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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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

Overall study start date
09/01/2000

Completion date
31/12/2005

Eligibility

Key inclusion criteria
Women aged 18 - 40 years.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
4800

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)

Sponsor details
P.O. Box 2215
Leiden
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Sponsor type
Not defined

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

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