist not involved in the

study. The interview included short questions on the woman's fear, her medical history, three yes/no-questions on mental health to exclude psychosis, dysthymia and schizophrenia, and three questions on motivation to participate in therapy to decrease the FOC. The participants sent their informed consent to the study coordinator. After completing the treatment, participants were briefly interviewed about their experience of participation by a research midwife not involved in the treatment. A follow-up interview by telephone was held three months after the delivery by the same midwife, asking about the women's actual health situation, mode of delivery, delivery experience, and eventual FOC-related support during pregnancy. A verbal W-DEQ B was conducted by telephone.

Participants: Recruitment to the study was open from January 2012 to December 2013. Forty-two women logged in to fill in the application form. Seven did not complete the application, or did not enter the treatment program. Two of the remaining 35 applicants had a W-DEQ sum score <85, two were parous, and one had a miscarriage before enrolment. Thirty women were included and offered the ICBT. Women that had completed at least the first week's homework were counted as participants (n= 28). Finally, fifteen participants followed all eight weeks of therapy. The flowchart (Figure1) shows the participants and discontinuers week by week. Twenty-four (86%) of the 28 women that followed the program could be reached three months after the delivery for the follow-up telephone interview.

Statistics: Statistical analyses were performed using IBM SPSS© Statistics for Macintosh [28]. FOC was weekly measured by the W-DEQ for each participant. The intention to treat-principle was followed bringing the last reported result forward when measuring within group effects. A student's paired t-test was used to compare the W-DEQ scores before treatment with the last reported W-DEQ scores before delivery. Cohen's *d* was used to measure the

within group effect size. A Chi square test and Fishers' exact test were used to compare nonparametric measurements at inclusion. A repeated measures ANOVA was conducted on the 15 participants who had completed all eight weeks of therapy. A Bonferroni post hoc test was used to identify the point in the therapy at which a significant change occurred. To minimize type-1 errors, we did not correct for the missing values, and therefore chose to interpret the results more carefully. Differences were assumed to be statistically significant at $p<0.05$. Whilst a formal power calculation is not required, we hoped to detect a mean reduction of around 25 points in W-DEQ sum score, from a sample initially experiencing severe fear of childbirth. Therefore, with a mean of approximately W-DEQ 95, estimates using 80% power and $p< 0.05$ indicated we needed N=14, which determined our minimum sample size.

Results

Before therapy, the participants (n=28) had a mean W-DEQ sum score of 125 (sd 18.2, range 90-159, CI 118-132). Twenty-four women (86%) had a phobic FOC (mean 130 sd 14.2, range W-DEQ sum score 108-159, CI 124 -136). The demographic data and the delivery outcome of the participants are shown in Table 2. The majority had a university degree. The mean age was 30.5 years.

In the group following all eight weeks of treatment, 1/15 had severe anxiety and 1/15 had severe depression, according to HADS. In the discontinuing group the number of women with severe anxiety was 3/13, and with severe depression 0/13 according to HADS.

The week-by-week W-DEQ sum scores are shown in Figure 2. The results indicate that the level of FOC declined as the therapy proceeded. The within-group decrease of FOC, i.e. from the W-DEQ sum score at inclusion compared with the last reported

W-DEQ before delivery, was statistically significant (paired t-test $p<0.0001$) with a large within-group effect size (Cohen's $d = 0.95$).

A repeated measurements ANOVA was performed to test changes in the weekly measurements of FOC in those who followed all eight weeks of therapy. Mauchly's test for sphericity indicated that the assumption of sphericity was violated, $X^2(35)=61.9$ p<0,005, and therefore degrees of freedom were corrected using Greenhouse-Geisser estimates of sphericity (e=0.43). The corrected results show a statistical significant decrease of FOC during treatment, with $F(3.4,48.2)=27.35$, $p<0.0001$. As non-parametric and parametric testing gave similar results, parametric tests were chosen because of their robustness. The Bonferroni post hoc correction revealed that the decrease started after module three (difference in W-DEQ sum score from pre-treatment to module four: 16.6 +/- 6.4 $p=0.02$), which corresponded with the introduction of exposure tasks in module three in the program.

After eight weeks of therapy, those participants who had continued working with the modules (n=15) had a lower FOC than at inclusion, i.e. a mean W-DEQ sum score of 81.6 (sd 22.5, range 31-122, CI 69 -94) after treatment, compared with a mean W-DEQ sum score of 120 (sd 18.6, range 90-147, CI 110 -131) at inclusion. All these 15 participants had reduced their level of FOC. Eight women (53%) no longer had severe FOC (mean W-DEQ sum score 64.7, sd 14.8, range 31-78, CI 52 - 77), four women (27%) had reduced their FOC from phobic to severe FOC (mean W-DEQ sum score 94.5, sd 3.1, range 94-99, CI 90 -99). Three women (20%) still had phobic FOC (mean W-DEQ sum score 109, sd 11.4, range 100-120, CI 81 - 138) but during therapy their W-DEQ sum scores fell by 19-22 points (mean 20.1 sd 1.53).

For those who participated in the postpartum follow-up (n=24), the mean W-DEQ B sum score was 53 (range 8-138, sd 26,6), showing that most participants had a level of FOC in conformity with the normal population of primiparous women five weeks postpartum [2,3] but lower than an untreated group of women with phobic FOC three months postpartum (W-DEQ B 73.7) [28]. At the follow-up, two participants spontaneously described an adverse experience of the delivery; one had a vaginal delivery (postpartum W-DEQ B sum score 138). Her W-DEQ A score at inclusion was118. Her level of FOC during therapy changed from phobic to severe FOC. In addition to her phobic FOC, she appeared to suffer from a blood phobia, which she was not especially treated for. The other participant reporting an adverse experience had an emergency caesarean section (postpartum W-DEQ B sum score 90). Her W-DEQ sum score at inclusion was 147. She had mentioned previous sexual abuse; her scores on the HADS also indicated high anxiety (HADS 16 points) and depression (HADS 12 points) at inclusion.

When questioned in the post-treatment interview, the participants found it positive to be able to work with the modules whenever convenient for themselves, without the need to travel to a clinic or fit in an appointment. For many participants the time needed to work with the program was more than expected and came as a surprise. In the introduction they were advised to plan for two to three hours per week for homework. Participants highly appreciated the brief feedback received from their Internet-therapist. One of the participants would have preferred to meet a therapist face-to-face. In total 22 of the 24 women who could be reached for the postpartum follow-up reported that the program had been helpful for them during the pregnancy and labor. One participant did not find the program helpful because she found it frightening to read about the delivery, but she said that participating in half the

program made her realize she needed help, which prompted her to tell the midwife about her FOC.

For the therapists the secure contact system became a virtual therapy room, and the contact with the patients resembled a traditional therapist relationship, but in text. The therapists used 5-22 minutes for one session (mean 12 minutes, sd 2.3), per patient, per week.

Discussion

Main findings: The results of this feasibility study suggest, that the level of FOC as measured with the W-DEQ is reduced when a group of motivated nulliparous women are treated with ICBT. This is the first report on an ICBT program developed for the treatment of severe FOC. The program takes several weeks to complete, and therefore it is beneficial that women with severe FOC are identified early in the pregnancy in order to be offered help. As anxiety often makes people avoid their fearful impulses, thus helping them to decrease the level of fear experienced at a given moment, it is understandable that many pregnant women with severe FOC avoid thinking about the delivery for as long as possible, but eventually have to confront their fears. Ten of the 28 women included in the project (36%) were in the last trimester of their pregnancy; six of them did not follow the entire program, four of these because they were delivered before they had worked with all modules. The late inclusion can partly explain the discontinuation rate. Avoidance of fearful stimuli might also explain why some participants had great difficulty doing the homework continuously, and needed more time to complete several modules. Avoidance is a frequent and well-used way of coping with fear, and so it is often seen in effective treatments that the level of fear initially increases when exposure to treatment starts and patients are challenged to confront what they are afraid of [20-22]. This

phenomenon was explained to the participants in advance. Some participants might have found exposure too difficult to handle, which could explain the discontinuation of the four non-responders. A special module to prepare for the exposure treatment could probably have facilitated compliance, and the same might be true if complementary weekly personal contact, for example by telephone, had been added.

Strengths and Limitations:

Given the lack of a control group and the small sample, it is not possible to attribute the outcomes solely to the ICBT program. The participants were self-recruited directly from the project home page, without obtaining further information about clinical support from their home clinic. Therefore, we did not have the possibility to control for possible additional healthcare they were offered during the therapy (and which could have confounded the results), except in regard to what they reported themselves at inclusion and follow-up. Self-recruitment could also have given a recruitment bias. According to the reported postal codes, participants were spread around the country. After the delivery, 57% (n=16) reported that they had met a midwife or obstetrician 1-10 times in order to plan their delivery. Due to the lack of comparable studies, we cannot tell how these meetings may have influenced the participants' FOC. Exposure has been shown to be the most powerful treatment for anxiety problems [22]. This might explain why in our study a substantial decrease of FOC started when exposure was introduced in the modules. Given the small sample size, we replaced the missing values with the last reported value; a procedure that can lead to bias - in our sample probably reduced effect size. The results of completed cases are reported as comparison.

The participants in this study were motivated to work with their fear, as questions of motivation were part of the inclusion interview. This might give a bias in the results, but on the other hand motivation is crucial in all psychotherapies[20,23,24,29]. The majority of the participants had a higher level of education than the average population, which also may lead to bias, as is known from other ICBT studies [23-25]. Participants with higher education might be more familiar with reading texts and using the Internet in their normal working field. To work over the Internet also gives the participants greater anonymity and can be seen as less stigmatizing than going to appointments at a clinic.

The short time needed for the therapist to give feedback enables more women to get the same individual treatment than in traditional therapy. The cost per treatment session should therefore be far lower compared to face-to-face therapy, once the program is established. As the treatment is online, even women from rural areas can easily be offered treatment, which is not the case with face-to-face therapy.

Our modules were designed to treat FOC in general. Women with other psychological problems might have complementary needs of help. This is an important fact to consider in future trials, either by excluding persons with other disorders, or by completing the program with modules addressing, for example, post-traumatic stress, depression or specific phobias such as blood-, injection- or hospital phobia.

Interpretation:

Our results offer an indication that ICBT can be used in the treatment of severe FOC. Positive results after treatment with ICBT were also achieved in a qualitative study of the changes in 15 pregnant women’s descriptions of their appraisals of the imminent labor and

delivery before and after therapy [26].

The present study is the first published program reporting the use of ICBT for severe FOC. It is in agreement with earlier trials on treatment of other kinds of anxiety [23-25,29,30]. Previous studies on the treatment of FOC have also had promising results. Rouhe et al. (2012) showed that women with a W-DEQ A sum score ≥100 at inclusion, receiving conventional care, had higher levels of FOC three months postpartum (W-DEQ B sum score 68.4) than women who had attended an intervention (W-DEQ B sum score 63.5). The same research group has even documented other positive results with intervention trials for FOC [31].

It has previously been reported that FOC and traumatic stress symptoms correlate significantly [32-35], and that there is a positive relation between psychological difficulties and drop-out from treatments [36,37]. The findings of our study are in accordance with these results.

The therapist support during ICBT has been shown in several studies to be favorable for compliance with completing the treatment [23,29,38]. In the post-treatment interview, the participants in our study were in general very positive about the feedback from the therapist.

ICBT requires hard work and can be as demanding as face-to-face therapy. Therefore, ICBT should be provided by people who are able to interact professionally with clients. To achieve lasting psychological change (a re-orientation) by ICBT in participants, a certain period of time is needed to integrate the new way of thinking. The most important work is done between the on-line sessions. As the participants themselves have to complete the exercises, motivation for therapy is crucial, and some limited contact with a coaching therapist seems to be of value.

Conclusion:

ICBT is feasible for treating severe FOC in motivated nulliparous pregnant women. During ICBT, FOC levels as measured by the W-DEQ decrease in women motivated to challenge their fear.

More research with randomized controlled studies is needed to support the results of this feasibility study. Currently, there are no studies published comparing the results of traditional therapist-led treatment and ICBT for severe FOC. This feasibility study is followed by a randomized controlled trial comparing face-to-face therapy with ICBT (ClinicalTrials.gov ID: NCT02266186).

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Current knowledge on the subject:

-Severe FOC interferes substantially with a pregnant woman’s life, and is a risk factor for a complicated delivery and postpartum mental problems.

- Pregnant women with severe FOC, also have more FOC during labor and delivery as well as postpartum, than women with lower FOC during pregnancy and postpartum.

-There are few previous studies on treatment of women with severe FOC, but trials using elements of CBT show promising results.

What this study adds:

-This is the first quantitative report on psychotherapy for severe FOC over the Internet.

-This study indicates new treatment possibilities for pregnant women suffering from severe FOC.

-ICBT appears to be feasible in the treatment of severe FOC.

-The results can be seen as offering general support for using CBT for severe FOC in nulliparous women.

Table 1. Outline of the modules week by week in the ICBT program for severe FOC

	Information path	CBT path
Module 1	Normal pregnancy: first trimester	CBT as treatment method. Psycho-education concerning fear and anxiety in general and FOC especially. How physical conditions (e.g. sleep deprivation, hunger etc.) can influence people. Description of own expectations of the imminent labour and delivery.
Module 2	Normal pregnancy: second trimester	Goal setting – what can be realistic to expect during labour and delivery. Participants set their own goals for the therapy. Exposure to other women's stories about labour and delivery.
Module 3	Normal pregnancy: third trimester	Instruction in and practice with tools to deal with the physical reactions to fear e.g. breathing retraining, focusing techniques. Testing the tools in everyday situations.
Module 4	Normal labour: preparations and start	Difference between thoughts and feelings and how they interact. Participants identify and challenge own fearful thoughts and then produce alternative, more helpful thoughts about labour and delivery.
Module 5	Normal labour: pain relief	Exposure in vivo (i.e. pictures, films etc).
Module 6	Normal labour: first and second stage	How to manage situations one cannot influence? What is control? How to control one's own thoughts.
Module 7	Normal labour and delivery: acute situations	Advantages of different modes of delivery for one's own situation. Summary of the program.
Module 8	Normal labour and delivery: third stage	How to deal with setbacks. Participants work out an individual program for maintaining their progress. Description of own expectations of the imminent labour and delivery.

Table 2. Socio-demographic characteristics of nulliparous pregnant women participating in the ICBT program (n=28)

		Women starting the treatment (n=28)
Age in years, mean (range)		30.5 (24-39) years
≥30 years		15 (54%)
Gestational age at inclusion (weeks)		24 (13-30)
Cohabiting		27 (96,5%)
University degree/education		19 (68%)/ 23 (82%)
HADS at inclusion		
Anxiety of clinical significance (>11p)		20 (71%)
Severe anxiety (>15p)		5 (18%)
Depression of clinical significance (>11p)		2 (7%)
Severe depression (>15p)		1 (4%)
Preferred mode of delivery		
Vaginal		19 (68%)
Caesarean section		9 (32%)
Delivery outcome		
Vaginal		17 (61%)
Vacuum extraction		2 (7%)
Caesarean section		6 (21%)
Unknown		3 (11%)
Caesarean section (n=6)	ES on maternal request	4 (66%)
	Elective medical indication	1(17%)
	Urgent Caesarean section	1 (17%)

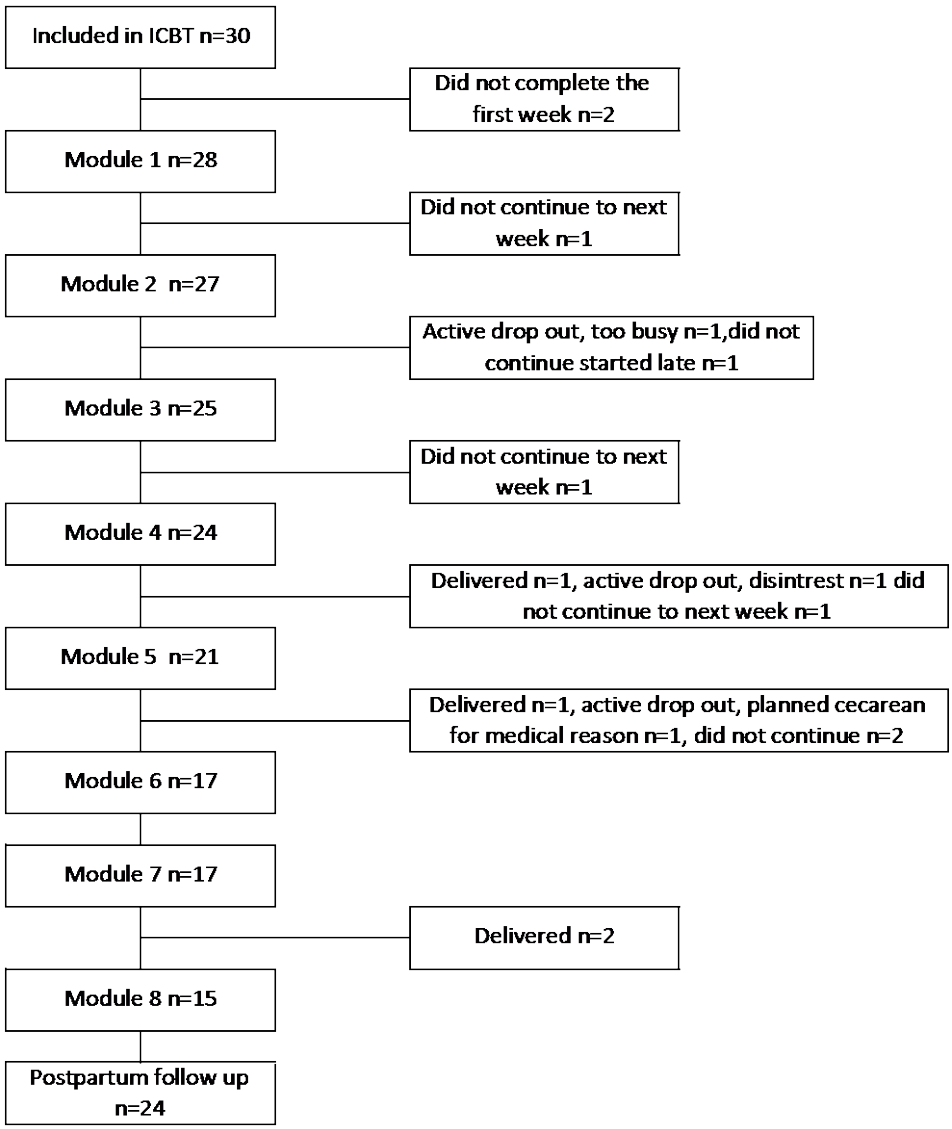

Figure 1. Flowchart of the participants

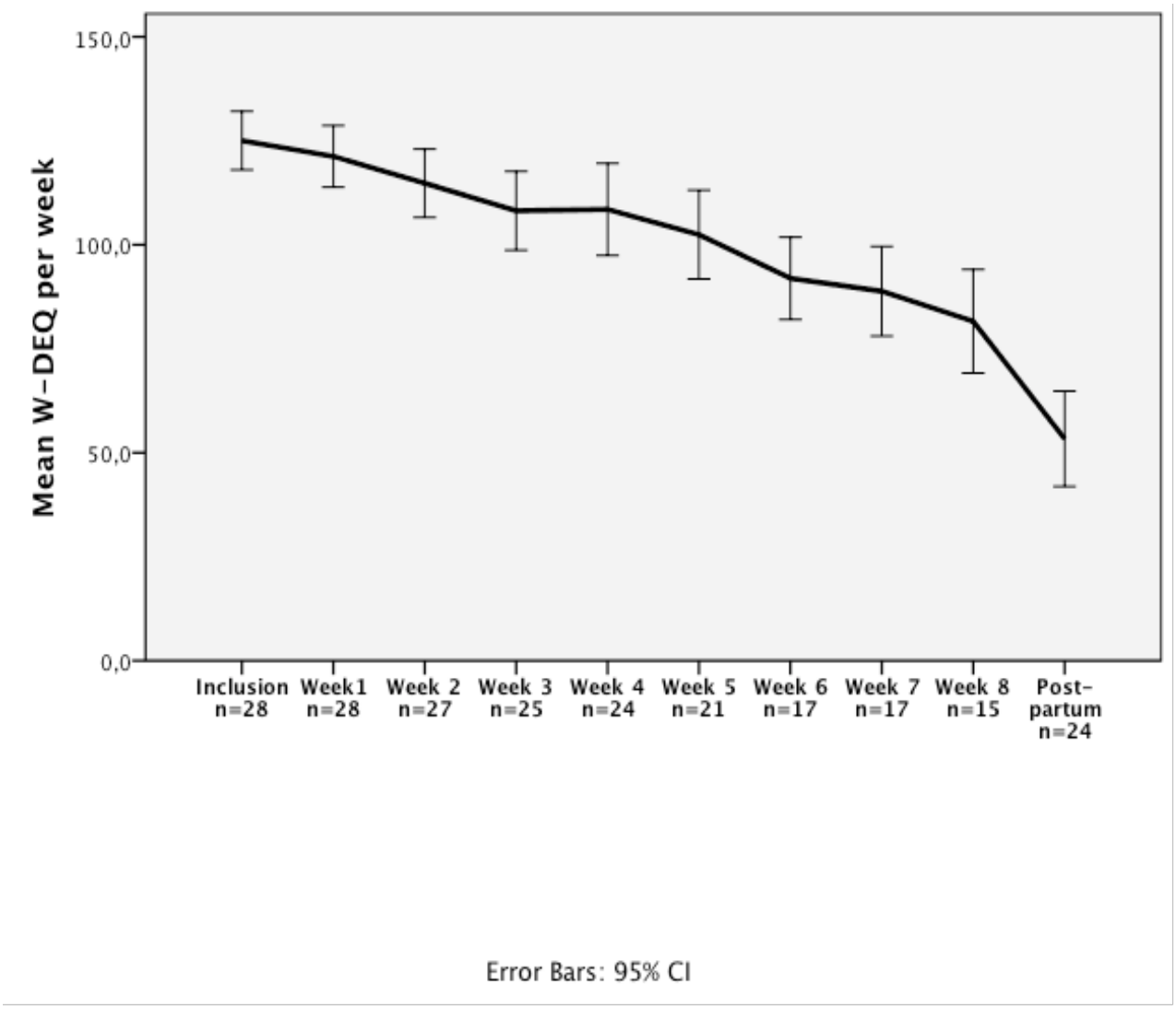

Figure 2. Mean of W-DEQ sum scores week by week