Smoke and Alcohol Free with EHealth and Rewards (SAFER) pregnancy study

Published: 04-01-2019
Last updated: 19-08-2024

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...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON48044

Source
ToetsingOnline

Brief title
SAFER pregnancy study

Condition

- Other condition
- Pregnancy, labour, delivery and postpartum conditions

Synonym
Smoking and alcohol use during pregnancy

Health condition

Roken en alcoholgebruik tijdens de zwangerschap

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Fonds NUTS-OHRA,lokale ondernemers

Intervention

Keyword: Cessation of smoking and alcohol use, Incentives, Pregnancy

Outcome measures

Primary outcome

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.

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 (identity factors associated with smoking status and/or drinking status)

Study description

Background summary

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.

Study 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.

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.

Study burden and risks

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.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 40
Rotterdam 3015 GD
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 40
Rotterdam 3015 GD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion 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;

Exclusion criteria

- 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

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-04-2019
Enrollment:	66
Type:	Actual

Ethics review

Approved WMO Date:	04-01-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	04-09-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 29169
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL67428.078.18
Other	NL7493