Sexual & Reproductive Healthcare 13 (2017) 75–82

Contents lists available at ScienceDirect

Sexual & Reproductive Healthcare

journal homepage: www.srhcjournal.org

A randomized controlled study comparing internet-based cognitive behavioral therapy and counselling by standard care for fear of birth – A study protocol

Elin Ternström [a,*], Ingegerd Hildingsson [a,b], Helen Haines [c], Annika Karlström [d], Örjan Sundin [e], Johanna Ekdahl [e], Birgitta Segeblad [f], Birgitta Larsson [a,g], Elisabet Rondung [e], Christine Rubertsson [a]

[a] Department of Women's and Children's Health, Uppsala University, Uppsala, Sweden
[b] Department of Health Science, Mid Sweden University, Sundsvall, Sweden
[c] Rural Health Academic Centre, University of Melbourne, Victoria, Australia
[d] Department of Nursing, Mid Sweden University, Sundsvall, Sweden
[e] Department of Psychology, Mid Sweden University, Östersund, Sweden
[f] Uppsala University Hospital, Uppsala, Sweden
[g] Research and Development Centre, Sundsvall Hospital, Sundsvall, Sweden

ARTICLE INFO

Article history:
Received 23 January 2017
Revised 4 June 2017
Accepted 13 June 2017

ABSTRACT

Fear of birth is a concern that requires evidence based treatment. The aim of this study is to present the protocol of a randomized controlled multi-center trial to compare internet-based cognitive therapy with counseling as standard care for pregnant women reporting fear of birth. Participants will be recruited in mid-pregnancy. Women who score 60 or above on the Fear of Birth Scale will be offered to participate in this study. Data will be collected by questionnaires including validated instruments at baseline and follow-ups at gestational weeks 30 and 36, two months and one year after birth. The primary outcome will be level of fear of birth measured with the Fear of Birth Scale at 36 weeks of gestation. Secondary outcome measures are level of fear of birth at two months and one year after giving birth, preferences for mode of birth, requests for elective cesarean section, compliance and satisfaction with treatment and birth outcomes. A power calculation based on a 20% reduction of fear implies that approximately 200 will be included in the trial. The study outlined in this protocol will be the first randomized controlled trial comparing internet-based cognitive therapy with counseling for women reporting fear of birth. An effective treatment may result in better overall health for women with fear of birth and a reduction in cesarean sections for non-medical reasons. Evidence regarding treatment options of fear of birth will also provide a greater choice for women.

Introduction

Fear of birth (FOB) is common during pregnancy, affecting both primiparous and multiparous women. In the Nordic countries, the reported prevalence of FOB among pregnant women ranges between 8 and 22% depending on the instrument of measurement and the chosen population [1–5]. Recognizing and responding to a woman's fear is an important component of comprehensive psycho-social maternity assessment and care.

FOB has been associated with longer duration of labour [6–9], increased use of pharmacological pain relief [9–11] and emergency cesarean sections [8,11–13]. Importantly, an earlier negative birth experience is the most central factor for explaining FOB one year after birth and during a subsequent pregnancy [14–17]. An earlier negative birth experience with FOB as a consequence also influences women to request a cesarean section without medical indication in the subsequent pregnancy [18,19]. However, a fulfilled request of a cesarean section (CS) does not guarantee a positive birth experience; on the contrary, it is associated with a negative birth experience and higher levels of FOB [20].

The socio-demographic features of women with FOB vary between studies and settings. Sometimes younger women are reported to be more likely to be more fearful than older women [13,21], while studies from Finland and Sweden indicated that women older than 30 years are more at risk of FOB [3,22]. Some

* Corresponding author.
E-mail addresses: elin.ternstrom@kbh.uu.se (E. Ternström), bingegerd.hildningsson@miun.se (I. Hildingsson), hhaines@unimelb.edu.au (H. Haines), annika.karlstrom@miun.se (A. Karlström), orjan.sundin@miun.se (Ö. Sundin), johanna.ekdahl@miun.se (J. Ekdahl), birgitta.segeblad@akademiska.se (B. Segeblad), birgitta.larsson@kbh.uu.se (B. Larsson), elisabet.rondung@miun.se (E. Rondung), christine.rubertsson@kbh.uu.se (C. Rubertsson).

http://dx.doi.org/10.1016/j.srhc.2017.06.001
1877-5756/

studies showed no association between age and fear [23,24]. Being in paid employment was associated with both moderate and severe FOB in a recent Australian study [25]. Contrary to this, studies from Denmark and Sweden showed that women with FOB were more likely to be unemployed and have a low level of education [13,21,26]. A higher prevalence of depression and anxiety have been associated with FOB in pregnant women in several studies [4,17,27,28].

There is no clear evidence guiding the most effective treatment of FOB, and, to date, only a few randomized controlled trials (RCT) have been conducted. In those trials, varying types of treatments have been used, making comparisons problematic. A Finnish research team has conducted two RCTs to improve women's birth experiences and to decrease levels of FOB. In 2001, Saisto et al. [29] randomized women with FOB to either an intensive six-session programme led by an obstetrician with insight in cognitive therapy or conventional care with two sessions including routine obstetric information and check-ups. Birth-related concerns decreased significantly in the intervention group. Requests for CS decreased in both groups. Recently, Rouhe et al. [30] offered group-psycho-education with relaxation to nulliparous women with FOB. The psycho-education, led by a psychologist, consisted of guided discussions, mindfulness and relaxation. Compared to standard care (SC), the intervention reduced FOB and improved the women's birth experiences. The intervention group had lower levels of postpartum depression symptoms after birth.

In Australia, Toohill et al. [31] undertook an RCT in a large cohort of Australian women, aiming to reduce FOB. The intervention included two sessions of antenatal telephone psycho-education, performed by specially trained midwives. The aim of that intervention was to review the women's feelings towards FOB and support them to deal with their fears. Compared to the control participants, who received SC offered by publicly-funded maternity services, women who received additional psycho-education reported reduced FOB-levels and increased childbirth efficacy [31].

The Swedish national guidelines state that the SC for women who report FOB should include additional visits to the antenatal midwife. Women recognized as having moderate to severe FOB by the antenatal midwife are referred to specially trained midwives and obstetricians for counselling [24,32]. There is no empirical evidence to confirm the efficacy of the current treatment. In contrast, research evaluating the counselling has concluded that it has a minor effect on FOB, birth experiences and CS rates. However, the same studies found that women are satisfied with the counselling they received [24,33].

Psychological interventions delivered over the internet is a growing field [34]. Randomized controlled trials for several anxiety disorders and for depression report that internet-based cognitive behavior therapy (iCBT) is as effective as traditional cognitive behavior therapy (CBT) [35–39]. ICBT has several advantages over traditional face-to-face CBT in terms of its accessibility, timing and pacing for the individual participant. In addition, the level of therapist involvement is clearly lower than in face-to-face interventions, making the therapist available for a larger amount of patients and thereby increasing overall efficacy of the healthcare system. Although iCBT seems to be a promising alternative within clinical care, certain aspects need to be addressed in order to secure the therapeutic effects. An increasing amount of research suggests that treatments that are preceded by a diagnostic interview, and careful screening procedures, yield larger treatment effects [40], while programmes open to anyone and without any type of guidance tend to have higher dropout rates and smaller effects [41]. In addition, there is clear empirical agreement in favor of systematic support and guidance to clients engaged in iCBT-treatment programmes [42–45]. Finally, previous studies also point to the importance of treatment specificity in terms of tailoring the intervention towards the specific target population instead of administering general treatment programmes [46]. In summary, support for iCBT for psychological disorders is growing and clinical practice points to a number of pros. However, certain characteristics of the treatment need to be fulfilled in order to secure treatment efficacy. FOB has been described as a construct within the domain of anxiety [47] and fits the profile of psychological disorders, which may respond to iCBT. Since iCBT has proven effective in treating several forms of clinical anxiety, it is motivated to apply iCBT also for anxiety relating to childbirth. Recent results from a non-randomized study support the potential effect of iCBT in treating intense FOB among nulliparous women [48]. To our knowledge, no previous RCTs have been conducted to determine the effects of iCBT in pregnant women with clinical levels of FOB.

Aim

To present the protocol of a randomized controlled trial aiming to compare iCBT with SC for pregnant women reporting FOB.

Methods

The present study is the protocol of a prospective randomized controlled trial with a multi-centre design. The study is called the U-CARE: pregnancy trial and it is associated with the Uppsala University Psychosocial Care Programme (U-CARE), a government-funded project aimed at preventing and reducing emotional distress for patients with somatic diseases via the internet [49]. Within the programme, an internet platform called the U-CARE portal has been developed (www.u-care.se). The portal is used for randomization, data collection and interventions undertaken within the U-CARE programme [49]. The study follows CONSORT guidelines and is registered at Clinicaltrials.gov (No. NCT02306434).

Outcome measures

The primary outcome will be level of FOB measured with the Fear of Birth Scale (FOBS) [50,51] at 36 weeks of gestation (with scores of 60 or higher constituting FOB). Secondary outcome measures are level of FOB at two months and one year after giving birth, preferences for mode of birth, requests for elective CS, compliance and satisfaction with treatment and birth outcomes.

Sample size estimation

A previous Swedish study [1] showed that 59% of women who reported FOB during pregnancy reported no FOB one year after giving birth. A power calculation based on a 20% reduction of FOB, a two-sided test, a power of 0.80 and a level of significance of 5%, showed that approximately 200 women need to be enrolled in the study.

Study centres

This study will be undertaken at three study centres in Sweden (see Fig. 1, Study centres). At the study centres, midwives or research assistant nurses working at the ultrasound clinic will hand out the screening questionnaires. The research midwives will collect the screening questionnaires once a week.

Recruitment

The recruitment process will follow two steps (see Fig. 2, Flow diagram of the study).