Promoting informed decision making about maternal pertussis vaccination among pregnant women

Gepubliceerd: 29-07-2020 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25018

Bron
NTR

Verkorte titel
TBA

Aandoening

Pertussis

Ondersteuning

Primaire sponsor: N/A
Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Vaccination uptake

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

- 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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

Maastricht University/TNO
Charlotte Anraad

0634367059

Wetenschappelijk

Maastricht University/TNO
Charlotte Anraad

0634367059

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Factorieel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2020
Aantal proefpersonen:	2496
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	29-07-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8811
Ander register	TNO Institutional Review Board (IRB) : 2018-050

Resultaten