Early Time Restricted Eating with Caloric Restriction as Weight Loss Strategy Based on the Mediterranean Diet for Adults with Type 2-Diabetes and/or overweight: a Randomized Controlled Trial.

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Primary Objective: 1. What is the difference in effectiveness of Early Time-restricted Eating (eTRE) in glycaemic regulation when compared to isocaloric continues caloric restriction (CCR) after one year in overweight adults with type 2 diabetes?...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON54132

Source
ToetsingOnline

Brief title
TIMED trial

Condition

- Other condition
- Glucose metabolism disorders (incl diabetes mellitus)
- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Diabetes Mellitus Type 2, Non-insulin dependent diabetes

Health condition

overgewicht

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Stichting Achmea Gezondheidszorg

Intervention

Keyword: Diet, Intermittent fasting, Mediterranean, Type 2 diabetes

Outcome measures

Primary outcome

Between-group difference in HbA1c (mmol/mol) from baseline to one year. HbA1c will be measured with routine clinical lab procedures.

For the (pilot) subpopulation, body weight (kg, Seca 888 compact digital flat scale) form baseline to one year will be the primary outcome.

Secondary outcome

• Nutritional assessment: Body weight (kg, Seca 888 compact digital flat scale), waist circumference (cm), grip strength (kg, Jamar), Resting Energy Expenditure (Via Q-NRG, Cosmed Benelux B.V., Nieuwegein, The Netherlands), and fat mass and lean body mass measured with Bio-electrical Impedance Analysis (Bodystat 4000, Euromedix, Leuven, Belgium)

• Cardiovascular risk factors: LDL cholesterol (mmol/l), total cholesterol (mmol/l), HDL cholesterol (mmol/l), triglycerides (mmol/l), fasting blood glucose (mmol/l), fasting insulin (mIU/l), and blood pressure (mmHg), measured

with routine lab procedures

• Quality of life (SF-36 Questionnaire)

• Demographic variables, drug use, smoking and drinking habits, exercise and medication use will be measured using a self-developed questionnaire

• Diabetes medication usage (Type and dose)

• Food intake, adherence to the diet interventions and compliance to the time restriction (3-day food diary)

• Patient satisfaction (Diabetes Treatment Satisfaction Questionnaire (DTSQ))

• Chronotype questionnaire (Morningness Eveningness Self-Administered Questionnaire (MEQ-SA))

• Sleep quality (Pittsburgh Sleep Quality Index (PSQI))

• Chrononutrition questionnaire (Chromes Questionnaire Louis Bolk)

• Attrition: number of participants that drop-out (categorized by reason for drop-out)

• Satisfaction and feedback of provided lifestyle book (DCN Voeding en Leefstijlboek Questionnaire)

• Process evaluation (qualitative interview)

- Work productivity, measured via the ARBO questionnaire developed by the Erasmus MC MGZ department.

Study description

Background summary

Type 2 diabetes (T2D) prevalence is steadily increasing. It is estimated that worldwide 463 million people are affected by T2D, with a predicted value of 578

million by 2030. According to the World Health Organization, T2D is ranked fourth as cause of death by non-communicable diseases.

Overweight or obese patients have a higher mortality rate due to T2D-related complications than normal weight individuals. Therefore, patients with T2D are advised to lose weight, since weight loss induces positive effects on glycaemic control, blood pressure, and lipid profile, lowering cardiovascular disease risk.

At present, there is no consensus on the best diet for patients with T2D. Several dietary interventions have been shown to be effective for patients with T2D, including the Mediterranean diet and the carbohydrate restricted diet. However, the effect on weight and CVD risk is still somewhat disappointing, especially in the long term. So we are still searching for new, innovative ways to improve the long-term health of patients with T2D.

Fasting is known to improve metabolic homeostasis, organismal function, tissue repair, and resilience. Due to the absence of glucose during fasting, ketones and fatty acids are used as fuel. Systemic and cellular adaptations are needed for this metabolic switch, improving autophagy, DNA repair, and mitochondrial stress resistance. Metabolic switching can be achieved by different types of fasting, such as continuous fasting, fasting mimicking diets (such as ketogenic diets) and intermittent fasting, specifically time-restricted eating.

During time-restricted eating, individuals reduce their daily eating window to less than 10 hours per day. It is shown that this type of intermittent fasting results in positive changes of many health markers in healthy, overweight, obese and pre-diabetic adults, regardless of weight loss. In a 2-week proof-of-principle controlled eating study, Sutton et al. studied the effectiveness of Early Time-Restricted Eating (eTRE, where the eating window ends in the late afternoon) in overweight and obese pre-diabetic men. The authors showed improved markers of glycaemic regulation, without significant differences in weight loss between the intervention and control group. It is, however, unknown whether eTRE is also effective in improving glycaemic regulation in people with T2D, in the longer term.

To our knowledge, long-term research to determine the effectiveness and efficacy of eTRE, against a background of a low carbohydrate Mediterranean diet, in patients with T2D and/or overweight is absent.

Study objective

Primary Objective:
1. What is the difference in effectiveness of Early Time-restricted Eating (eTRE) in glycaemic regulation when compared to isocaloric continues caloric restriction (CCR) after one year in overweight adults with type 2 diabetes?
Secondary Objective(s):

2. What is the difference in weight loss, body composition, cardiovascular risk factors and diabetic medication usage between a CCR and eTRE after one year in overweight adults with type 2 diabetes?
3. What is the difference in quality of life, treatment satisfaction, compliance, and adherence between the two diet interventions?
4. Is there an association between patient characteristics and the effectivity of the two diet interventions?
5. What is the effect of the dietary intervention in people with overweight, without type 2 diabetes?

Study design

Above presented objectives will be answered by conducting a randomized controlled trial, where eligible participants will be randomized to either the control or intervention group.

Intervention

Both groups receive individual and group (lifestyle)treatments, a high quality Mediterranean diet prescribed by a dietitian, and a supportive app in combination with literature. In addition, the intervention group is asked to eat for a maximum of 10 hours, so that they fast for at least 14 hours a day.

Study burden and risks

The burden and risk of participation is considered low. Adding a time restriction to a dietary intervention that is considered standard of care will not impose any additional risks or burdens on participants, other than the burden of being more aware of one's own illness. Participants are asked to come to the outpatient clinic four times more for measurements (same for control and intervention groups), to give a blood sample three times (combined with routine care lab) and to complete questionnaires at three time points about general data, lifestyle, medication, diet, quality of life, experiences with lifestyle book, regularity of eating, morning or evening preference, eating and sleeping patterns and satisfaction with the treatment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Type 2 Diabetes (main cohort)
• Body Mass Index greater than or equal to 27 kg/m2
• 18-75
• Owns a smart phone

Exclusion criteria

• Insufficient command of the Dutch language
• Pregnancy or lactation during the trial
• Severe psychiatric disorders , use of antipsychotic drugs
• Serious heart conditions such as: significant heart arrhythmia , unstable angina pectoris, decompensated congestive heart failure
• Organ failure
• Untreated hypothyroidism
• End-stage renal failure
• Carcinomas
• Transplants, myocardial infarct, cerebrovascular accident, or any large scale surgery within the last 3 months
• Corticosteroid induced diabetes (in patients still using corticosteroids)

• Start with GLP-1 agonists within the last 3 months

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-10-2022
Enrollment:	222
Type:	Actual

Ethics review

Approved WMO Date:	24-12-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-01-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	18-08-2023
Application type:	Amendment

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	26-04-2024
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-12-2024
Application type:	Amendment
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

ID: 20271
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL78344.078.21