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

Gepubliceerd: 12-11-2013 Laatst bijgewerkt: 13-12-2022

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...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20727

Bron
Nationaal Trial Register

Verkorte titel
Perinatal depression prevention

Aandoening

Depressive symptoms

Ondersteuning

Primaire sponsor: Trimbos-instituut, Utrecht, The Netherlands
Overige ondersteuning: ZonMw. The Netherlands Organization for Health Research and Development

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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?

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Having suicidal thoughts and plans

- Heavily impaired in daily functioning because of depressive symptoms

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2014
Aantal proefpersonen:	290
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	12-11-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4047
NTR-old	NTR4263
Ander register	ZonMw 200210011 : METC NL39196.041.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A