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Improving decision support about prenatal screening for pregnant women and counselors

Submission date
14/07/2022

Recruitment status
No longer recruiting

Registration date
04/11/2022

Overall study status
Completed

Last Edited
06/03/2025

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
During pregnancy, women are typically offered 3 types of prenatal screening:
1. A screening for Down, Edwards', or Patau's syndrome through a blood test from 11 weeks of pregnancy
2. A 13-week ultrasound to check for structural fetal malformations
3. A 20-week ultrasound to check for structural fetal malformations

Up to 25% of pregnant women do not make an informed decision about prenatal screening: decisions are value-inconsistent and based on insufficient knowledge and deliberation. Counselors have difficulty providing adequate support for pregnant women and their partners, especially for couples with low literacy skills. More than one-third (36%) of all people have limited literacy skills; most of them are lower educated or have a migration background. They experience serious problems in understanding health information and taking an active role in decision-making. The Health Council (2016) therefore pleas for improved decision support by counselors for pregnant women and their partners.

The project aims to improve informed decision-making about prenatal screening by means of two interventions:
1. An eLearning for counselors to improve their self-efficacy and communication with pregnant women with low literacy skills, which should result in improved shared decision making
2. An interactive, tailored video-decision support tool for pregnant women and their partners, to empower them in taking an active role in the communication with the counselor and to make a more informed decision

Who can participate?
The study population consists of pregnant women, and counselors. Pregnant women can participate in the study if they have not yet received the prenatal screening (blood test and 13-week and 20-week ultrasound). Midwives/counselors in primary care that have been educated and contracted by one of the regions for prenatal screening can participate in the study.

What does the study involve?
The interventions consist of an interactive, tailored video-decision support tool for pregnant

women and counselors about prenatal screening and an e-Learning for counselors to improve recognition of and communication about prenatal screening with pregnant women with low literacy skills, and to promote the use of the interactive, tailored video-decision support tool. Midwifery practices, counselors, and pregnant women in the control condition will receive usual care, and counselors will receive access to both interventions after the final post-test measurement is received. Besides usual care, midwifery practices and counselors in the intervention condition will receive a link to both interventions (tailored video-decision tool and e-Learning), and pregnant women will receive a link to the tailored video-decision tool. Counselors and pregnant women can visit the interventions via a unique log-in in their own time, place (e.g., at home or together in the midwifery practice office), as often as they want, and via different devices (computer, tablet, mobile phone). The tailored video-decision support tool and the e-Learning will each take approximately 30 to 60 minutes to complete. The tailored video-decision support tool can be used by counselors and pregnant women individually to prepare for the counseling and together during counseling. Pregnant women can additionally use the video-decision support tool for informed decision-making. Counselors can use e-Learning to prepare for counseling with pregnant women with low literacy skills in order to improve recognition of and communication with pregnant women with low literacy skills. Besides, pregnant women and counselors will be asked to fill in two questionnaires (pre- and post-test).

Counselors and pregnant women in the control condition will receive usual care. For pregnant women, usual care consists of individual counseling with a professional, mostly a midwife, and universal information via a leaflet and a website (www.onderzoekvanmijnongeborenkind.nl). For counselors, it consists of skills training, skills examination every two years, a counseling aid, and e-learning.

What are the possible benefits and risks of participating?
Because the study is limited to the effect of information provision on informed choice and shared decision-making, and does not involve any intervention or interference regarding the screening itself, the nature of the study is as such that we expect no risks of participating.

We are eager to receive remarks about the interventions (negative and positive) to be able to develop a better service for counselors and pregnant women. These can be sent to us by e-mail or phone as is indicated in the information for participants.

Possible benefits of participation are contributing to increased information provision by counselors to pregnant women and their partners who have difficulty in understanding information about prenatal screening, and an informed choice regarding whether or not to undergo prenatal screening for the pregnant women and their partners.

Where is the study run from?
The Netherlands Organization for Health Research and Development (ZonMw) (Netherlands)

When is the study starting and how long is it expected to run for?
March 2020 to May 2025

Who is funding the study?
The Netherlands Organization for Health Research and Development (ZonMw) (Netherlands)

Who is the main contact?
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Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
ZonMw 543002007

Study information

Scientific Title
Interactive, tailored video decision support about prenatal screening for counselors, pregnant women and their partners

Acronym
PNS decision support

Study objectives
Participants in the intervention condition will improve more on the primary and secondary outcomes from pre- to post-test than participants in the control condition.

1. What are needs and requirements of counselors, pregnant women and their partners for the two interventions (an interactive, tailored video-decision support tool for pregnant women and an eLearning for counselors)?
2. What is the effectiveness of the two interventions compared to usual care on:

2.1. Shared decision making and self-efficacy of counselors in prenatal screening counseling?
2.2. Informed decision making regarding prenatal screening, and its determinants (e.g. knowledge, attitude, decisional certainty, intention, screening uptake) among pregnant women?
3. What is the acceptability and use of the two interventions among pregnant women and counselors?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/05/2020, Institutional Review Board TNO (Anna van Buerenplein 1, 2595 DA Den Haag, Netherlands; +31888668464; toetsing_Mensgebondenonderzoek@tno.nl), ref: 2020-035.

Study design
Pre-post test cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Screening

Participant information sheet
See additional files in Dutch

Health condition(s) or problem(s) studied
Informed decision-making regarding prenatal screening

Interventions
The intervention effects will be tested by means of a pre-post test cluster randomized trial. Participating midwifery practices will be randomly assigned to the control or intervention group by means of a randomization program (https://www.randomizer.org/). This program will generate a random number sequence (1 for the control group, 2 for the intervention group) for the participating practices. This random number sequence will be coupled with the list of anonymized participating practices to complete randomised assignment. This will be done by a researcher not involved in the project. Midwives and pregnant women are aware of the group assignment.

The interventions are:
1. An interactive, tailored video-decision support tool for pregnant women and counselors about prenatal screening
2. An e-Learning for counselors to improve recognition of and communication about prenatal screening with pregnant women with low literacy skills, and to promote use of the interactive, tailored video-decision support tool.

Besides usual care, midwifery practices and counselors in the intervention condition will receive a link to both interventions (tailored video-decision tool and e-Learning), and pregnant women will receive a link to the tailored video-decision tool. Counselors and pregnant women can visit the interventions via a unique log-in in their own time, place (e.g. at home or together in the midwifery practice office), as often as they want, and via different devices (computer, tablet, mobile phone). The tailored video-decision support tool and the e-Learning will each take approximately 30 to 60 min to complete. The tailored video-decision support tool can be used by counselors and pregnant women individually to prepare for the counseling and together during counseling. Pregnant women can additionally use the video-decision support tool for informed decision-making. Counselors can use e-Learning to prepare for counseling with pregnant women with low literacy skills in order to improve recognition of and communication with pregnant women with low literacy skills.

The control condition is a waiting list control condition for midwives only. Midwives in the control group will receive access to the interventions after the final post-test measurement is completed in both conditions. Midwifery practices, counselors, and pregnant women in the control condition will receive usual care, and counselors will receive access to both interventions after the final post-test measurement is received.

Intervention Type
Behavioural

Primary outcome measure
1. Informed decision making (knowledge and attitude towards prenatal screening and the screening uptake) measured using uptake of screening (or the intention towards participation, instead of the uptake itself, as the screening for the 20-week ultrasound which takes place after the post-test) at pre-test (between 6 and 9 weeks of pregnancy, before counseling about prenatal screening, and before the intervention condition will receive a link to the tailored video-decision support tool) and post-test (between 15 and 18 weeks of pregnancy, after counseling about prenatal screening, and approximately 5 weeks after the intervention condition has received access to the tailored video-decision support tool)
2. Shared decision making (the pregnant women is collaboratively supported by the counselor to make a decision that meets the pregnant women’s values and circumstances, in which trustworthy information is provided accessibly about the decision options and its consequences, and in which the concerns and needs of pregnant women play a major role in the decision) measured using:
2.1. The Shared Decision Making Questionnaire-Physician Version (SDM-Q-Doc) for counselors at pre-test (at the start, after inclusion of the midwifery practice and counselor), and at post-test (6 weeks after baseline, approximately after 4 to 6 counseling conversations; this is also 5 to 6 weeks after the intervention condition has received access to the e-Learning and tailored video-decision support tool)
2.2. The Shared Decision Making Questionnaire (SDM-Q-9) among pregnant women at the post-test (between 15 and 18 weeks of pregnancy)

Secondary outcome measures
Pregnant women:
1. Determinants of informed decision-making regarding prenatal screening are measured among pregnant individuals:
1.1. Knowledge is measured using items based on Van Agt et al. (2012) at the pre- and post-test
1.2. Attitude is measured using items based on Van Agt et al. (2012) at the pre- and post-test
1.3. Intention is measured using items based on Van Agt et al. (2012) at the pre- and post-test

1.4. Screening uptake is measured using items based on Van den Berg et al. (2006) at the post-test
2. Decisional certainty is measured among pregnant individuals using items based on the certainty subscale of the Decisional Conflict Scales of O'Connor et al., (2002) at the pre- and post-test
3. Shared-decision making is measured among pregnant individuals using items based on the Shared Decision Making Questionnaire (SDM-Q-9), Rodenburg-Vandenbussche et al. (2015), at the post-test
4. Intervention use is measured among pregnant individuals in the intervention group using an item asking whether or not they used the decision aid at the post-test
5. Acceptability of the intervention is measured among pregnant individuals in the intervention group using the following items, based on Pot et al. (2020), at the post-test:
5.1. Their overall satisfaction with the intervention (on a 10-point scale)
5.2. Whether they learned something new of the decision aid (no/don't know/yes)
5.3. Whether the information in the decision aid was understandable (no/don't know/yes)
5.4. Whether the decision aid was easy to use (no/don't know/yes)
5.5. Whether the decision aid was helpful in making an informed decision about prenatal screening (no/don't know/yes)

Counselors:
1. Self-efficacy of counselors regarding prenatal screening counseling with pregnant individuals and their partners, both in general and for those with low literacy skills, is measured using items based on the Shared Decision Making Questionnaire-Physician Version (SDM-Q-Doc), Rodenburg-Vandenbussche et al. (2015), at the pre- and post-test
2. Shared decision-making regarding prenatal screening among couselors is measured using items based on the Shared Decision Making Questionnaire-Physician Version (SDM-Q-Doc), Rodenburg-Vandenbussche et al. (2015), at the pre- and post-test
3. Intervention use measured by asking counselors in the intervention group to what extent they used the e-Learning and decision aid, to what extent they brought the decision aid to the attention of pregnant individuals, and to what extent they used the decision aid during prenatal screening counseling at post-test
4. Acceptability of both interventions (e-Learning and decision aid) is measured among counselors in the interventions group by asking them to indicate their overall satisfaction with both interventions (10-point scale) at post-test. With regard to the e-Learning we ask counselors whether it was user-friendly, usable, understandable, useful, helped them with prenatal screening counseling, made them feel more confident in prenatal screening counseling, and how likely it is that they would recommend the e-Learning to colleagues, advantages of the e-Learning and points for improvement. With regard to the decision aid, we ask counselors whether it was user-friendly, usable, understandable, whether the information was easy to find, whether it helped them with prenatal screening counseling, whether it made them improve their prenatal screening counseling, made them feel more confident in prenatal screening counseling with individuals with low literacy skills, how likely it is that they would recommend the decision aid to colleagues, pregnant individuals, and pregnant individuals with low literacy skills, advantages of the decision aid as well as points for improvement. These items were based on Pot et al. (2020).

Overall study start date
01/03/2020

Completion date
01/05/2025

Eligibility

Key inclusion criteria
1. Pregnant women, who have not yet received the prenatal screening (blood test and 13-week and 20-week ultrasound)
2. Midwives in primary care that have been educated and contracted by one of the regions for prenatal screening

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
1200 pregnant women and 50 midwives from 30 midwifery practices (1 a 2 midwifes per practice, 24 pregnant women per midwife, and 40 pregnant women per practice) including accounting for 25% dropout and 40% oversampling to include pregnant women with low literacy skills

Key exclusion criteria
1. Women who are not pregnant
2. Women who have received the prenatal screening (blood test and 13-week and 20-week ultrasound)
3. Counselors who have not been contracted by one of the regional centers for prenatal screening or who are no midwife

Date of first enrolment
01/10/2022

Date of final enrolment
01/10/2024

Locations

Countries of recruitment
Netherlands

Study participating centre
TNO Child Health
Schipholweg 77-79
Leiden
Netherlands
2316 ZL

Sponsor information

Organisation
Netherlands Organisation for Health Research and Development

Sponsor details
Laan van Nieuw Oost-Indië 334
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Sponsor type
Research organisation

Website
https://www.zonmw.nl/nl/

ROR
https://ror.org/01yaj9a77

Funder(s)

Funder type
Research organisation

Funder Name
ZonMw

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/01/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository. We will facilitate access to data by using the repository of ZENODO (https://zenodo.org).
The following end products we will make available for further research and verification after the project has ended:
(Several versions of) processed data, documentation of the research process, including documentation of all participants, data documentation, syntaxes, raw data. Data descriptions will be published. We will further specify which software and which version thereof was used. All data and end products will be made available in an anonymous form.
Data description will be made available after closing of the project, and data itself will be made available based on restricted access.
Our data will comply with the FAIR guidelines as the data description will be publicly accessible. The data itself will be available under a set of terms of use. These terms may be related to publications, purpose of re-use and handling fee.
During the project, anonymous data will be kept separate from personal data (e-mail address) and linked by means of a unique participant code until six weeks after people filled out the final questionnaire (this gives us time to raffle and provide the vouchers). After this period of time, the personal data will be deleted so that there will not be the possibility to trace back individuals. Thus, personal data will be deleted within six weeks after the last questionnaire of phase 2 is filled in, the separated anonymous data will be kept for 15 years in accordance with ZonMw recommendations.
During the project, access to the personal data is limited to the researchers of the project on a need to know basis.
Consent was obtained from all participants before participation.
The full data management plan has been approved by ZonMw (https://www.zonmw.nl/en/).

IPD sharing plan summary
Stored in publicly available repository, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Information sheet for counselors in Dutch language	28/06/2022	16/08/2022	No	Yes
Participant information sheet	Information sheet for pregnant women in Dutch language	27/06/2022	16/08/2022	No	Yes