DAPPER-studie.

Gepubliceerd: 08-08-2011 Laatst bijgewerkt: 07-12-2022

N/A

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

Samenvatting

ID

NL-OMON22224

Bron
Nationaal Trial Register

Verkorte titel
DAPPER

Aandoening

Psychiatry, psychiatrie
mental disorder, psychiatrische stoornissen
pregnancy, pregnant women, zwanger
personality disorders, persoonlijkheidsstoornissen
grouptherapy, groepsbehandeling

Ondersteuning

Primaire sponsor: Erasmus Medical Center Rotterdam
Overige ondersteuning: Erasmus Medical Center Rotterdam, MRACE doelmatigheidsonderzoek.
Stichting Coolsingel.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To evaluate the efficiency of the daycare for psychiatric, pregnant women.
Degree of (maternal) psychiatric complain reduction, based on psychiatric questionnaires, ie % EPDS <13.

Toelichting onderzoek

Achtergrond van het onderzoek

During pregnancy there are big physical, social en psychological changes. These changes can induce psychiatric complaints which makes professional treatment needed. Approximately 1 out of 8 pregnant women has a psychiatric disorder, that needs to be treated. Severe depression and anxiety disorders have an adverse effect on pregnancy, delivery and the development of the child.

Recent studies in Rotterdam confirmed a high prevalence of psychopathology among pregnant women. 10.8% of the pregnant women had clinical, relevant depressive complaints and 12,1% had clinical, relevant anxiety complaints. This group of pregnant women request, based on the high prevalence of psychopathology, in combination with the adverse obstetrics outcomes for extra psychiatric and obstetric treatment. Until now, there is no appropriate treatment for this group. It would be ideal, if this treatment would be on the interface of psychiatry and obstetrics.
In the Erasmus Medical Centre there is a structered collabration between the departments of psychiatry and obstetrics.

This was the beginning of the daycare treatment for pregnant women with psychiatric disorders, started as a pilot from 2005. This groupwise approach is an unique treatment for a multicultural group, to manage a decrease of psychiatric complaints and to promote a medical uncomplicated pregnancy and delivery.

A real treatment, like a weekly daycare treatment with involvement of a psychiatrist and gynaecologist seems to be promising but the effectiveness and efficiency, in a psychiatric and obstetric point of view, has to be proved with this study. In this RCT we compare daycare with treatment as usual. Primary outcome is the psychiatric symptom reduction, based on questionaires (EPDS).

Doel van het onderzoek

N/A

Onderzoeksopzet

EPDS at intake (>12 weeks gestational age), during treatment every 5 weeks, until 6 weeks postpartum. BSI and Hamilton depression scale at intake and after 6 weeks postpartum.

Onderzoeksproduct en/of interventie

RCT: Daycare vs treatment as usual (TAU).

At the Erasmus MC psychiatry department there's a weekly daycare for (max 8) psychiatric, pregnant women. This multidisciplenary treatment consists of the following components:

1. Theme discussion guided by a social psychiatric nurse;

2. Psychoeducation by a psychiatrist;

3. Psychomotor therapy, focused on contact between mother and child;

4. Cognitive-behavioral therapy;

5. Relaxation therapy.

The individual outpatient care (TAU) is a low frequency counseling / treatment provided by a social psychiatric nurse or doctor in training as a psychiatrist, with the primary goal of psychological education and symptom reduction, related to psychiatric symptoms.

Contactpersonen

Publiek

Erasmus Medical Center Rotterdam (Room Dp0404)
Postbus 2040
L.M. Ravesteyn, van
Rotterdam 3000 CA
The Netherlands
+31 (0)6 42940948

Wetenschappelijk

Erasmus Medical Center Rotterdam (Room Dp0404)
Postbus 2040
L.M. Ravesteyn, van
Rotterdam 3000 CA
The Netherlands
+31 (0)6 42940948

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Pregnant (>12 weken);

2. Psychiatric and/or personality disorder;

3. Informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Clinical care not indicated;

2. Homeless patients;

3. Practical reasons that patient can't come to the hospital every week;

4. (Very) suicidal and/or can't function in a group;

5. Insufficient knowledge of the Dutch language.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	14-01-2010
Aantal proefpersonen:	170
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	08-08-2011
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	NL2870
NTR-old	NTR3015
Ander register	METC Erasmus MC / CCMO : 2009-370 / NL27577.078.09;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

1. Wewerinke A, Honig A, Heres MH, Wennink JM. Psychiatric disorders in pregnant and puerperal women. Ned Tijdschr Geneeskd 2006;150(6):294-8
2. M.P. van den Berg (2006), Parental psychopathology and the early developing child.

Academisch proefschrift. Rotterdam: Erasmus Universiteit.
3. Grote, N. A Meta-analysis of Depression During Pregnancy and the Risk of Preterm Birth, Low Birth Weight, and Intrauterine Growth Restriction. Arch Gen Psychiatry, vol 67 (no.10), oct 2010.