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

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

Samenvatting

ID

NL-OMON21869

Bron
NTR

Verkorte titel
eFUSE

Aandoening

overweight

Ondersteuning

Primaire sponsor: Erasmus MC, University Medical Center Rotterdam
Overige ondersteuning: Erasmuc MC, Obstetrics and Gynaecology

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2021
Aantal proefpersonen:	626
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	23-02-2021
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	NL9264
Ander register	METC Erasmus MC : MEC-2020-0113

Resultaten