ISRCTN16131117 https://doi.org/10.1186/ISRCTN16131117

The effectiveness of Nurse Family Partnership intervention

Submission date	Recruitment status	[_] Prospectively registered
11/04/2007	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
11/04/2007	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
14/11/2022	Pregnancy and Childbirth	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

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

Primary study design
Interventional

Study design
Randomised, active controlled, parallel group, single blinded trial

Study type(s)
Quality of life

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(s)
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

Key secondary outcome(s)
1. Pre-conditions necessary for an optimal implementation
2. Cost-effectiveness of the intervention

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

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)

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

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?
Protocol article		21/10/2011		Yes	No