

POP-UP Study. Psychiatry, Obstetrics, Pediatrics & Psychology: Pregnancy Under Pressure

Published: 23-12-2014

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Aims of this study is to explore factors that are related to (sub)optimal mother-child bonding in mothers with mental health disorders.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	Observational non invasive

Summary

ID

NL-OMON50561

Source

ToetsingOnline

Brief title

POP-UP Study

Condition

- Pregnancy, labour, delivery and postpartum conditions
- Psychiatric and behavioural symptoms NEC

Synonym

mental health disorders, psychiatric disorders

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg

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

Intervention

Keyword: Mental Health Disorders, Mother-Child Bonding, Pregnancy

Outcome measures

Primary outcome

The main outcomes in the current study are the prenatal mother-child bond.

Secondary outcome

- Mothers* mental health problems (depression, anxiety, characteristics of borderline personality disorder, Big 5 personality traits)
- Partner support
- Mothers* own attachment history

Study description

Background summary

The symptoms of the disorders in pregnant women with mental health or psychosocial problems (e.g., emotional detachment in depression, emotional imbalance in borderline), high levels of stress, and complex social circumstances will often hinder the bonding process. Despite the pivotal role of early mother-child bonding in women with mental health problems, little is known about factors that optimize or hinder the bond.

Study objective

Aims of this study is to explore factors that are related to (sub)optimal mother-child bonding in mothers with mental health disorders.

Study design

A cross-sectional design will be used, with one measurement moment ranging from 8 to 36 weeks of gestation. Expectant mothers will complete questionnaires.

Study burden and risks

We do not expect this study to harm the mothers or their babies in any way. As we include pregnant women who are being treated in the *POP-poli*s*, they will furthermore be guided by professionals (psychiatrists, obstetricians, and pediatricians, social workers, psychologists and nurses). Hence, they will also be able to assist the pregnant woman regarding the current proposed study if needed.

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

Women referred to the POP-poli are included in case of (a) presence or history of psychiatric disorder; (b) prior problems during pregnancy or childbirth ((post-partum) depression, psychosis, PTSD); (c) use of psychopharmaceuticals; (d) presence or history of (post-partum) psychotic or bipolar disorder in

closest relatives; (e) presence or history of substance abuse/ dependence; (f) complex psychosocial circumstances, including domestic violence and serious financial, housing, and relationship problems.

Exclusion criteria

Women referred to the POP-poli are excluded in case of (a) inability to give informed consent; (b) intention to deliver outside the region; (c) poorly spoken or written Dutch; (d) presence of current psychosis or manic episode; (e) known mental retardation.

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 26-02-2015

Enrollment: 200

Type: Actual

Ethics review

Approved WMO

Date: 23-12-2014

Application type: First submission

Review commission: METC Brabant (Tilburg)

Approved WMO

Date: 28-01-2016

Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	19-08-2019
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	04-11-2020
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL51248.028.14