



## Research paper

# Internet delivered cognitive behavior therapy for antenatal depression: A randomised controlled trial<sup>☆</sup>



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## ABSTRACT

Major depression occurs in 5–10% of pregnancies and is associated with many negative effects for mother and child, yet treatment options are scarce. To our knowledge, this is the first published randomised controlled trial on Internet delivered Cognitive Behavior Therapy (ICBT) for this group.

**Objective:** To test the efficacy of a pregnancy adapted version of an existing 10-week ICBT-program for depression as well as assessing acceptability and adherence

**Design:** Randomised controlled trial.

**Setting:** Online and telephone.

**Population or sample:** Self-referred pregnant women (gestational week 10–28 at intake) currently suffering from major depressive disorder.

**Methods:** 42 pregnant women (gestational week 12–28) with major depression were randomised to either treatment as usual (TAU) provided at their antenatal clinic or to ICBT as an add-on to usual care.

**Main outcome measures:** The primary outcome was depressive symptoms measured with the Montgomery-Åsberg depression rating scale-self report (MADRS-S). The Edinburgh Postnatal Depression Scale and measures of anxiety and sleep were used. Credibility, satisfaction, adherence and utilization were also assessed.

**Results:** The ICBT group had significantly lower levels of depressive symptoms post treatment ( $p < 0.001$ , Hedges  $g = 1.21$ ) and were more likely to be responders (i.e. achieve a statistically reliable improvement) (RR = 0.36;  $p = 0.004$ ). Measures of treatment credibility, satisfaction, utilization, and adherence were comparable to implemented ICBT for depression.

**Limitations:** Small sample size and no long-term evaluation.

**Conclusion:** Pregnancy adapted ICBT for antenatal depression is feasible, acceptable and efficacious. These results need to be replicated in larger trials to validate these promising findings.

## 1. Introduction

For women of child bearing age depression is the leading cause of disease burden worldwide and 5–10% of all pregnant women suffer from antenatal depression (AND; Becker et al., 2016).

AND is associated with negative outcomes such as increased risk of

premature delivery, decreased breastfeeding initiation (Grigoriadis et al., 2013), and poor attachment (Lefkovic et al., 2014). AND is also the strongest risk factor for postpartum depression which is associated with several negative effects for both mother and child (Vigod et al., 2016). Perinatal depression is a severe condition that needs to be identified and treated as early as possible (Vigod et al., 2016). Still

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there is a paucity of treatment research for antenatal depression. Though antidepressant medication is generally considered safe by clinicians, and is being used at least in severe cases<sup>5</sup>, most women are reluctant to use them (Goodman, 2009; Vigod et al., 2016). So far no randomized controlled trial has evaluated treatment-, or fetal, effects of antidepressant medication during pregnancy.

Perinatal women seem to prefer individual therapy for depression over group therapy or medication (O'Mahen and Flynn, 2008; Goodman, 2009), and individual face-to-face CBT has been found to be effective in this group (Burns et al., 2013; O'Mahen et al., 2013a; Sockol, 2015; Milgrom et al., 2015). However, qualitative studies suggest that women perceive a lack of knowledge among health care professionals as a barrier to treatment seeking (Jarrett, 2016), and feel that psychotherapy needs to take perinatal women's specific situation into account in order to feel relevant (O'Mahen et al., 2012). This suggests that specialized treatments are warranted. Other important perceived barriers to treatment in this group are stigma, cost, lack of time, transportation, and childcare issues (Goodman, 2009; Kopelman et al., 2008; O'Mahen and Flynn, 2008). Perhaps then, making treatments available both from home, via the internet, and with relative anonymity, while adding a specific perinatal focus might be an attractive option for this group.

Internet delivered CBT with brief therapist guidance (ICBT) is effective for a variety of psychiatric disorders including depression (Andersson et al., 2008; Cuijpers et al., 2010) and can be cost-effective (Hedman et al., 2012) and implemented in routine care (Hedman et al., 2014). Postpartum depression has been targeted in four online trials so far (Danaher et al., 2013; O'Mahen et al., 2013b, 2014; Pugh et al., 2016). Two trials used weekly live or telephone sessions together with online material (Danaher et al., 2013; O'Mahen et al., 2014) and two used a fully online approach (O'Mahen et al., 2013b; Pugh et al., 2016) similar to that described by Andersson et al. (2008). Pugh et al. (2016) used a pregnancy-adapted version of an existing ICBT-protocol while O'Mahen et al. (2013b; 2014) seem to use a pregnancy adapted ICBT protocol based on behavioral activation while not directly adapted from an existing ICBT protocol. Of the trials included in a recent systematic review (Ashford et al., 2016) however, no full-on ICBT trial that targeted pregnant women with depression has been published so far. For AND, there has been one trial on face-to-face CBT with supplementary online assistance showing promising results (Kim et al., 2014).

### 1.1. Study objective

This study aimed to strengthen the overall evidence for CBT for antenatal depression and specifically to test the efficacy of an ICBT program for antenatal depression.

### 1.2. Hypothesis

Adding ICBT to treatment as usual (TAU) will be significantly more effective than TAU alone in reducing depressive symptoms.

## 2. Methods

### 2.1. Participants

Participants were recruited by advertisements on social media websites, in blogs, online forums and newspapers. Information, posters and flyers were also distributed to maternity clinics all over Sweden. The study also featured in an article in the midwives' association's newsletter as well as a popular commercial pregnancy magazine. The study was also promoted on the website of the Internet Psychiatry Clinic in Stockholm (Hedman et al., 2014). All patients were self-referred.

### 2.2. Inclusion criteria

To be eligible for inclusion women had to be 18 years or older, have adequate access and ability to use the internet and a mobile phone as well as an adequate ability to speak, read and write Swedish. Women also had to meet diagnostic criteria for major depression according to a Structured Clinical Interview for DSM Axis I Disorders (SCID-I; First and Gibbon, 2004). Women had to have a screening score on the Montgomery-Åsberg Depression Rating Scale- Self report version (MADRS-S; Montgomery and Asberg, 1979; Svanborg and Asberg, 1994, 2001) between 15 and 35. Only women with no or a low risk of suicide as indicated by a score of 4 ("I often think that I'd be better off dead, and though I do not really want it, sometimes suicide feels like a possible way out") or less on item 9 on MADRS-S and the clinician's assessment during the semi-structured telephone interview were included. Current antidepressant medication was allowed if the treatment and dose had been stable for at least three weeks.

To minimise dropout due to miscarriages and to ensure that treatment was given during pregnancy, and not after, women had to be at least 10 and no more than 28 weeks pregnant. To ensure that participation in the current study was considered as an add-on and not as an alternative to maternity care, participants had to provide information on listing at a maternity clinic and were informed to attend regularly.

### 2.3. Exclusion criteria

Women scoring 5 or 6 ("I am actually convinced that my only way out is to die, and I think a lot about how to best go about killing myself") on MADRS-S item 9 at screening were excluded after a risk assessment and referral to adequate level of care. Ongoing psychological treatments that could potentially interfere with the current treatment led to exclusion. As did any current psychiatric or medical condition that was deemed as a significant contraindication for participation (for example psychosis or advanced cancer) or expected to be adversely affected by participation.

Also, participants who had a markedly high risk of terminated pregnancy (for any reason) or severe pregnancy related complications (for example preeclampsia) were excluded from participation.

### 2.4. Procedure

Women interested in participation logged on via the Internet Psychiatry Clinic's website (www.internetpsykiatri.se), filled out an informed consent e-form and completed an online questionnaire. Women eligible after screening were contacted for a semi-structured telephone interview that primarily consisted of the depression segment of the SCID-I interview and everything but the depression segment from the M.I.N.I. interview (version 6; Sheehan et al., 1998) to cover potential co-morbidities. Regular supervision with psychologists, obstetricians and psychiatrist were held to decide on all cases.

Eligible women were asked to log on and fill out an online questionnaire pre-measurement after which they were randomised to either treatment as usual (TAU) defined as a continuation of their current maternity care for 10 weeks, followed by optional ICBT, or to be given ICBT immediately as an add-on to maternity care. Post-measurement was performed 10 weeks later both online and with a telephone interview. The interviewer was not the woman's own therapist but was otherwise not blinded concerning treatment allocation. Fig. 1 shows the CONSORT-flow-chart for participants.

For ethical reasons participants in TAU were offered the ICBT, with therapist support, after they had completed post-measurements. Those who after their 10-week TAU-period had passed gestational week 28 were offered the ICBT starting 3–6 weeks postpartum instead.

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