

The effectiveness of Nurse Family Partnership intervention.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26375

Source

Nationaal Trial Register

Brief title

Nurse Family Partnership

Sponsors and support

Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

At the start of the study women will be interviewed about their physical condition (diseases, diet, cigarette smoking, drug abuse, etc.), emotional (feelings of anxiety and depression, a history of abuse or neglect), relational (partner, social support), and social determinants (education, financial problems, housing, use of current health care). Mothers' sense of control about her circumstances is determined. Partners are being asked to report emotional or behavioral problems. A urine sample will be taken to determine urinary infections. During the entire study measurements of height and weight, breast- or bottle feeding, and development according to Van Wiechen, 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. At the age of 6 months, we measure development, anxiety and

mother-child interactions. At the ages of 1 and 2 years the home situation will be observed according to safety, availability of food and fruit and of toys. At the age of 2 other determinants are: child abuse, finance, home, education, anti conception, pregnancies, stability relation with the father, psychopathology of the mother.

Secondary outcome

1. Preconditions necessary for an optimal implementation;
2. Cost-effectiveness of the intervention.

Study description

Background summary

Implementation and research of the Nurse Family Partnership intervention, in which risk factors threatening the physical, the cognitive and the behavioral development during pregnancy and in the first 2 years of life are being reduced in yet-to-be-born children of high-risk mothers. The ultimate goal is to improve pregnancy and birth outcomes for mother and child, to improve personal development and the opportunities for education and work for the mothers in order to make her more available for her child.

The study design is based on a trial with 456 selected pregnant high-risk mother randomly divided into a control and an intervention group. The high-risk pregnant women will be visited regularly by nurses during pregnancy, after the child is born, and 6 months, 1 year and 2 years after birth. During these visits the nurses will systematically address (1) changes in mothers' behavior to promote the infants' health and development and to improve mothers' living circumstances with an emphasis on the improvement of diet and physical health and the reduction of substance use during pregnancy, (2) the quality of supportive relationship, and (3) the link between the mother and the regular services.

Study objective

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

Intervention

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 2 years of age. The frequency is about 2 visits each month with a higher frequency (once a week) in the first month of the programme and the first 6 weeks after birth, with a declining frequency (once a month) in the last 4 months. Every home visit lasts 1 to 1.5 hours.

Control: care as usual.

Contacts

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Eligibility criteria

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: no (supportive) social network or partner, alcohol - or drugabuse, actual violence in family or partner, history of abuse, psychologic problems such as anxiety or depression, non-realistic approach about motherhood, drop-out of school, unemployed, financial or housing-problems.

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-01-2007
Enrollment:	456
Type:	Anticipated

Ethics review

Positive opinion	
Date:	19-12-2006
Application type:	First submission

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
NTR-new	NL840
NTR-old	NTR854
Other	: N/A
ISRCTN	ISRCTN16131117

Study results

Summary results
N/A