SAFER pregnancy studie

No registrations found.

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

Summary

ID

NL-OMON29169

Source
NTR

Brief title
SAFER

Health condition

Smoking and alcohol use during pregnancy

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: Fonds NutsOhra

Intervention

Outcome measures

Primary outcome

Biochemically validated cessation of smoking and/or alcohol use at:
- Week 34 to 38 of gestation (if they were pregnant at inclusion or became pregnant during the period with sessions); or
- The end of the project period if <34 weeks pregnant at the time; or
- On the last measurement after six group sessions in those who did not become pregnant during the period with sessions.

Secondary outcome

- Barriers and facilitators of implementation (process measures)
- Perceived efficiency and appreciation of the eHealth platform, the group sessions, and incentives
- Costs
- Pregnancy outcomes
- Identity changes

Study description

Background summary

Rationale
Smoking during pregnancy is associated with many adverse perinatal outcomes such as preterm birth, growth restriction, and perinatal death. Maternal alcohol use is also associated with adverse health outcomes of the child such as Fetal Alcohol Spectrum Disorder (FASD). Despite these major risks, 9% of pregnant women in the Netherlands smoke throughout their pregnancy and 20% uses alcohol during pregnancy. Particularly smoking is overrepresented among women with low socioeconomic status (SES).
Shortly before and during pregnancy, women and their partners are more receptive for lifestyle changes because of the extra responsibility for the health of their (unborn) child. Recent literature suggests that incentives can be an effective intervention to realize behavioural change. In addition, increasing knowledge and health literacy via group sessions and eHealth support are promising interventions for reducing cigarette and alcohol use among women who are pregnant or want to become pregnant. In this study we will investigate a multicomponent intervention, consisting of incentives, group sessions and use of an eHealth platform to reduce smoking and alcohol use before or during pregnancy: the SAFER pregnancy intervention.

Objective
The main objective of our research is to study the effectiveness of the SAFER pregnancy intervention in reducing risk behaviour (i.e. smoking and alcohol use) in pregnant women and women with the wish to conceive. The secondary objectives focus on the assessment of barriers and facilitators of implementing and complying with this intervention.

Study design
A pre-post design (uncontrolled before-after study) will be used in this intervention study.

Study population
The study will take place in the municipality of Zoetermeer. Pregnant women or women with a wish to conceive who smoke or drink alcohol will be informed about the study by their midwife, obstetrician, primary care physician or via promotion material. In total, 114 women will be included.

Intervention
In addition to ‘care as usual’ (i.e. referral by their health care professional to cessation services through existing care pathways), all participants will receive the SAFER pregnancy intervention. The SAFER pregnancy intervention consists of group sessions, active direction towards use of an existing eHealth platform and provision of incentives upon validated cessation of smoking and/or alcohol use.

Main study parameters
The primary outcome is biochemically validated cessation of smoking and/or alcohol use at:
- Week 34 to 38 of gestation (if participants were pregnant at inclusion or became pregnant during the period with sessions);
- The end of the project period if <34 weeks pregnant at the time;
- On the last measurement after six group sessions in those who were included before pregnancy and did not become pregnant during the period with sessions.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness
At inclusion and at the primary endpoint, smoking behaviour will be biochemically verified using urinary cotinine and a hand-held exhaled Carbon Monoxide (CO) monitor (Micro+ Smokerlyzer). During the study period, smoking behaviour will only be assessed with the CO monitor. Alcohol use will be assessed with a validated blood test (PhosphatidylEthanol; PEth). At inclusion, urinary cotinine, exhaled breath CO and serum PEth are quantified depending on whether participants report smoking and/or drinking. Participants will be asked to fill in a number of questionnaires during the study period. In addition, participants are invited to join up to six group sessions each lasting approximately two hours. The main potential benefit of participation is the extra support to quit smoking and alcohol use before and during pregnancy, which can directly benefit their health and the health of their (unborn) child. In addition, incentives representing monetary value will be issued as part of the intervention upon biochemically validated risk behaviour cessation.

Study objective

The combination of group sessions, an online platform and incentives will help women to stop smoking and/or drinking alcohol before and during pregnancy

Study design

- Shown at primary outcome
- Monthly before each group session

Intervention

Group sessions, an online platform and incentives

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, women must meet all of the following criteria:
- Pregnant or having a wish to become pregnant within six months;
- Smoking at least 1 cigarette a day and/or drinking three units of alcohol a week;
- Resident of the municipality of Zoetermeer or Benthuizen.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study if:
- less than 18 years of age;
- more than 20 weeks pregnant;
- inadequate mastery of the Dutch language;
- refuses the urinary test and/or breath test (when reporting smoking) or blood test (when reporting drinking alcohol);
- the urinary cotinine level is below 50 ug/L, the carbon monoxide (CO) level is less than 7 ppm (when reporting smoking) or the PEth test (when reporting drinking alcohol) is below 7 ug/L at inclusion;
- use of hard drugs.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2019
Enrollment:	66
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	04-02-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48044
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7493
CCMO	NL67428.078.18
OMON	NL-OMON48044

Study results