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

Submission date 27/01/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 27/01/2006	**Overall study status** Completed	
Last Edited 03/07/2009	**Condition category** Neonatal Diseases	

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

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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Screening

Participant information sheet

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 measure
1. Risk perception
2. Psychological well-being

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2000

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

Age group
Adult

Sex
Female

Target number of participants
3000

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
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Sponsor information

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

Sponsor details
Van der Boechorststraat 7
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Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output	Date	Date	Peer	Patient-

type	Details	created	added	reviewed?	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