

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

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| Submission date 27/01/2006 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 27/01/2006 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 03/07/2009 | Condition category Neonatal Diseases | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

NTR430; 2200.0085

Study information

Scientific Title

Study objectives

Not provided at time of registration

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Randomised, single blind, controlled, parallel group trial

Primary study design

Interventional

Study type(s)

Screening

Health condition(s) or problem(s) studied

Down syndrome, neural tube defect

Interventions

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

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. Risk perception
2. Psychological well-being

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/12/2005

Eligibility**Key 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.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

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

Date of first enrolment

01/01/2000

Date of final enrolment

31/12/2005

Locations**Countries of recruitment**

Netherlands

Study participating centre

VU University Medical Centre
Amsterdam
Netherlands
1081 B

Sponsor information**Organisation**

VU University Medical Center, EMGO-Institute and Department of Public and Occupational Health (Netherlands)

ROR

<https://ror.org/00q6h8f30>

Funder(s)

Funder type

Research organisation

Funder Name

The Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

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 | results on test uptake and participants' reasons | 01/01/2005 | | Yes | No |
| Results article | results on informed decision making about prenatal screening among participants | 01/05/2005 | | Yes | No |