

DAPPER-studie.

No registrations found.

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

Summary

ID

NL-OMON22224

Source

Nationaal Trial Register

Brief title

DAPPER

Health condition

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

Sponsors and support

Primary sponsor: Erasmus Medical Center Rotterdam

Source(s) of monetary or material Support: Erasmus Medical Center Rotterdam, MRACE
doelmatigheidsonderzoek.
Stichting Coolsingel.

Intervention

Outcome measures

Primary outcome

To evaluate the efficiency of the daycare for psychiatric, pregnant women.

Degree of (maternal) psychiatric complain reduction, based on psychiatric questionnaires, ie % EPDS <13.

Secondary outcome

1. Mother: Psychiatric morbidity:

A. Degree of psychiatric complain reduction, based on psychiatric questionnaires, ie % mean BSI and % Hamilton depression scale;

B. Degree of other (related psychiatric) care use.

2. Mother: Obstetric outcome:

A. Degree of psychiatric- and drugfree days;

B. Degree of other (obstetric) care use.

3. Child: Obstetric outcome:

A. Birth weight, gestational age, apgar-score, fetal death and first week hospitalization.

Study description

Background summary

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 structured collaboration 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 questionnaires (EPDS).

Study objective

N/A

Study design

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.

Intervention

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 multidisciplinary 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.

Contacts

Public

Erasmus Medical Center Rotterdam (Room Dp0404)

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

Scientific

Erasmus Medical Center Rotterdam (Room Dp0404)

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

Eligibility criteria

Inclusion criteria

1. Pregnant (>12 weken);
2. Psychiatric and/or personality disorder;
3. Informed consent.

Exclusion criteria

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.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	14-01-2010
Enrollment:	170
Type:	Anticipated

Ethics review

Positive opinion	
Date:	08-08-2011
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	NL2870
NTR-old	NTR3015
Other	METC Erasmus MC / CCMO : 2009-370 / NL27577.078.09;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

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.