The (cost) effectiveness of an online intervention (MamaKits) for pregnant women with affective symptoms: a randomised controlled trial

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We will examine effectiveness of the internet-based self-help intervention compared to a waiting list control condition on (1) reduction of depressive and anxiety symptoms post intervention and 6 weeks post-partum and (2) improvement in perinatal...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON39770

Source
ToetsingOnline

Brief title
Mamakits-online study

Condition

- Other condition
- Pregnancy, labour, delivery and postpartum conditions
- Mood disorders and disturbances NEC

Synonym
Depression postpartum; postnatal depression

Health condition

angststoornissen en -afwijkingen NEG

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Internet therapy, Pregnancy, treatment of depressive symptoms, treatment of anxiety symptoms

Outcome measures

Primary outcome

Decrease in depressive and anxiety symptoms shortly after the intervention and

6 weeks postpartum, as measured with the CES-D and the HADS-A

Secondary outcome

Improved perinatal outcome, as decreased pre-term birth and growth restriction)

Less costs in medical consumption and in the social field

Study description

Background summary

Background
Women in pregnancy and postpartum have an increased vulnerability to develop an affective disorder. The prevalence of depressive disorder, respectively anxiety disorder during pregnancy is 12 and 11% [1]. Prevalence rates of mild affective symptoms is 17% [2]
Affective disregulation in pregnancy is often not diagnosed because the overlapping symptomatology with pregnancy itself. It remains therefore often not recognised as a (developing) depressive or anxiety disorder [3]
Both depression and anxiety disorders - affective disorders - are associated with adverse perinatal outcomes such as an increased risk of prematurity, dysmaturity and impaired development [4,5,6]. Untreated affective disorders and their complications may also result in considerable cost [7] Moreover, antenatal depressive and/ or anxiety symptoms are a risk factor for the

development of post partum depressive disorder [8,9]. Prevention of the occurrence of an affective disorder during pregnancy is therefore important for mother, child and society at large.

A recent meta-analysis, which included 28 RCT*s, showed that pre- and postpartum psychological interventions reduced the number of women who developed postpartum depression [10]. Postpartum interventions were more effective than prepartum interventions, interventions aimed at women at high risk were more effective than interventions aimed at all women and individual interventions were more effective than group interventions. Attrition due to the fact that there are many unique barriers for pregnant women and new mothers to attend sessions outside their home, was noted as one of the main problems to accomplish a sufficient intervention dose. The following interventions appear to show promise in the prevention of postpartum depressive disorder: lay telephone support, home visits by nurses, and interpersonal therapy (IPT). There were no studies which used (Internet) self-help programs.

An internet-based self-help intervention can overcome various barriers with respect to face-to-face interventions as it is easy accessible, home-based and can be followed in one*s own time. There is no waiting list and there is also a reduction in therapist time and -costs. The intervention is therefore a promising approach in the treatment of affective disregulation in pregnant women.

In recent years self- help programs have become increasingly popular in mental health care. These interventions are based on evidence based psychological treatments and can be provided in different formats, e.g. in book-format as so-called *bibliotherapy* or online. Nowadays, numerous randomized controlled trials are available that demonstrate the effectiveness of internet-based self-help interventions for different mental disorders such as depression [11,12], anxiety [13,14], alcohol [15], and insomnia [16]. Various treatment modalities have been applied within these trials. For example, Cognitive Behavioural Therapy (CBT) and Problem-Solving Therapy (PST). It has demonstrated that (Internet) self-help treatments that are provided with support are more effective than those without any support [17].
To our best knowledge no evidence based self-help internet intervention for affective disregulation in pregnancy is available yet.

Study objective

We will examine effectiveness of the internet-based self-help intervention compared to a waiting list control condition on (1) reduction of depressive and anxiety symptoms post intervention and 6 weeks post-partum and (2) improvement in perinatal outcome (pre-term birth and growth restriction). We will (3) determine cost-effectiveness using a societal perspective alongside.

Study design

Study design
The study is a randomized controlled trial with an active intervention arm and a waiting list control condition.
The intervention is based on problem solving treatment and will be offered through the internet. It will be guided by a professional coach. Participants in the control condition and women who applicate when they are more than 30 weeks pregnant are offered access to an online depression treatment after the last follow-up of the trial (6 weeks post partum). Both groups are allowed to use treatment as usual as well. Additional care use will be registered.

Intervention

MamaKits online is based on an internet version of PST, which is proven effective for reducing anxiety and depressive symptoms in the general adult population [22]. The core assumption of PST is that depressive and anxiety symptoms are generated when people become overwhelmed by practical problems they face in their daily lives. When people are able to make a list of their worries and problems, and learn structured ways to resolve them, they feel less overwhelmed, are better able to cope and this will in turn alleviate their mood [23].
The course takes 6 weeks to complete, with one lesson each week. Each lesson consists of: information, examples and homework assignments. The intervention consists of three steps: 1. Participants describe what really matters to them. 2. Participants write down their current worries and problems and categorize them into three types: (a) unimportant problems (problems unrelated to the things that matter to them), (b) problems that can be solved, and (c) problems that cannot be solved (e.g. the loss of a loved one). 3. Participants make a plan for the future in which they describe how they will try to accomplish those things that matter most to them.
The core of the intervention consists of a structured approach to solve potentially solvable problems. It consists of six steps: (1) write a clear definition of the problem, (2) generate multiple solutions to the problem, (3) select the best solution, (4) work out a systematic plan for this solution, (5) carry out the solution, and (6) evaluate as to whether the solution has resolved the problem.
Trained coaches will give weekly feedback on the assignments through e-mail. Based on previous experience with e-mail coaching we expect this to take 15 minutes per participant per lesson. Feedback is aimed at supporting participants to work through the intervention and assignments, not to develop a therapeutic relationship. The e-mail support will be provided by trained prevention workers who have experience in providing mental health services to pregnant women. They work within a mental health care organization in Amsterdam. The main researcher and experienced psychiatrist (HH) will check the

integrity of these supportive e-mails.

Study burden and risks

Burden is estimated very small and consists predominantly of filling in questionnaires for about 2 hours pro participant for the whole study of 9 months. Additionally it is expected from the treatmentgroup that they spend 3 hours a week to the course. In the questionnaires there are one or 2 questions about the psychiatric history. The remaining questions and also the treatment course are aimed at present problems and their solvability. The risk of the intervention is very small.

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081HV
NL
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081HV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

participants are included if:
1 they are pregnant in any stage of their pregnancy until 10 weeks before the expected date of delivery
2 they are 18 years or older and
3 they return an informed consent and
4 they have symptoms of depression and/or anxiety as defined by scoring above the cut-off of 15 (*16) on the in the Center for Epidemiological Studies Depression scale (CES-D) and/or above the cut-off of 7 (* 8) on the Hospital Anxiety and Depressionscale (HADS) and
5 they have access to a computer and
6 they have sufficient knowledge of the Dutch language

Exclusion criteria

Exclusion criteria are:
1.age under 18
2.expected delivery date within 10 weeks. These women will be offered the intervention 6 weeks after giving birth at the same time as the controlgroup.
3.Symptoms are to mild as defined by a CES-D <16 and/or a HADS-A < 8
4. Severe suicidality as measured with one question of the Screening Questionnaire. Here the cut-off score is 3

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-03-2014

Enrollment:	286
Type:	Actual

Ethics review

Approved WMO Date:	27-11-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-10-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL42663.029.13