The development and effectiveness of a perinatal depression prevention intervention for Turkish/Moroccan women

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20727

Source
NTR

Brief title
Perinatal depression prevention

Health condition

Depressive symptoms

Sponsors and support

Primary sponsor: Trimbos-instituut, Utrecht, The Netherlands
Source(s) of monetary or material Support: ZonMw. The Netherlands Organization for Health Research and Development

Intervention

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. Depressive symptoms will be measured with the CES-D.

Secondary outcome

Cost-effectiveness: is the online course preferable in terms of costs and clinical outcomes as compared to the control group.

Study description

Background summary

Background of the study:

Depression is now the leading cause of disability worldwide. Particularly among pregnant Turkish/Moroccan women the prevalence of depressive symptoms and depressive disorder is higher. 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. Furthermore, maternal depressive symptoms are an important risk factor for perinatal morbidity. Preventing maternal depression during pregnancy and postpartum would benefit both the mothers and their newborns.

Objective of the study:

The objective of the study is to study the cost-effectiveness of a web based individual self-help intervention course called 'Positief zwanger', by comparing it to a no intervention control group. For this goal the course 'Mothers and Babies' developed by UCSF will be made suitable for Turkish and Moroccan women in the Netherlands.

Research questions are:

Primary: are there differences between the groups in depressive symptoms / complaints?

Secundary: Is the intervention preferable compared to a no preventive intervention control group in terms of cost-effectiveness from a societal perspective?

Study design:

The design is a randomized controlled trial with three arms:

1) The course in an individual online setting

2) A no intervention control group. This group receives usual care, but no active intervention.

Study population:

The study population consists of women who are:

- at least 18 years old;

- 12 to 30 weeks pregnant (at screening);

- have a CES-D score of 16 or higher;

- is not heavily impaired in daily functioning because of the depressive symptoms;

- who do not have suicidal thoughts and plans;

- have a Turkish or Moroccan background;

- have internet access and e-mail;

- gave informed consent;

- completed the baseline questionnaire.

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.

Primary outcome

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

Secundary 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

Study objective

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

control group?

Study design

Measures are taken at baseline; post intervention (or after 8 weeks), 4 months, 8 months and 12 months.

Intervention

The web based 'Positief zwanger' intervention consists of a Dutch version of a preventive course that was developed by UCSF called, 'the Mothers and babies course'. The course will be delivered in an individual online format.
The psychosocial preventive intervention includes 6 modules. The course is directed at behavior activation, social engagement to strengthen the social network. Also elements of cognitive behavior therapy are included.
The online course participants 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.

Contacts

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Eligibility criteria

Inclusion criteria

The study population consists of women who are:

- at least 18 years old;

- 12 to 30 weeks pregnant (at screening);

- have a CES-D score of 16 or higher;

- are not heavily impaired in daily functioning because of the depressive symptoms;

- have a Turkish or Moroccan background;
have internet access and e-mail;
gave informed consent;

- completed the baseline questionnaire.

Exclusion criteria

- Having suicidal thoughts and plans

- Heavily impaired in daily functioning because of depressive symptoms

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo

Recruitment

NL
Recruitment status:	Pending
Start date (anticipated):	01-01-2014

Enrollment:	290
Type:	Anticipated

Ethics review

Positive opinion Date:	12-11-2013
Application type:	First submission

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
NTR-new	NL4047
NTR-old	NTR4263
Other	ZonMw 200210011 : METC NL39196.041.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A