Factors that influence women*s utilization of prenatal screening for Down*s syndrome. Optimizing decision making and refining current and future screening policies by studying differences in uptake rates, between three European countries*

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The striking difference in uptake of Down*s Syndrome screening between countries that otherwise show close resemblance, particularly regarding healthcare policy, social and cultural factors (including non-directiveness of counselling, autonomous and...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Chromosomal abnormalities, gene alterations and gene variants
Study type	Observational non invasive

Summary

ID

NL-OMON38077

Source
ToetsingOnline

Brief title
Current and future uptake prenatal screening

Condition

- Chromosomal abnormalities, gene alterations and gene variants
- Maternal complications of pregnancy

Synonym

Down syndrome, trisomy 21

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Catharijne stichting/ Stichting vrienden UMC utrecht

Intervention

Keyword: down syndrome, pre eclampsia, prenatal screening, uptake, utilization

Outcome measures

Primary outcome

The approach of the study will be a *mixed method*, also called a sequential exploratory approach, consisting of a review, desk research, completed with stakeholders interviews in the three countries, qualitative focus group discussions and semi-quantitative large-scale questionnaires.

In this study, we are interested in participant*s reasons to decline or accept DSS. First, we want to determine which factors correlate with declining or accepting the test. As these data consider feelings, perceptions and interpretations of different levels, a qualitative approach is most suitable to provide this information. After we have determined discriminating factors of influence, we will perform large-scale questionnaires to determine if these findings are representative for large groups. Therefore a semi-quantitative approach is most applicable.

Secondary outcome

NA

Study description

Background summary

Down*s syndrome screening (DSS) is performed in the first trimester of pregnancy, with a foetal nuchal translucency measurement and quantification of biomarkers in maternal serum. Its goal is to inform prospective parents on their chance of having a Down*s syndrome (DS) affected child in a timely manner, in order to allow them the opportunity to act, that is to prepare for the birth of a child with DS or termination of pregnancy if DS is diagnosed (Gezondheidsraad 2007). In the Netherlands, since 2007 all women are informed about the possibility of prenatal screening for DS. Women who express interest in the screening, will be provided with further information on the test; information on decision-making, risk-assessment, possible subsequent diagnostic evaluation and possible subsequent termination of pregnancy. It is not the goal of this information to increase uptake, but to enable pregnant women and their partners to make autonomous informed decisions on participation on screening tests or otherwise. Because of the possible ethical implications of prenatal screening informed decision-making is necessary.
Since the implementation of the test in Northern Europe, in most countries prenatal screening for Down*s syndrome forms part of regular prenatal care. Uptake rates in DSS in the Netherlands are low as compared to other Northern European countries (27% in The Netherlands versus 66% in the UK and 99% in Denmark).
Social and cultural factors as well as the availability of resources and the prevailing legislation regarding TOP are factors that influence these uptake rates (Boyd et al 2008), however, in the mentioned countries these factors are generally similar. Besides in Northern Europe, autonomous choice in DSS, is highly valued and carried out by healthcare professionals. Balanced and non-directive information prior to screening is provided to facilitate pregnant women in making autonomous and informed decisions {{145 van den Heuvel,A. 2009; 146 van den Heuvel,A. 2008; 142 Hall,S. 2007}}. Therefore, the observed difference in uptake of DSS between countries that otherwise show close resemblance, particularly regarding healthcare policy, social and cultural factors (including non-directiveness of counselling, autonomous and informed choice) is hard to explain.
These differences require a thorough analysis of factors that influence women's utilization of screening. The results of the analysis will provide healthcare professionals and policy makers with information, directly collected from pregnant women, on reasons to accept or decline screening. This knowledge is relevant as it helps to optimize current screening policy and counselling.
Previous research on women*s reasons for participation in Down*s Syndrome screening has commonly focused on the relationship between attitudes towards undergoing testing and actual testing behaviour. Health care beliefs (attitudes, values and knowledge) will continue to improve our ability to

explain healthcare use, but the Northern-European uptake differences suggest correlations not only with individual characteristics, such as health beliefs, but also with healthcare system characteristics.
A suitable model to analyze the influence of these different levels is the Andersen model (1). This model not only considers the individual characteristics (predisposing factors e.g. health beliefs and need factors, such as (perceived) health/risk) but also health care characteristics (enabling factors: e.g. availability, accessibility, and their interaction.

Study objective

The striking difference in uptake of Down*s Syndrome screening between countries that otherwise show close resemblance, particularly regarding healthcare policy, social and cultural factors (including non-directiveness of counselling, autonomous and informed choice instigated us to conduct this study. We therefore question whether the Dutch uptake rate of 26% is a correct reflection of pregnant women*s preferences. The aim of this study is to answer the following questions: (1) What individual and environmental factors (need, predisposing factors and enabling) correlate with the participation for Down*s Syndrome screening in Dutch, Danish and British pregnant women? (2) To what extent can these factors explain the differences in uptake rates? (3) To what extent do the uptake rates reflect women*s preferences in Down*s Syndrome screening?
The results of the study will provide us with information directly from the demand side and will lead to unique information, as it not only considers attitudes and personal values, but also the surrounding environment(need, enabling factors and predisposing factors) and its relation with decision making and subsequent use.

Study design

In a qualitative study, we will collect data by using focus group interviews, consisting of Dutch pregnant women (purposive sampling). The aim of the focus group interview is to understand how women decide on utilization of prenatal screening for Down*s syndrome; what determinants are decisive in participation in Down's syndrome screening, pre en post counselling? By exploring feelings, needs, perceptions, attitudes, values, beliefs and thoughts on the subject we will collect data on reasons why women decline or accept prenatal testing for Down*s syndrome. Based on the Andersen model of health care use we will explore which factors significantly correlate with declining or accepting prenatal screening for Down*s syndrome. The following questions will be used in the group interviews: (1) Have you thought about participating in prenatal screening for Down*s Syndrome, why or why not?(2) What items are crucial in accepting or declining the offer of prenatal screening? (Need, Predisposing, Enabling). Preceding the interviews we will collect data on demography, perceived health, risk perception, illness perception, anxiety, knowledge and

uptake rates via validated questionnaires. Each interview will be audio and videotaped and transcribed verbatim. Data analysis will be performed on basic content and categorized into themes of the Andersen model. The results will be used as a base for large-scale quantitative questionnaires.

Study burden and risks

Time investment of three hours, including coffeebreaks and introduction and debriefing. Total interview time is 120 minutes. No risks. Preceding the interviews participants fill in a questionnaire (30 minutes).
total time investment (including preceding questionnaire, introduction, break and debriefing) 3,5 hours.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Pregnant women:
- Participants should be older than 18, and confirmed pregnancy
- Good understanding of Dutch language
- Gestational age <10 weeks, 11-13 weeks and 14-20 weeks
- Singleton pregnancy
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Exclusion criteria

- Non pregnant women
- Pregnant women age < 18
- Former history of fetal anomalies
• Current pregnancy with fetal anomalies or maternal complications
• Pregnancy perceived by assisted reproductive technology

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-07-2012
Enrollment:	112
Type:	Actual

Ethics review

Approved WMO

Date:	11-04-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
CCMO	NL35228.041.11