Efficiency of a blended care version of an effective diabetes diet

No registrations found.

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

Summary

ID

NL-OMON29277

Source
NTR

Brief title
E-DIET

Health condition

Type 2 diabetes mellitus

Sponsors and support

Primary sponsor: Erasmus Medical Center
Source(s) of monetary or material Support: 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.

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

- Quality of life, measured with the EuroQol vragenlijst EQ-5L
- Cardiovascular risk factors: Blood pressure (mmHg), total cholesterol (mmol/l), LDL cholesterol (mmol/l), HDL cholesterol (mmol/l), triglycerides (mmol/l), HbA1c (mmol/mol), fasting bloodglucose (mmol/l), all measured via routine clinical care/lab
- Food intake (dietary history)
- Body composition: waist circumference (cm), and fat mass and lean body mass measurement via Bio-electrical Impedance Analysis (bodystat quadscan 4000, Euromedix, Leuven, Belgium)
- Resting Energy Expenditure (Via Quark RMR, Cosmed Benelux B.V., Nieuwegein, The Netherlands)
- Patient satisfaction, measured via the Diabetes Treatment Satisfaction Questionnaire (DTSQ)
- Attitudes towards using e-health (general and specific for this diet app) to access health information, measured via the e-Health Impact Questionnaire (EHIQ)
- Depression and anxiety via the Hospital Anxiety and Depression Scale (HADS)
- Compliance and attrition (number of participants that drop-out and log-on information).

Study description

Background summary

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.

Study objective

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.

Study design

Baseline - 2months - 4 months - 1 year

Intervention

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.

Contacts

Public
Erasmus MC
Kirsten Berk

0617512121
Scientific
Erasmus MC
Kirsten Berk

0617512121

Eligibility criteria

Inclusion criteria

• Type 2 Diabetes
• Age 18-75 years
• Obesity (BMI>30 kg/m2)

• Smartphone with Android or iOS

Exclusion criteria

• 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)

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2021
Enrollment:	200
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	26-06-2019

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 56623
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results