Optimizing periconceptional lifestyle of overweight women using a blended personalized care intervention combining eHealth and Face-to-face coUnSEling: The Randomized Controlled eFUSE Trial

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21869

Source
NTR

Brief title
eFUSE

Health condition

overweight

Sponsors and support

Primary sponsor: Erasmus MC, University Medical Center Rotterdam
Source(s) of monetary or material Support: Erasmuc MC, Obstetrics and Gynaecology

Intervention

Outcome measures

Primary outcome

Lifestyle Risk Score (between baseline and 24 weeks) between the randomization arms (difference in differences)

Secondary outcome

Measurements defined as most relevant by International Consortium for Health Outcomes Measurement (ICHOM), including behavioral determinants, patient satisfaction, provider feasibility and maternal pregnancy and neonatal complications

Study description

Background summary

The eFUSE study will evaluate an innovative blended lifestyle care intervention combined with psychological therapy to improve periconceptional lifestyle behaviors in overweight women using an RCT. The intervention group will be provided with a blended care approach, including three face-to-face counseling sessions, and access to the periconception eHealth lifestyle care platform ‘Smarter Pregnancy’ and mobile health application Headspace. In the face-to-face counseling sessions motivational interviewing will be used and components of cognitive behavioral therapy, acceptance and commitment therapy and mindfulness will be practiced. The control group will receive standard care, which comprises of one face-to-face counseling session and access to the periconception eHealth lifestyle care platform ‘Smarter Pregnancy’.
Especially the addition of components of several psychological therapies to a proven effective blended care approach is new and might result in a powerful measure to improve parental lifestyle behaviors before and during pregnancy. We hypothesize that the two additional face-to-face counseling sessions, in which several psychological techniques will be practiced, will support the participating patient-couples towards a significant and more sustainable lifestyle change. Moreover, we expect that the effects of the face-to-face sessions and eHealth program reinforce each other. By choosing a proximal primary outcome measure, namely the Lifestyle Risk Score, we aim to assess the effects directly influenced by the intervention, so that the results can be clearly deduced from the content of our approach.

Study objective

We hypothesize that two additional face-to-face counseling sessions, in which several psychological techniques will be practiced, will support the participating patient-couples towards a significant and more sustainable lifestyle change compared with the control group.

Study design

6 weeks, 12 weeks, 18 weeks, 24 weeks after start of intervention/control condition

Intervention

Blended personalized periconception lifestyle approach, consisting of:
1. A periconception eHealth platform, providing personalized risk assessment and nutrition and lifestyle counselling via the evidence-based eHealth interventions ‘Preparing for Pregnancy’ (www.zwangerwijzer.nl) and ‘Smarter Pregnancy’ (www.slimmerzwanger.nl).
2. Three face-to-face lifestyle counselling sessions, provided by trained eFUSE counsellors, as previously practiced in the (proven effective) outpatient antenatal clinic ‘Achieving a Healthy Pregnancy’.In the intervention group, the blended care approach will be offered next to care as usual in accordance with the national guidelines. All elements offered in the blended care approach are personalized tot the individual patient-couple, based on the results of the risk assessment and lifestyle questionnaires filled out on the eHealth platform.

Contacts

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Eligibility criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2021
Enrollment:	626
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	23-02-2021
Application type:	First submission

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
NTR-new	NL9264
Other	METC Erasmus MC : MEC-2020-0113

Study results