Prevention of prenatal alcohol use.

Gepubliceerd: 20-10-2009 Laatst bijgewerkt: 18-08-2022

We hypothesize that offering Health Counseling combined with Motivational Interviewing by midwives or Computer Tailoring to pregnant women who drink alcohol during their pregnancy, results in: 1. A higher percentage of women who don’t drink...

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

Samenvatting

ID

NL-OMON25014

Bron
NTR

Aandoening

Alcohol use of pregnant women (alcohol consumption, pregnancy, health counseling, computer tailoring)
Alcohol gebruik van zwangere vrouwen (alcohol consumptie, zwangerschap, gezondheidsadvisering, advies op maat)

Ondersteuning

Primaire sponsor: STAP
Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary objective is to test the effect of health counseling (first experimental condition) and computer tailoring (second experimental condition) compared to usual care (control condition) on the main outcome parameters (percentage of women that has stopped drinking alcohol after 3 months and 6 months on the follow-up; percentage of women that lowered the

average alcohol intake per week; number of glasses of alcohol used per occasion; average alcohol consumption during pregnancy).

Toelichting onderzoek

Achtergrond van het onderzoek

Alcohol consumption during pregnancy is a leading preventable cause of birth defects and developmental disabilities. Exposure to maternal drinking has been associated with difficulties in thinking, learning and memory, as well as behavioral problems, physical problems and alcohol disorders. Furthermore, prenatal alcohol consumption increases the risk of stillbirth, spontaneous abortion and premature birth. Harmful effects are found with individuals whose mothers drink heavily during pregnancy as well as with individuals whose mothers are light-to-moderate drinkers. An average consumption of less than one standard drink per day may increase the risk of adverse effects. The risk and the severity of the effects are dose related. When consumption exceeds 6 drinks, there is an increased risk of major malformations and specific facial characteristics of fetal alcohol syndrome (FAS). Despite clinical research on the hazards of alcohol use during pregnancy, there has been comparatively little attention paid to researching potential preventative strategies designed to reduce prenatal alcohol consumption. In the Netherlands an estimated 80% of all women of child-bearing age drink alcoholic beverages. Of the 200.000 women who become pregnant every year, approximately 35% to 50% continue to drink alcohol throughout their pregnancy. The pregnant woman’s midwife and her partner can play an influential role on her alcohol consumption. The aim of this project is to develop two tailored brief intervention programs for pregnant women, which can be implemented in prenatal care and to test the effectiveness of the interventions using a randomized control trial with three conditions. The aim of both interventions is to stimulate pregnant women to stop drinking, in accordance with the advice stated by the Health Council of the Netherlands in 2005. The first intervention is based on the Health Counseling Model combined with motivational Interviewing and the second is a Computer Tailored intervention. Effects will be studied for women with high and low social economic status.

Doel van het onderzoek

We hypothesize that offering Health Counseling combined with Motivational Interviewing by midwives or Computer Tailoring to pregnant women who drink alcohol during their pregnancy, results in:

1. A higher percentage of women who don’t drink alcohol after 3 months and 6 months on the follow-up;

2. A higher percentage of women that lowered the average alcohol intake per week;

3. A smaller number of glasses of alcohol used per occasion;

4. A lower average alcohol consumption during pregnancy compared to usual care during pregnancy.

Onderzoeksopzet

In January 2011 the baseline questionnaire will be filled out by all respondents. At the most one week and six weeks later, respondents in the two experimental conditions receive their first and second interventions. In May 2011 the first follow-up questionnaire will be filled out by all respondents. At the most one week later, the respondents in the two experimental conditons receive their third intervention. In August 2011 the second follow-up questionnaire will be filled out by all respondents.

Onderzoeksproduct en/of interventie

Respondents in the health counseling group (first experimental condition) will receive three counseling sessions on alcohol from their midwives.
Respondents in the computer tailoring group (second experimental condition) will receive three computer tailored feedback messages.
Respondents in the group that will receive usual care (control group) will not receive any additional intervention.

All respondents are asked to fill in a baseline questionnaire and two follow-ups, 3 months and 6 months after baseline measurements.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Female;

2. Pregnant;

3. Drink alcohol;

4. 18 years or older;

5. Client of a midwife practice.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. No client of midwife practice;

2. Not drinking alcohol;

3. Not pregnant;

4. Younger than 18;

5. Insufficient understanding of Dutch language;

6. Illiterate.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd

Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2011
Aantal proefpersonen:	300
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	20-10-2009
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	NL1941
NTR-old	NTR2058
Ander register	METC : 28561
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A