

Daycare Alternative Psychiatric Pregnant women Efficiency Research

Published: 14-01-2010

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Primary objective: To evaluate the efficiency of the daycare treatment of pregnant women with a psychiatric disorder. Secondary objective: Differs groupwise daycare treatment in efficiency towards standard individual outpatient care, in terms of: a....

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Maternal complications of pregnancy
Study type	Interventional

Summary

ID

NL-OMON38415

Source

ToetsingOnline

Brief title

DAPPER

Condition

- Maternal complications of pregnancy
- Psychiatric and behavioural symptoms NEC

Synonym

mental illness, psychopathology

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W, Stichting Coolsingel

Intervention

Keyword: efficiency research, pregnant women, psychiatric disorders

Outcome measures

Primary outcome

1. Mother-psychiatric morbidity. The participants are treated for their psychiatric disorder (depression and anxiety disorders). Psychiatric treatment success is defined as a reduction of complaints (GAF-score >-60) and a symptom reduction based on the scores under the validated cut-off points of the used questionnaires.

2. Mother-obstetrics outcome. The way of delivery towards the average population and the degree of other care use.

3. Child-obstetric outcome. The child's health is defined by the hard obstetric outcomes and care use of the child.

Secondary outcome

see above

Study description

Background summary

During pregnancy there are big physical, social and 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. Among the pregnant women with a non-Dutch ethnicity these percentages were even higher, till 29.8%. 41% of the participated women had a non-Dutch ethnicity. In addition, the number of pregnancy rises among non-Dutch populationgroups, both relative as absolute. This increasing group of non-Dutch pregnant women request, based on the high prevalence of psychopathology, in combination with the adverse obstetrics outcomes for extra psychiatric and obstetrics 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.

Study objective

Primary objective:

To evaluate the efficiency of the daycare treatment of pregnant women with a psychiatric disorder.

Secondary objective:

Differs groupwise daycare treatment in efficiency towards standard individual outpatient care, in terms of:

- a. Reduction of psychiatric complaints of the mother?
- b. Reduction of complicated pregnancies and deliveries?
- c. Reduction of care use during and after the pregnancy?

Study design

Randomised controlled trial.

Intervention

Daycare treatment vs 'treatment as usual'

This groupwise daycare treatment is a weekly, structured program on the department Psychiatry of the Erasmus Medical Center. This contains: themediscussion with a social psychiatric nurse, psycho-education by a psychiatrist, psychomotor therapy by a movement therapist focussed on a

connection between mother and child, cognitive behavioral by a psychologist and relaxing therapy by an activity counsellor.

Study burden and risks

Het invullen van de vragenlijsten elke 5 weken en het wekelijks bijhouden van een dagboek kost veel tijd en is zeker voor de zwangere vrouw een belasting, maar mogelijk heeft het een therapeutisch effect.

To fill in the questionnaires every 5 weeks and to fill in a diary weekly takes a lot of time, especially for pregnant women. Probably it has a therapeutical benefit.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- informed consent
- > 12 weeks pregnancy
- psychiatric disorder, including personality disorder

Exclusion criteria

- clinical psychiatric care is needed
- pregnant women with public psychological healthcare problems
- pregnant women whom are unable to come weekly for practical reasons
- pregnant women with severe behaviour issues whom are not able to function within a group or severe suicidal
- pregnant women whom are unable to speak Dutch

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	15-01-2010
Enrollment:	275
Type:	Actual

Ethics review

Approved WMO	
Date:	14-01-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	
Date:	12-08-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	
Date:	12-11-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	
Date:	19-11-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL27577.078.09
Other	NTR (TC = 3015)

Study results

Date completed:	01-10-2013
Actual enrolment:	161