

# Healthy Pregnancy 4 All -2: Maternity care

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<b>Ethische beoordeling</b>	Positief advies
<b>Status</b>	Anders
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Interventie onderzoek

## Samenvatting

### ID

NL-OMON29568

### Bron

Nationaal Trial Register

### Verkorte titel

Healthy Pregnancy 4 All-2 (HP4All) study.

### Aandoening

Pregnancy, patient tailored care, maternity care, antenatal care, maternal empowerment

## Ondersteuning

**Primaire sponsor:** The research team has received funding from the Ministry of Health, Welfare and Sports in order to execute the Healthy Pregnancy 4 All study. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of a manuscript.

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## Onderzoeksproduct en/of interventie

## **Uitkomstmaten**

### **Primaire uitkomstmaten**

The primary outcome is the mean overall maternal empowerment score (range 1-4), assessed using the Maternal Empowerment Questionnaire (MEQ) between day 7 and 14 postpartum.

## **Toelichting onderzoek**

### **Achtergrond van het onderzoek**

This study uses a cluster randomized controlled trial design in six municipalities in the Netherlands, including 12 maternity care organisations at 15 different locations throughout the country. In each municipality, both an intervention, and a control cluster are formed. The intervention under study is a systematic risk assessment for medical and non-medical risk factors during pregnancy in conjunction with client-tailored care during pregnancy and the postpartum period. The primary outcome is maternal empowerment measured between day six and 14 postpartum. The results from this trial will provide evidence on whether structured risk assessments in conjunction with patient-tailored care for high-risk pregnant women by maternity care providers is feasible in terms of effectiveness and implementation.

### **Doel van het onderzoek**

The results from this trial will provide evidence on whether structured risk assessments and customized maternity care for high-risk pregnant women by maternity care providers is feasible in terms of effectiveness, especially regarding maternal empowerment.

### **Onderzoeksopzet**

Risk-assessment during pregnancy (between 28-37 weeks of pregnancy). Follow questionnaires postpartum; firstly 7-14 days postpartum, and secondly 6-12 weeks postpartum.

### **Onderzoeksproduct en/of interventie**

The study is embedded in the Healthy Pregnancy 4 All- 2 program (HP4All-2), a nationwide program in the Netherlands that aims to reduce health inequalities and improve the care for young children and their mothers.

Within the intervention clusters, participants will receive a structured risk assessment during pregnancy. The risk assessment focuses on medical and non-medical risk factors. The consequent content of the intervention is informed by these outcomes with proactive, client-

tailored care during pregnancy, labour, and the postpartum period. The risk assessment is based on the Mind2Care (M2C); a Dutch screen-and-advice tool developed and validated for routine use in antenatal obstetric care, complemented with an adjusted form of the Maternal Empowerment Questionnaire (MEQ).

The personalised care pathways are based on standard care pathways within each participating organisation and within the participating municipality. Participants in the control clusters will receive the same risk assessment. This assessment will however be followed by conventional maternity care during pregnancy, labour, and the postpartum period.

The local researcher, a trained maternity care professional or assistant, will be the contact between the study-team and the participants. All local researchers involved in interviewing participants will be educated extensively to use the risk assessment and to guide the participants in answering the questions within the risk assessment. This education exists of two sessions of three hours and will be guided by a well-established Dutch educational agency together with the principal investigator of the research team. In-service training consists of the risk factors that will be evaluated using the risk assessment tool, the association between risk factors and adverse health outcomes, the possible tailored care towards women's circumstances and needs, and strengthening women's capabilities. It further contains group exercises in communication and respect, in order to correctly include participants in a research project and to answer questions of participants in an proper way.

## Contactpersonen

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Support for the study in a maternity care organisation was sought from senior staff, and executives with responsibility for clinical quality and safety. Maternity care organisations were required to demonstrate sufficient capacity to maximise their engagement with the study. The studied intervention requires an interview scheduled at home for each client. All pregnant women cared for by participating maternity care organisations, which have a scheduled home visit during pregnancy, within the selected postal codes of the participating municipalities, are invited to take part in the trial.

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria are not having a planned home visit during pregnancy and inadequate knowledge of the Dutch language, English language, Polish language, or Turkish language.

## Onderzoeksopzet

### Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

### Deelname

Nederland	
Status:	Anders
(Verwachte) startdatum:	15-08-2015
Aantal proefpersonen:	1711
Type:	Onbekend

## Ethische beoordeling

Positief advies

Datum: 27-03-2017

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	NL6164
NTR-old	NTR6311
Ander register	MEC : 2015-156

## Resultaten