

'Parents to Be' - The effectiveness of systematic population-based preconception advice and counselling initiated by GPs

Submission date 27/01/2006	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 27/01/2006	Overall study status Completed	☐ Protocol
Last Edited 02/11/2022	Condition category Pregnancy and Childbirth	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
ZonMw Project number 22000044 and 2200.0135; NTR456

Study information

Scientific Title
GP-initiated preconception counselling

Acronym

Parents to Be

Study objectives

At least 20% of the pregnancies in the Netherlands end in an adverse pregnancy outcome (spontaneous abortion, preterm birth, low birth weight, perinatal death, congenital anomaly). Information on risk factors before pregnancy together with preventive measures (preconception counselling) will lead to behavioural changes and thus to reduced adverse pregnancy outcomes.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Medical Ethics Committee of Leiden University Medical Centre.

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Adverse pregnancy outcome

Interventions

In the intervention group women 18 - 40 years received an invitation for preconception counselling. When interested and contemplating a pregnancy within a year a risk-assessment questionnaire was used to systematically assess risks of the couple. Counselling was provided based on risks identified as well as risks which apply to all women.

The control group received care as usual.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

The effect of GP-initiated preconception counselling (PCC) on adverse pregnancy outcome (spontaneous abortion, preterm birth, low birth weight, perinatal death, congenital anomaly).

Key secondary outcome(s)

1. Evaluation of womens knowledge of risk factors for the foetus and the influence of PCC on this knowledge
2. Prevalence of risk factors
3. Response to invitation of PCC

4. Anxiety induction by invitation or counselling
5. Satisfaction with counselling
6. Influence of PCC on risk-reducing behavior
7. GP satisfaction with the systematic PCC program and barriers for implication

Completion date

31/12/2005

Eligibility

Key inclusion criteria

Women aged 18 - 40 years.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Female

Key exclusion criteria

1. Completed family
2. Uterus extirpation
3. Sub-fertility or infertility
4. Insufficient understanding of Dutch
5. Adverse social circumstances

Date of first enrolment

09/01/2000

Date of final enrolment

31/12/2005

Locations

Countries of recruitment

Netherlands

Study participating centre

TNO Quality of Life

Leiden
Netherlands
2301 CE

Sponsor information

Organisation

TNO Quality of Life, Division of Child Health, Prevention and Physical Activity (The Netherlands)

ROR

<https://ror.org/03b1hdw57>

Funder(s)

Funder type

Research organisation

Funder Name

ZonMw

Alternative Name(s)

Netherlands Organisation for Health Research and Development

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

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?
Results article		07/07/2006		Yes	No
Results article		03/11/2006		Yes	No