

PROMISE

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

Samenvatting

ID

NL-OMON26983

Bron

Nationaal Trial Register

Verkorte titel

PROMISE

Aandoening

Roken

Ondersteuning

Primaire sponsor: Trimbos-instituut - Netherlands Institute of Mental Health and Addiction

Overige ondersteuning: Fonds NutsOhra and Ministry of Health, Welfare and Sport

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary objective of PROMISE is that midwives / gynaecologists discuss stop-smoking strategies with pregnant women more often.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Smoking during pregnancy is in particular prevalent among women with a lower socioeconomic status (SES). Because of the health consequences for the (unborn) child, it is important to provide suitable stop-smoking counselling to these women. In the Netherlands, primary care midwives are required to implement the 'V-MIS' stop-smoking counselling in their daily practice. However, research showed that this counselling program is often not optimally implemented and is not adapted to new (scientific) insights. In addition, the V-MIS does not continue after pregnancy and hence does not extensively address (the high) relapse after childbirth.

Objective:

The main goal of PROMISE is to implement a smoking cessation counselling protocol for natal care professionals that helps them provide stop-smoking counselling that is suited to their clients. These clients are women who are pregnant or who recently gave birth. Most of these women have a low socioeconomic status. With PROMISE, it is aimed that the natal care professionals become more enthusiastic for helping these women quit smoking and for discussing strategies for smoking cessation more often (primary outcome measure). This might result in a more effective delivery of stop-smoking counselling. This more effective delivery might lead to higher smoking cessation rates among pregnant women (a secondary objective). This research project evaluates this implementation process.

Doel van het onderzoek

It is expected that PROMISE leads to more enthusiastic natal care professionals for helping pregnant women quit smoking and for discussing strategies for smoking cessation more often and that this results in a more effective delivery of stop-smoking counselling.

Onderzoeksopzet

Midwives and gynaecologists will be asked to fill out six brief online questionnaires: one at baseline, four after each series of trainings (i.e. at each interval of the stepped wedge approach) and one two months after the last training.

Professionals in both maternity care and youth health care will be asked to fill out two

questionnaires: one before they start with PROMISE and one after they supervised their last participating clients. For maternity care professionals, this will be in the summer of 2018 and for youth health care professionals this will be in December 2018.

The pregnant women fill out three questionnaires:

- Baseline: shortly after their intake at the midwife or gynaecologist;
- 1st follow-up: shortly after childbirth
- 2nd follow-up: six months after childbirth.

Onderzoeksproduct en/of interventie

PROMISE is an innovation on the existing stop-smoking counselling for pregnant women, the 'V-MIS'. PROMISE is adapted to the needs of smoking pregnant women (in particular those of low socioeconomic status) and professionals (e.g., midwives). Before giving birth, pregnant women will receive smoking cessation counselling from their midwives or gynaecologist. The professional assesses and, if needed, enhances the motivation to quit. A CO-monitor (comparable with an alcohol breath test and already used by some midwives) may be used (voluntary) to provide insight in the smoking status (the outcome of these tests will not be known or used by the research team). The pregnant women receive a 'workbook' which contains all information the professionals have told and in which they can write down their quit

date, potential barriers, action plans etc. In addition, a professional can refer the pregnant women to more intensive coaching (which is a usual procedure within V-MIS). After giving birth, women who quit smoking will receive counselling from professionals in maternity care and youth health care in order to prevent relapse. As multiple professionals are involved during pregnancy and after giving birth, PROMISE also stimulates a clear transfer of women's smoking status between midwives / gynaecologists and maternity care / youth health care.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a women must meet all of the following criteria:

- Being at least 18 years;
- Being female;
- Being pregnant (a maximum of three months);
- Currently smoking or recently quit smoking within the six months before pregnancy;
- Being registered in a practice or hospital that takes part in PROMISE.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

There are no specific exclusion criteria for this study. The midwife makes an initial assessment whether a women is capable of and willing to participate in PROMISE (which consists of filling out brief questionnaires).

Onderzoekopzet

Opzet

Type:

Interventie onderzoek

Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2017
Aantal proefpersonen:	250
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	20-12-2016
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	NL6158
NTR-old	NTR6305
Ander register	METC ErasmusMC Rotterdam : MEC-2016-605

Resultaten

Samenvatting resultaten

We intend to publish in national and international peer reviewed journals