Engaging Turkish/Moroccan women in a tailor-made perinatal depression intervention; transforming an evidence-based intervention developed in the US to the Dutch context.

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON39483

Source
ToetsingOnline

Brief title
Perinatal depression prevention

Condition

- Mood disorders and disturbances NEC

Synonym
depressive symptoms, down

Research involving
Human

Sponsors and support

Primary sponsor: TRIMBOS-INSTITUUT
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Depression, Intervention, Perinatal, Prevention

Outcome measures

Primary outcome

The primary outcome is the difference between the intervention group and the control group in changes in depressive symptoms from baseline to follow-up measurements (8 weeks and 4, 8 and 12 months). Depressive symptoms will be measured with the CES-D.

Secondary outcome

An economical evaluation will be executed to study the cost-effectiveness of the intervention compared to the controle group.

Costs that will be taken in considerations are those from:

- health care use

- the intervention

- production losses

Questionnaires that will be administered for this goal are (relevant parts) of:

- Tic-P

- PRODISQ

- EQ-5D

Also, the intervention group will be asked to evaluate the intervention.

Study description

Background summary

Women have the highest risk on a first episode of depression during child bearing years (Weissman & Jensen, 2002). Particularly among pregnant Turkish/Moroccan women the prevalence of depressive symptoms and depressive disorder is relatively high (Goedhart et al., 2010; De Wit et al., 2008). Maternal depression can interfere with the early bonding and attachment process between mother and baby. Children of mothers with depression are known to be at risk for behavior problems, and are also at high risk for depression or other mood disorders in later childhood and adolescence (Beardslee et al., 1983). Furthermore, maternal depressive symptoms are an important risk factor for perinatal morbidity (Goedhart, 2010). Preventing maternal depression during pregnancy and postpartum would benefit both the mothers and their newborns. Therefore, a Dutch version of the online "Mothers and Babies" (Le et al, 2010; Muñoz, 2007) course will be developed and the cost-effectiveness of this intervention will be studied.

Study objective

The objective is to study the cost-effectiveness of an adapted version of an American course (developed at UCSF), the online 'Mothers and Babies' intervention (Dutch name: "Positief zwanger"), by comparing it to a no intervention control group. For this goal the course will be made suitable for Turkish and Moroccan women in the Netherlands and thereafter the study will take place.

Research questions are:
Primary: are there differences between the course group and the control group in the change in depressive symptoms / complaints from baseline to follow-up measurements?
Secundary: Is the intervention cost-effective compared to a no preventive intervention control group?

Study design

The design is a randomized controlled trial with three arms:
1) The online course .
2) A no intervention control group. This group has access to care as usual, but does not receive an active intervention in this study.

Intervention

The psychosocial preventive intervention includes 6 modules / lessons.
The intervention is directed at:
- increasing engagement in activities, individually or with others, that result in greater experiences of reward (pleasure or mastery),
- decreasing engagement in activities that are unpleasant or result in negative consequences / feelings, and
- solve problems or learning to cope with problems that limit access to positive feelings.
The online course participants in addition receive e-mails to help them work their way through the course and will be stimulated to monitor their mood and course related activities online.

Study burden and risks

The study entails:
- cooperating in a screening by means of a screening questionnaire
- filling in questionnaires at the start, after 8 weeks and after 4, 8 and 12 months.
Filling in the questionnaires will take about 20 minutes each.

- For those offered the online intervention: There are 6 lessons with a time investment about 30 minutes per lesson and 1 hour for homework assignments per lesson.
The course is psychoeducation in nature and does not pose any risks.

Questionnaires that will be used:
- sociodemografics (at baseline only)
- symptoms of depression (CES-D)
- health care services use, productivity and quality of life (see secundary outcomes)
- evaluation of the course (intervention group only)

Use of the intervention will be gathered automatically in an online database and does not require any efforts of the participants.

Contacts

Public
TRIMBOS-INSTITUUT

DA COSTAKADE 45
UTRECHT 3521 VS

NL
Scientific
TRIMBOS-INSTITUUT

DA COSTAKADE 45
UTRECHT 3521 VS
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Women who (a) are at least 18 years of age; (b) are between 12 to 30 weeks pregnant; (c) have a CES-D score >= 16 but (d) are not heavily impaired in daily functioning; (e) do not have frequent suicidal thoughts; (f) have Turkish/Moroccan ethnicity; (g) have Internet access and and e-mail address; (i) gave informed consent (j) completed the baseline questionnaire.

Exclusion criteria

1) Suicidal thoughs and concrete plans and 2) impairment in daily functioning because of depressive complaints.

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	290
Type:	Anticipated

Ethics review

Approved WMO Date:	05-11-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL39196.041.13