

Intermittent fasting for weight loss in people with type 2 diabetes

Published: 28-09-2021

Last updated: 15-05-2024

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	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON20271

Source

NTR

Brief title

TIMED

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Health condition

Type 2 Diabetes

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC

Source(s) of monetary or material Support: Stichting Achmea Gezondheidszorg

Intervention

- Food (substances)

Explanation

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

Secondary outcome

• Body composition • Cardiovascular risk factors • Resting Energy Expenditure • Quality of life • Demographic variables, drug use, smoking and drinking habits, exercise and (diabetes) medication use • Food intake, adherence to the diet interventions and compliance to the time restriction • Patient satisfaction • Chronotype score • Sleep quality • Chrononutrition score • Attrition • Satisfaction and feedback of provided lifestyle book • Process evaluation

Study description

Background summary

Type 2 diabetes prevalence is steadily increasing . Risks are increased in those with overweight or obesity. Weight loss reduces cardiovascular risk and may even lead to remission of diabetes. There is no consensus yet on the most effective weight loss strategy for T2D. Early time restricted eating (eTRE), a form of intermittent fasting, has shown great potential in improving glycaemic regulation in patients with prediabetes. However, eTRE has not been studied in people with T2D and obesity.

Study objective

Primary Objective: 1. What is the difference in effectiveness of Early Time-restricted Eating (eTRE) in glycaemic regulation when compared to isocaloric continuous 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?

Study design

Baseline, 3 months, 6 months and 12 months

Intervention

Control group: group treatment with a carbohydrate restricted Mediterranean diet

Intervention group: group treatment with a carbohydrate restricted Mediterranean diet and an eating window limited to 10 hours per day (eTRE)

Contacts

Public

Erasmus MC
Carmen Dietvorst
Dr. Molewaterplein 40
3015 GD
Rotterdam
Nederland

(010)7033055

Scientific

Erasmus MC
Carmen Dietvorst
Dr. Molewaterplein 40
3015 GD
Rotterdam
Nederland

(010)7033055

Eligibility criteria

Age

Adults (18-64 years)

Adults (18-64 years)

Elderly (65 years and older)

Elderly (65 years and older)

Inclusion criteria

- Diagnosed T2D
- BMI ≥ 27 kg/m²
- Aged 18 - 75 years
- Smartphone with android or IOS

Exclusion criteria

- Insufficient command of the Dutch language (spoken and written)
- 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 phase:	N/A
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:	172
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

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

Study registrations

Followed up by the following (possibly more current) registration

ID: 54132
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9756
CCMO	NL78344.078.21
OMON	NL-OMON54132

Study results