Development of brief intervention for prenatal alcohol use

Published: 31-03-2010
Last updated: 06-05-2024

The goal of this study is to develop and test two tailored intervention programs to stimulate pregnant women to stop drinking alcohol. These intervention programs are a health counseling and a computer tailored intervention. The efficacy of the...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	Interventional

Summary

ID

NL-OMON35376

Source
ToetsingOnline

Brief title
Prevention of prenatal alcohol use

Condition

- Pregnancy, labour, delivery and postpartum conditions
- Lifestyle issues

Synonym
Alcohol use, prenatal alcohol exposure

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Alcohol consumption, Computer Tailoring, Health counseling, Pregnancy

Outcome measures

Primary outcome

The primary outcome parameters are: 1. The percentage of women that has stopped drinking alcohol after 3 months and 6 months on the follow-up; 2. The percentage of women that lowered the average alcohol intake per week; 3. The number of glasses of alcohol used per occasion; 4. The average alcohol consumption during pregnancy.

Secondary outcome

The secondary study parameters are the differences for women with low and high SES and for women in their first pregnancy or women with one or more children as well as the effect of the intervention on the partner.

Study description

Background summary

Alcohol consumption during pregnancy is a leading preventable cause of birth defects and developmental disabilities. Harmful effects are found with individuals whose mothers drink heavily during pregnancy as well as with individuals whose mothers are light-to-moderate drinkers. Of the 200.000 women in the Netherlands who become pregnant every year, approximately 35% to 50% continue to drink alcohol throughout their pregnancy. Thus far, little attention has been paid to researching potential preventative strategies designed to reduce prenatal alcohol consumption. The hypothesis of this research is that interventions from the experimental group will lead to 20% of the women refraining from alcohol use.

Study objective

The goal of this study is to develop and test two tailored intervention

programs to stimulate pregnant women to stop drinking alcohol. These intervention programs are a health counseling and a computer tailored intervention. The efficacy of the interventions is tested by means of a randomized control trial with three conditions.

Study design

A randomized control trial with three conditions with a baseline assessment and 2 follow-ups, 3 months and 6 months after baseline measurement. Subjects will be randomly assigned to one of three conditions.

Intervention

The subjects will be randomly assigned to the following conditions:
1: Control condition, consisting of filling out a baseline questionnaire and two follow-up questionnaires.
2: A Health Counseling intervention, that consists of a developed protocol for midwives combined with the developed materials for target groups. This condition implies pregnant women filling out a baseline questionnaire and two follow-up questionnaires.
3: Computer tailored intervention. This condition implies filling out a baseline questionnaire and two follow-up questionnaires, and receiving personalized feedback through internet.

Study burden and risks

The burden for the subjects is to fill out three questionnaires. The Health Counseling condition also contains counseling during the consult of the midwife. It is expected that this does not take extra time than a similar consult without the alcohol counseling. The Computer Tailored intervention receives personal feedback through internet after filling out the three questionnaires. Reading this feedback will cost extra time. The interventions do not involve any risks.

Contacts

Public
Universiteit Maastricht

Postbus 616
6200 MD Maastricht
NL
Scientific
Universiteit Maastricht

Postbus 616
6200 MD Maastricht
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Female
Pregnant
Drink alcohol
18 years or older
client of a midwife practice

Exclusion criteria

no client of midwife practice
not drinking alcohol
not pregnant
younger than 18
insufficient understanding of Dutch language
illiterate

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-02-2011
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO

Date:	31-03-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL28561.068.09