Efficiency of a blended care version of an effective diabetes diet

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We hypothesize that a blended care (combination of face-to-face treatment with e-health solutions) version of a very low-calorie weight loss intervention, is as (cost)effective as the usual care (face-to-face only) very low-calorie weight loss...

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

Samenvatting

ID

NL-OMON29277

Bron
NTR

Verkorte titel
E-DIET

Aandoening

Type 2 diabetes mellitus

Ondersteuning

Primaire sponsor: Erasmus Medical Center
Overige ondersteuning: Internal funding by The Erasmus MC Efficiency Research Fund. Cambridge Meal Plan Benelux B.V. will kindly provide the meal replacements necessary in the first phase of the diet intervention, in both control and intervention group.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main study endpoint is the difference in weight (kg) between the control and intervention group after 1 year, plus the difference between the total costs of the treatment in the control and intervention groups in euro’s.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Despite preventive measures, the number of people with type 2 diabetes and obesity is increasing. Obesity increases morbidity and mortality in people with type 2 diabetes, therefore weight loss is a cornerstone of treatment. We previously developed a diet program (POWER diet) that effectively reduced weight in people with type 2 diabetes in the long term. In order to help more people, we aim to develop a blended care version of our diet, in which face-to-face contact is combined with e-health solutions.
Objective: The primary aim of the current study is to determine the efficiency of a blended care version of the POWER diet (‘Blended POWER’): whether it is equally effective in reducing weight while lower in costs, compared to the ‘usual care’ POWER diet. The secondary aims are to investigate the effectiveness of Blended POWER with regard to cardiovascular risk factors and quality of life, and to evaluate patient satisfaction, compliance, and to study whether there is a difference in effectivity and patient satisfaction when categorizing the group in males and females and in participants of Dutch or other origin.
Study design: Randomised, controlled trial with non-inferiority design.
Study population: Adults with type 2 diabetes, aged 18-75, with BMI>30 kg/m2.
Intervention: The control group will receive the standard of care POWER diet intervention program during 1 year, the intervention group will receive the Blended POWER intervention. In the Blended POWER intervention, the face-to-face contact will be partly replaced by an e-health application.
Main study parameters/endpoints: The main study endpoint is the difference in weight (kg) between the control and intervention group after 1 year, plus the difference between the total costs of the treatment in the control and intervention groups in euro’s.

Doel van het onderzoek

We hypothesize that a blended care (combination of face-to-face treatment with e-health solutions) version of a very low-calorie weight loss intervention, is as (cost)effective as the usual care (face-to-face only) very low-calorie weight loss intervention in people with type 2 diabetes and overweight.

Onderzoeksopzet

Baseline - 2months - 4 months - 1 year

Onderzoeksproduct en/of interventie

The control group will receive the usual care diet intervention program during 1 year, the intervention group will receive the blended care diet intervention where the face-to-face contact will be partly replaced by an e-health application.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Type 2 Diabetes
• Age 18-75 years
• Obesity (BMI>30 kg/m2)
• Smartphone with Android or iOS

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Pregnancy or lactation during the trial
• Severe psychiatric problems, use of antipsychotic drugs
• Significant cardiac arrhythmias; unstable angina; decompensated congestive heart failure; carcinomas; major organ system failure; untreated hypothyroidism; end-stage renal disease;
• Myocardial infarction, cerebrovascular accident or major surgery during the previous 3 months.

• Corticosteroid induced diabetes (in patients still using corticosteroids)

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2021
Aantal proefpersonen:	200
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:	26-06-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 56623
Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7832
CCMO	NL69176.078.19
OMON	NL-OMON56623

Resultaten