

# The effectiveness of Nurse Family Partnership intervention

<b>Submission date</b> 11/04/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 11/04/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 14/11/2022	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Ms Mieke de Haan

**Contact details**  
EMGO instituut  
Afd. Sociale Geneeskunde  
Van der Boechorststraat 7  
Amsterdam  
Netherlands  
1081 BT  
+31 (0)20 444 8108  
mi.dehaan@vumc.nl

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

# Study information

## Scientific Title

The effectiveness of Nurse Family Partnership intervention

## Acronym

Nurse Family Partnership

## Study objectives

Compared to children receiving usual care, children receiving the Nurse Family Partnership (NFP)-intervention will have better birth outcome, growth and development, psycho-social outcomes and behavioural outcomes in the first years of life, and also later in life.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics approval received from the local medical ethics committee

## Study design

Randomised, active controlled, parallel group, single blinded trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Quality of life

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied

Pregnancy in at-risk mothers-to-be

## Interventions

Intervention group:

The Nurse Family Partnership intervention consists of an intensive schedule of approximately 30 home visits (maximal 60) by experienced youth health nurses. The home visits will start from the 16th week of pregnancy and will last until the child is two years of age. The frequency is about two visits each month with a higher frequency (once a week) in the first month of the programme and the first six weeks after birth, with a declining frequency (once a month) in the last four months. Every home visit lasts one to 1.5 hours.

Control group:  
Care as usual.

## **Intervention Type**

Other

## **Phase**

Not Specified

## **Primary outcome measure**

1. At the start of the study women will be interviewed about the following conditions:

- a. physical: diseases, diet, cigarette smoking, drug abuse, etc.
- b. emotional: feelings of anxiety and depression, a history of abuse or neglect
- c. relational: partner, social support
- d. social determinants: education, financial problems, housing, use of current health care

The mothers' sense of control about her circumstances is determined. Partners are being asked to report emotional or behavioural problems. A urine sample will be taken to determine urinary infections

2. During the entire study measurements of the following will be used in the study:

- a. height and weight
- b. breast- or bottle-feeding
- c. development according to Van Wiechen classification scheme

These will be collected by the regular health system will be used in the study. Also, data of the delivery and first week after birth will be collected from the files of primary health care.

3. At the age of six months, we measure development, anxiety and mother-child interactions.

4. At the ages of one and two years the home situation will be observed according to:

- a. safety
- b. availability of food and fruit and of toys

5. At the age of two other determinants are:

- a. child abuse
- b. finance
- c. home
- d. education
- e. anti-conception
- f. pregnancies
- g. stability relation with the father
- h. psychopathology of the mother

## **Secondary outcome measures**

- 1. Pre-conditions necessary for an optimal implementation
- 2. Cost-effectiveness of the intervention

## **Overall study start date**

01/01/2007

## **Completion date**

01/07/2009

# Eligibility

## Key inclusion criteria

1. No previous born child (a number of pregnant women did have an abortion)
2. Pregnancy duration of maximum 28 weeks
3. Low education grade
4. Some knowledge of the Dutch language
5. Furthermore, one or more of the following secondary inclusion criteria:
  - a. no (supportive) social network or partner
  - b. alcohol or drug abuse
  - c. actual violence in family or partner
  - d. history of abuse
  - e. psychological problems such as anxiety or depression
  - f. non-realistic approach about motherhood
  - g. drop-out of school
  - h. unemployed
  - i. financial or housing-problems

## Participant type(s)

Patient

## Age group

Adult

## Sex

Female

## Target number of participants

456

## Key exclusion criteria

1. Heavy psychiatric problems or obvious psychosis
2. Heavy drugs or alcohol addiction

## Date of first enrolment

01/01/2007

## Date of final enrolment

01/07/2009

# Locations

## Countries of recruitment

Netherlands

## Study participating centre

EMGO instituut

Amsterdam

Netherlands  
1081 BT

## Sponsor information

### Organisation

VU University Medical Centre (The Netherlands)

### Sponsor details

Department of Public Health  
P.O. Box 7057  
Amsterdam  
Netherlands  
1007 MB

### Sponsor type

Hospital/treatment centre

### Website

<http://www.vumc.nl/english/>

### ROR

<https://ror.org/00q6h8f30>

## Funder(s)

### Funder type

Research organisation

### Funder Name

The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

## Results and Publications

### Publication and dissemination plan

Not provided at time of registration

### Intention to publish date

### Individual participant data (IPD) sharing plan

Not provided at time of registration

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>		21/10/2011		Yes	No