Web-based education to support mothers in their decision making about the HPV-vaccination of their daughter

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

Samenvatting

ID

NL-OMON29388

Bron
NTR

Aandoening

HPV, cervical cancer (HPV, baarmoederhalskanker)

Ondersteuning

Primaire sponsor: TNO
Maastricht University
Overige ondersteuning: ZonMw
TNO
RIVM

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

HPV-vaccination uptake registered in Praeventis, the National Immunization Register in the Netherlands. Timepoint: 18 months after baseline (or earlier, as soon as the HPV-vaccination uptake of 2015 has been completed in Praeventis)

Toelichting onderzoek

Achtergrond van het onderzoek

In 2009, the Dutch government started a nationwide human papillomavirus (HPV)-vaccination program (i.e., three vaccinations) for 12-year-old girls to prevent cervical cancer. The uptake (58%) is still much lower than expected. Research indicated that mothers played the most important role in the immunization decision of these girls. Socio-cognitive determinants largely (80%) contributed to the explained variance of the HPV-vaccination decision of mothers. Besides, a large proportion of the mothers did not actively process information about the HPV-vaccination and felt ambivalent about their final decision. Because informed decision making will make mothers less vulnerable for counter arguments, mothers need structured support for their decision making. Such an intervention should be interactive and tailored, because mothers indicated their preference for personal interaction over and above the usually applied general approach, and because they expressed differential needs concerning the amount and scope of information. The current project aims to develop and evaluate the effects of a tailored intervention providing mothers of girls-to-be-invited with interactive feedback from a virtual assistant on the possible HPV-vaccination of their daughter.

Computer tailoring has proven to be an effective strategy for health-related behaviors. The effects have been attributed to greater message attention and acceptance. Computer-tailored interventions can reach large groups of people at relatively low costs, and have substantial impact at the population level. This especially accounts for second-generation (i.e., web-based) tailored feedback. So far, tailored interventions to promote vaccine uptake do not exist. The intended feedback will be delivered by a virtual assistant, because this already showed effects in the field of stress management and health-related self-management.

The research questions are:
1) What is the efficacy and effectiveness of an interactive web-based tailored feedback on HVP-vaccination uptake of participants' daughters (primary outcome), on the mothers' informed decision making and related determinants (secondary outcomes) regarding the HPV-vaccination of their daughter?
2) To what extent are mothers exposed to the planned intervention components (program adherence), and what is their subjective evaluation of the feedback?
3) What is the response rate of mothers from the National Immunization Register to the invitation to visit the web-site for receiving interactive support for their decision making about the HPV-vaccination of their daughter?

The effects will be tested by an RCT among two samples of participants: (1) derived from an internet panel for efficacy testing, and (2) derived from Praeventis, the National Immunization Register (i.e., 'naturalistic sample'), for effectiveness testing. The primary outcome will be requested once from Praeventis (after closure of the vaccination round). Secondary outcomes will be measured at baseline and 4 weeks follow-up (before the first vaccination). The rate of response to the invitation to visit the web-based feedback will be assessed among the 'naturalistic sample'. A process evaluation will assess feasibility and program adherence.

The proposed intervention will be developed in three phases:
1) Preparation: Literature review, intervention development, experiments and pretests, and consultation of experts, mothers and girls-to-be-invited.
2) Field experiment: Data collection at baseline and follow-up. After baseline, a random sample drawn from both a 'naturalistic sample' and an internet panel will be exposed to the intervention. HPV-vaccination uptake behavior will be requested from the Praeventis after closure of the HPV-vaccination round.
3) Completion and dissemination: Data-analyses, reporting, and implementation of project results into the next HPV-vaccination round.

Intervention pretests will be conducted with mothers of girls-to-be-invited to maximize intervention exposure and fit. A linkage group of mothers and girls-to-be-invited will be formed to advise on the development of the intervention. Representatives of important linking agents (e.g. Public Health Services) and professionals involved in delivering the HPV-vaccination will participate in an advisory board. RIVM, responsible for the national HPV-vaccination, is full member and co-financier of the project team.

Doel van het onderzoek

A 10% point difference between the experimental and control group in HPV-vaccination uptake is expected. Assuming 58% of participants daughters in the control group receive two HPV-injections and a 10% point difference between the experimental and control group, we expect 68% of participants daughters to receive two HPV-injections in the experimental group.

Onderzoeksopzet

At baseline, mothers in the experimental and control group will receive an invitation to fill out a survey with questions about the HPV-vaccination. Two weeks after baseline, mothers in the experimental group will receive an invitation to visit the website for interactive, tailored support in their decision about the HPV-vaccination. Participants' daughters in the experimental and control groups will then also receive an information package (invitation letter and brochure) for the HPV-vaccination from their Municipal Health Service. Four weeks after baseline, mothers in the experimental and control groups will receive an invitation to fill out a second questionnaire about the HPV-vaccination. Mothers in the experimental group will also receive questions about their opinion of the website. We will request the HPV-vaccination uptake of participants' daughters via Praeventis after the uptake has been completed (at maximum, 18 months after baseline).

Between 2 weeks and 2 months after the second survey, participants' daughters will receive the actual call for the first HPV-injection from their Municipal Health Services, followed by the call for the second injection six months later.

Onderzoeksproduct en/of interventie

The intervention consists of interactive, web-based, tailored education about the HPV-vaccination.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Mothers/female caregivers of girls born in 2002.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- No mother/female caregiver of girls born in 2002

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Factorieel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	05-01-2015
Aantal proefpersonen:	2400
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	23-12-2014
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	NL4795
NTR-old	NTR4935
Ander register	: ZonMw200330007

Resultaten