

'Parents to be' The effectiveness of systematic population-based preconception advice and counselling initiated by GP's.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25143

Source

NTR

Brief title

Parents to Be

Health condition

Risk factors of adverse pregnancy outcome and adverse outcome itself being: spontaneous abortion, preterm birth, low birth weight, perinatal death, and congenital anomaly.

Sponsors and support

Primary sponsor: TNO Quality of Life, Leiden, the Netherlands and Department of General Practice and Nursing Home Medicine, Leiden University Medical Center, Leiden, the Netherlands

Source(s) of monetary or material Support: ZON-MW Project number 22000044 and 2200.0135.

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Evaluation of women's knowledge of risk factors the foetus and the influence of PCC on this knowledge. Prevalence of risk factors, response to invitation of PCC, anxiety induction by invitation or counseling, satisfaction with counseling. Influence of PCC on risk-reducing behavior. GP satisfaction with the systematic PCC program and barriers for implication.

Study description

Background summary

'Parents to be' is a project that evaluates routine preconception advice and counselling given to couples before pregnancy (PAC), initiated and given by their own general practitioner (GP) in order to prevent adverse pregnancy outcomes. The couples' personal situation is evaluated with respect to risk factors for the pregnancy and the unborn child. Questions are asked about the couples' medical history, medication, lifestyle (smoking, alcohol consumption and nutritional habits) as well as about hereditary and congenital disorders in the family. If specific risk factors are found the couple receives information about these personal risk factors along with information on general risk factors for pregnancy. The GP offers general and specific health education and refers to a specialist if genetic counselling is needed. The effect of routine PAC on health behaviour, risk perception, frequency of risk factors in the general population is studied.

Study objective

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 counseling) will lead to behavioural changes and thus to reduced adverse pregnancy outcomes.

Study design

N/A

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

Women aged 18-40.

Exclusion criteria

Completed family, uterus extirpation, sub-fertility or infertility, insufficient understanding of Dutch, or adverse social circumstances.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	09-01-2000
Enrollment:	4800
Type:	Actual

Ethics review

Positive opinion	
Date:	14-10-2005
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	NL416

Register

NTR-old

Other

ISRCTN

ID

NTR456

: ZON-MW Project number 22000044 and 2200.0135

ISRCTN53942912

Study results

Summary results

1. BMC Fam Pract. 2006 Jul 7;7:41.

2. BMC Fam Pract. 2006 Nov 3;7:66.
