

# Erasmus MC Care Innovation for a healthy pregnancy. Efficacy of "Smarter Pregnant", an interactive food and lifestyle program on the mobile phone.

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Investigate whether the "Smarter Pregnant" intervention in comparison with four screenings with food- and lifestyle advising leads to an improvement in unhealthy food habits (vegetables, fruit, folic acid use) after 24 weeks intervention,...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON43778

### Source

ToetsingOnline

### Brief title

Smarter Pregnant II - RCT

### Condition

- Other condition
- Sexual function and fertility disorders

### Synonym

period before fertilisation and pregnancy, Preconception period and gestation

### Health condition

Preconceptieperiode en zwangerschap

## Research involving

Human

## Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Chance to become pregnant, Food Risk Score, Interactive food and lifestyle program, Preconception period and pregnancy

## Outcome measures

### Primary outcome

Percentage of reduction of unhealthy food habits after 24 weeks as measured with the Food Risk Score of future parents (short term).

### Secondary outcome

- Percentage of reduction in smoking habits after 24 weeks of future parents.
- Percentage higher chance to become pregnant.
- Percentage of reduction of Big3 complications.
- Percentage of reduction of medical costs as a result of fertility treatments and perinatal and neonatal care of newborns.

## Study description

### Background summary

In The Netherlands, especially in big cities such as Rotterdam, not only the mortality rates of newborns are higher than in the rest of Europe, but also Big3 complications (foetal growth retardation, premature birth, and congenital disorders) occur more frequent. Besides this, reduced fertility is an increasing problem. In more than 80% unhealthy food- and lifestyle habits of future parents and subfertile couples play a part.

## Study objective

Investigate whether the "Smarter Pregnant" intervention in comparison with four screenings with food- and lifestyle advising leads to an improvement in unhealthy food habits (vegetables, fruit, folic acid use) after 24 weeks intervention, measured as a decrease in the Food Risk Score of women and men with a wish to become pregnant.

## Study design

This randomized clinical trial will be carried out in 2 independent and different study populations.

## Intervention

Study Group: 6 screenings of food-and lifestyle habits with \*Smarter Pregnant\* and personal coaching during a period of 6 months.

Control group: 4 screenings of food- and lifestyle habits and information provision with \*Smarter Pregnant\*.

## Study burden and risks

Advantage of participation is that both groups will be well informed about the importance of food- and lifestyle habits during the preconception period en during pregnancy. A pregnancy without complications and a healthy child can however never be guaranteed. There are no risks associated with participation. The study is carried out in these study populations as \*Smarter Pregnant\* is developed specifically for these target groups.

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- 1) 18 years or older.
- 2) Desire for a child or <12 weeks pregnant.
- 3) Having a smartphone with access to internet.
- 4) Knowledge of the Dutch language.
- 5) Heterosexual relationship.
- 6) Written informed consent.

### Exclusion criteria

- 1) No written informed consent of the female partner. If the male partner does not want to participate, the female partner can still participate.
- 2) Age female partner > 45 years.
- 3) Women and partner who undergo IVF/ICSI treatment and are living in the Rotterdam area will be excluded for Studypopulation I and will be invited for Studypopulation II.
- 4) Women advised by their treating gynaecologist or fertility physician to follow a diet because of their IVF/ICSI treatment.
- 5) Persons following a specific diet, such as vegetarians and vegans.
- 6) Persons with an alcohol or drug addiction.

## Study design

### Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

## Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	14-05-2014
Enrollment:	3000
Type:	Actual

## Ethics review

Approved WMO	
Date:	19-07-2013
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO	
Date:	18-07-2014
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO	
Date:	31-03-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO	
Date:	21-03-2016
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

No registrations found.

### In other registers

Register	ID
CCMO	NL40414.078.12