Promoting informed decision making about maternal pertussis vaccination among pregnant women

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25018

Source
NTR

Brief title
TBA

Health condition

Pertussis

Sponsors and support

Primary sponsor: N/A
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

Vaccination uptake

Secondary outcome

- Informed decision making
- Decisional conflict
- Determinants of uptake

Study description

Background summary

In 2019, maternal pertussis vaccination (MPV) was implemented in the National Immunization Program of the Netherlands to protect infants in their first months of life. The choice about MPV among pregnant women is largely determined by socio-psychological determinants (79%), but emotions are thought to play a role too. Furthermore, many pregnant women in the Netherlands (32.7%) experience decisional uncertainty about MPV.

To promote informed decision making about MPV, we developed two interventions using intervention mapping.
1. A Centering Pregnancy (CP) intervention about MPV. A training was given to midwives about discussing the MPV in Centering Pregnancy (group prenatal care) sessions.
2. An online tailoring (OT) intervention in the form of a decision aid, providing information, the possibility to test knowledge about MPV, practice a conversation about MPV, and weigh the pros and cons of MPV.

Our research questions are:
1. What is the relative effectiveness of OT and CP compared to the control group and of OT+CP compared to OT on informed decision making, decisional conflict and the determinants of uptake in pregnant women?
2. To what extent do participants use the intervention components (program adherence)?
3. How do participants subjectively evaluate the interventions?

The study population consists of pregnant women in the Netherlands. Recruitment will take place via midwifery clinics. There will be four groups in the trial at clinic level: A group receiving the OT intervention, a group receiving the CP intervention, a group receiving both interventions, and a control condition receiving only the regular information. Because not all clinics in the Netherlands offer CP, clinic allocation to the OT+CP and CP conditions will be non-random. Allocation to OT and control conditions will be at random.

Baseline measurements will be done using questionnaires after enrollment in the study (before or at 16 weeks gestational age). Between 16 and 20 weeks gestational age, the intervention groups will receive the CP and OT interventions. At 20 to 22 weeks gestational age, a follow-up questionnaire will be done including measures of informed decision making, decisional certainty, and acceptance and usability of the interventions. Vaccination status will be derived from Praeventis, the National Immunization Register.

Study objective

A 10% point difference between the experimental groups and control group in MPV uptake is expected.

Study design

- Baseline measurement before or at 16 weeks gestational age
- Follow-up measurement at 20 to 22 weeks gestational age
- Vaccination-status will be derived from Praeventis at the end of the trial, when all participants are no longer pregnant.

Intervention

1. A Centering Pregnancy (CP) intervention in which maternal pertussis vaccination is discussed.
2. An online tailored (OT) decision aid regarding maternal pertussis vaccination.

Contacts

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Eligibility criteria

Inclusion criteria

- pregnant women
- living in the Netherlands
- 16 weeks gestational age or less at the time of inclusion
- a good command of the Dutch language
- having access to the internet on smartphone, tablet or pc.

Exclusion criteria

- more than 16 weeks gestational age at the time of inclusion.

Study design

Design

Study type:	Interventional
Intervention model:	Factorial
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2020
Enrollment:	2496
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	29-07-2020
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	NL8811
Other	TNO Institutional Review Board (IRB) : 2018-050

Study results