

Risk perception, informed decision making, and psychological well-being of pregnant women who are offered prenatal screening for congenital defects.

No registrations found.

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

Summary

ID

NL-OMON26208

Source

NTR

Brief title

N/A

Health condition

Down syndrome, neural tube defects.

Sponsors and support

Primary sponsor: VU University Medical Center,
EMGO-institute,
Dept of Public and Occupational Health

Source(s) of monetary or material Support: ZonMw Prevention Program.

Intervention

Outcome measures

Primary outcome

1. Risk perception;
2. Psychological well-being.

Secondary outcome

N/A

Study description

Background summary

The main reasons to accept prenatal screening were knowledge and test characteristics;

the main reasons to decline prenatal screening were unfavorable test characteristics, anxiety/uncertainty, and adverse characteristics of invasive testing.

The role of risk perception in the decision to accept or decline prenatal screening is limited.

Offering prenatal screening does not seriously affect anxiety levels of pregnant women.

Study objective

N/A

Study design

N/A

Intervention

The offer of a prenatal screening test (either the nuchal translucency measurement, or the maternal serum screening test) by means of an information booklet and an oral explanation by the woman's midwife or gynaecologist.

Contacts

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Eligibility criteria

Inclusion criteria

Pregnant women attending 1 of 44 participating midwifery or gynaecology practices from May 2001 to May 2003 were asked for their informed consent.

Exclusion criteria

1. Gestational age of more than 16 weeks;
2. No command of the Dutch language.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2000
Enrollment:	3000
Type:	Actual

Ethics review

Positive opinion	
Date:	02-09-2005
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	NL390

Register

NTR-old

Other

ISRCTN

ID

NTR430

: 2200.0085

ISRCTN24427684

Study results

Summary results

1. Accepting or declining the offer of prenatal screening for congenital defects: test uptake and women's reasons. van den Berg M, Timmermans DR, Kleinveld JH, Garcia E, van Vugt JM, van der Wal G.

Prenatal Diagnosis 2005;25(1):84-90.

2. Are pregnant women making informed choices about prenatal screening? van den Berg M, Timmermans DR, Ten Kate LP, van Vugt JM, van der Wal G. Genetics in Medicine 2005;7(5):332-8.

3. Prenatal Diagnosis (in press). Johanna H. Kleinveld, Danielle R.M. Timmermans, Denhard J. de Smit, Herman J. Adèr, Gerrit van der Wal , Leo P. ten Kate. Does prenatal screening influence anxiety levels of pregnant women? A longitudinal randomised controlled trial.