Optimizing lifestyle behaviors in women at high risk for pregnancy complications and their partners before and in early pregnancy by combining personalized eHealth & Face-to-face coUnSEling.

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To study if a blended personalized periconception lifestyle care approach aimed at women with a high risk for pregnancy complications who are contemplating pregnancy or already pregnant (*12 weeks) can significantly reduce Lifestyle Risk Score.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON49808

Source
ToetsingOnline

Brief title
eFUSE study

Condition

- Other condition
- Sexual function and fertility disorders

Synonym
fertilisation period and pregnancy, Periconceptional period and gestation

Health condition

Periconceptionele periode 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: High risk pregnancy complications, Lifestyle Risk Score, Mental health, Personalized periconception lifestyle care

Outcome measures

Primary outcome

Percentage of women reaching recommended levels of 5 lifestyle behaviors;

translated in to a Lifestyle Risk Score, via online questionnaires in week 0,

6, 12 and 24.

Secondary outcome

Several questionnaires, in particular the most relevant ICHOM measurements:

- Lifestyle-related behavioral determinants (such as attitude, action control,

self-efficacy, intention and motivation) using the Behavioral

Determinant Questionnaire, measured at week 0, 6, 18 and 24.

- Patient satisfaction measured using Six Simple Questions (SSQ) at week 12 and

24.

- Provider feasibility using a 5-point Likert scale 6 and 12 months after the

start of this study.

- Health status measured using EQ-5D questionnaire at week 12, 18 and 24.

- Health-related costs: intramural medical costs (hospital registration),

iMCQ52 (extramural medical costs), iPCQ53 (productivity loss).

- Maternal pregnancy and neonatal complications. Retrieved from medical files.

Study description

Background summary

Overweightness (Body Mass Index (BMI)*25), and specifically obesity (BMI*30) is a pressing public health issue. One of the groups most heavily affected by this global epidemic are women of reproductive age. Maternal obesity has a significant impact on fertility, maternal pregnancy complications, such as hypertensive disorders and gestational diabetes, as well as on neonatal outcomes, which even can lead to transgenerational health problems. Moreover, these outcomes can as well be influenced by an impaired mental health. All these consequences increase health care utilization and expenditures. Improved adherence to a healthy lifestyle can significantly decrease overweightness and obesity prevalence for this group. Therefore, optimizing lifestyle, including mental health, is imperative. An intervention targeting patient couples, starting periconception care early and using personalized medicine is therefore warranted.

Study objective

To study if a blended personalized periconception lifestyle care approach aimed at women with a high risk for pregnancy complications who are contemplating pregnancy or already pregnant (*12 weeks) can significantly reduce Lifestyle Risk Score.

Study design

A randomized controlled trial in an academic center.

Intervention

Blended personalized periconception lifestyle approach with a mental health component.

Study burden and risks

No burden or risks are associated with participation. Both the intervention group and control group (usual care) will receive the evidence-based lifestyle program Smarter Pregnancy for free.

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

Patient-couples will be screened for eligibility by their treating physician if:
- woman is in reproductive age (18-45 year)
- they are contemplating pregnancy or are pregnant (*12 weeks gestation)
- they visit the outpatient antenatal clinic in this academic care hospital
- the woman is overweight (BMI *25)

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- multiple pregnancy

- insufficient knowledge of Dutch language
- fetal anomalies
- inability to provide informed consent
Women can be included as single participant if the partner does not participate.

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:	Will not start
Enrollment:	626
Type:	Anticipated

Ethics review

Approved WMO

Date:	11-06-2020
Application type:	First submission
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	NL72582.078.20