WHO International Clinical Trials Registry information for the RESET trial

Adapted from: https://apps.who.int/trialsearch/Trial2.aspx?TrialID=NCT03854656

Main

Note: This record shows only 22 elements of the WHO Trial Registration Data Set. To view changes that have been made to the source record, or for additional information about this trial, click on the URL below to go to the source record in the primary register.

Register:	ClinicalTrials.gov
Last refreshed on:	9 December 2019
Main ID:	NCT03854656
Date of registration:	18/02/2019
Prospective Registration:	Yes
Primary sponsor:	Kristine Færch
Public title:	Effect of Time-restricted Eating on Behaviour and Metabolism in Overweight Individuals at High Risk of Type 2 Diabetes RESET
Scientific title:	Effect of Time-restricted Eating on Behaviour and Metabolism in Overweight Individuals at High Risk of Type 2 Diabetes - the RESET Study
Date of first enrolment:	February 25, 2019
Target sample size:	100
Recruitment status:	Recruiting
URL:	https://clinicaltrials.gov/show/NCT03854656
Study type:	Interventional

Study design:	Allocation: Randomized. Intervention model: Parallel Assignment. Primary purpose: Prevention. Masking: None (Open Label).
Phase:	N/A

Countries of recruitment

Denmark

Contacts

Name:	Kristine Færch, PhD	**Name:**	Kristine Færch, PhD	**Name:**	Kristine Færch, PhD
Address:		**Address:**		**Address:**	
Telephone:	+45 30913061	**Telephone:**	+45 30913061	**Telephone:**	
Email:	kristine.faerch@regionh.dk	**Email:**	kristine.faerch@regionh.dk	**Email:**	
Affiliation:		**Affiliation:**		**Affiliation:**	Steno Diabetes Center Copenhagen

Key inclusion & exclusion criteria

Inclusion Criteria:

- BMI =30 kg/m2 or BMI =25 kg/m2 in combination with pre-diabetes (HbA1c =39-<48 mmol/mol)

- Habitual eating/drinking window =12 hours (including foods/snacks and energy containing beverages e.g. soft drinks (except of water)) and an eating/drinking window of =14 hours minimum one day per week

Exclusion criteria

- Daily smoking

- For women: pregnancy, planned pregnancy (within the study period) or lactating

- Frequent travels over time zones (max one return trip/travel over times zones (?one hour time difference) during the 13 weeks intervention).

- Shift work or partner engaged in shift work (if it affects the person's sleep and eating pattern)

- Unable to understand the informed consent and the study procedures

- Self-reported history of an eating disorder during the past three years

- Self-reported weight change (>5 kg) within three months prior to inclusion

- Diabetes

- HbA1c =48 mmol/mol

- Uncontrolled medical issues including but not limited to cardiovascular pulmonary, rheumatologic, hematologic, oncologic, infectious, gastrointestinal or psychiatric disease; diabetes or other endocrine disease; immunosuppression

- Current treatment with medication or medical devices which significantly affect glucose metabolism, appetite, or energy balance

- Current treatment with antidepressants

- Bariatric surgery

- Implanted or portable electro-mechanical medical device such as a cardiac pacemaker, defibrillator or infusion pump

- Celiac disease, Crohn's disease, ulcerative colitis or proctitis

- Alcohol/drug abuse or in treatment with disulfiram at time of inclusion

- Concomitant participation in other intervention studies

- Not able to eat =85% of the test meal because of e.g. allergy

Specific exclusion criteria for participants receiving SmartPillTM (n=60)

- Gastrointestinal symptoms or diseases such as regular (weekly) abdominal pain, dysphagia, gastric bezoars, strictures, fistulas, bowel obstructions or diverticulitis

- Current treatment with medication or medical devices which significantly affect gastrointestinal motility or transit time (prokinetics, antidiarrheals, laxatives, or opioids)

- Gastrointestinal surgery within 3 months before inclusion

Age minimum: 30 Years
Age maximum: 70 Years
Gender: All

Health Condition(s) or Problem(s) studied

Overweight and Obesity

PreDiabetes

Intervention(s)

Other: Time-restricted eating

Primary Outcome(s)

Change in body weight (kg) [Time Frame: Change from baseline to the end of the intervention (after 12 weeks)]

Secondary Outcome(s)

Arousal measured using galvanic skin response [Time Frame: Changes from baseline. Fasted state at all four visits (Baseline and after 6, 12, and 26 weeks) and during a mixed meal test at baseline and end of the intervention (after 12 weeks)]

Attention measured using eye tracking [Time Frame: Changes from baseline. Fasted state at all four visits (Baseline and after 6, 12, and 26 weeks) and during a mixed meal test at baseline and end of the intervention (after 12 weeks)]

Body mass index (kg/m^2) [Time Frame: Changes from baseline. Fasted state at all four visits (Baseline and after 6, 12, and 26 weeks)]

Body weight (kg) [Time Frame: Changes from baseline. Fasted state at all four visits (Baseline and after 6, 12, and 26 weeks)]

Circulating proteins that associate with low-grade inflammation and lipid metabolism [Time Frame: Changes from baseline. Fasted state at all four visits (Baseline and after 6, 12, and 26 weeks)]

Continuous overall net glycaemic action (CONGA) [Time Frame: Changes from baseline. Measured 7 days after the test days at baseline and after 6 and 12 weeks]

Daily eating/drinking window (hh:min) [Time Frame: Registrered every day (13 weeks intervention and 13 weeks follow-up period)]

Daily time spent above different glucose concentrations (e.g. >6.1 mmol/L, >7.0 mmol/L, >7.8 mmol/L, and >11.1 mmol/L) [Time Frame: Changes from baseline. Measured 7 days after the test days at baseline and after 6 and 12 weeks]

Diastolic blood pressure (mmHg) [Time Frame: Changes from baseline. Measured at all four visits (Baseline and after 6, 12, and 26 weeks)]

Emotions measured using facial expression analyses [Time Frame: Changes from baseline. Fasted state at all four visits (baseline and after 6, 12, and 26 weeks) and during a mixed meal test at baseline and end of the intervention (after 12 weeks)]

Energy intake (kcal/day) [Time Frame: Changes from baseline. Registered 3 days after the test days at baseline and after 6 and 12 weeks]

Explicit liking [Time Frame: Changes from baseline. Fasted state at all four visits (Baseline and after 6, 12, and 26 weeks) and during a mixed meal test at baseline and end of the intervention (after 12 weeks)]

Explicit wanting [Time Frame: Changes from baseline. Fasted state at all four visits (Baseline and after 6, 12, and 26 weeks) and during a mixed meal test at baseline and end of the intervention (after 12 weeks)]

Fat free mass (kg) [Time Frame: Changes from baseline. Fasted state at all four visits (Baseline and after 6, 12, and 26 weeks)]

Fat mass (kg) [Time Frame: Changes from baseline. Fasted state at all four visits (Baseline and after 6, 12, and 26 weeks)]

Fat percentage (%) [Time Frame: Changes from baseline. Fasted state at all four visits (Baseline and after 6, 12, and 26 weeks)]

Feasibility of the intervention (qualitative methods) [Time Frame: Visits at baseline and after 12 and 26 weeks. Potential drop-outs will be interviewed at the specific time point.]

Food choice [Time Frame: Changes from baseline. Fasted state at all four visits (Baseline and after 6, 12, and 26 weeks) and during a mixed meal test at baseline and end of the intervention (after 12 weeks)]

Gastric emptying time (hours and minutes) [Time Frame: Changes from baseline. Time after consumption of the standard mixed meal at baseline and end of the intervention (after 12 weeks).]

HbA1c (mmol/mol and %) [Time Frame: Changes from baseline. All four visits (Baseline and after 6, 12, and 26 weeks)]

Heart rate (bpm) [Time Frame: Changes from baseline. Measured at all four visits (Baseline and after 6, 12, and 26 weeks)]

Heart rate response to forced exhalation during rest (valsalva maneuver) [Time Frame: Changes from baseline. Measured at visits at baseline and end of the intervention (after 12 weeks)]

Heart rate response to inhalation and exhalation [Time Frame: Changes from baseline. Measured at visits at baseline and end of the intervention (after 12 weeks)]

Heart rate response to standing up from the supine position [Time Frame: Changes from baseline. Measured at visits at baseline and end of the intervention (after 12 weeks)]

Hip circumference (cm) [Time Frame: Changes from baseline. Fasted state at all four visits (Baseline and after 6, 12, and 26 weeks)]

Hormones [Time Frame: Changes from baseline. Measured in the blood in the fasted state at all four visits (Baseline and after 6, 12, and 26 weeks) and during a mixed meal test (4 hours) at baseline and end of the intervention (after 12 weeks)]

Implicit wanting [Time Frame: Changes from baseline. Fasted state at all four visits (Baseline and after 6, 12, and 26 weeks) and during a mixed meal test at baseline and end of the intervention (after 12 weeks)]

Insulin resistance (indices) [Time Frame: At all four visits (Baseline and after 6, 12, and 26 weeks)]

Insulin sensitivity (indices) [Time Frame: At all four visits (Baseline and after 6, 12, and 26 weeks)]

Large bowel transit time (hours and minutes) [Time Frame: Changes from baseline. Time after consumption of the standard mixed meal at baseline and end of the intervention (after 12 weeks).]

Macronutrient intake (energy percentage) [Time Frame: Changes from baseline. Registered 3 days after the test days at baseline and after 6 and 12 weeks]

Mean amplitude of glycaemic excursions (MAGE) [Time Frame: Changes from baseline. Measured 7 days after the test days at baseline and after 6 and 12 weeks]

Mean glucose concentrations [Time Frame: Changes from baseline. Measured 7 days after the test days at baseline and after 6 and 12 weeks]

Metabolites [Time Frame: Changes from baseline. Measured in the blood in the fasted state at all four visits (Baseline and after 6, 12, and 26 weeks) and during a mixed meal test (4 hours) at baseline and end of the intervention (after 12 weeks)]

Microbiome content and diversity [Time Frame: Changes from baseline. Collected before or during test days at visits at baseline and after 12 weeks]

Motility index [Time Frame: Changes from baseline. Time after consumption of the standard mixed meal at baseline and end of the intervention (after 12 weeks).]

Motivation for participation (qualitative methods) [Time Frame: Visits at baseline and after 12 and 26 weeks. Potential drop-outs will be interviewed at the specific time point.]

Physical activity (counts/min) [Time Frame: Changes from baseline. Measured 7 days after the test days at baseline and after 6 and 12 weeks]

Physical activity (MET hours) [Time Frame: Changes from baseline. Measured 7 days after the test days at baseline and after 6 and 12 weeks]

Physical activity (time spent at different intensities) [Time Frame: Changes from baseline. Measured 7 days after the test days at baseline and after 6 and 12 weeks]

Physical activity energy expenditure (kcal/day) [Time Frame: Changes from baseline. Measured 7 days after the test days at baseline and after 6 and 12 weeks]

Respiratory and glycolytic capacities of isolated peripheral blood mononuclear cells (PBMCs) [Time Frame: Changes from baseline. Fasted state at all four visits (Baseline and after 6, 12, and 26 weeks) and during a mixed meal test at baseline and end of the intervention (after 12 weeks)]

Resting energy expenditure (kcal/day) [Time Frame: Changes from baseline. Measured at visits at baseline and after 12 weeks]

Satisfaction with the intervention (qualitative methods) [Time Frame: Visits at baseline and after 12 and 26 weeks. Potential drop-outs will be interviewed at the specific time point.]

Self-reported autonomic symptoms [Time Frame: Changes from baseline. Assessed at all four visits (Baseline and after 6, 12, and 26 weeks)]

Self-reported chronotype [Time Frame: Changes from baseline. Assessed at all four visits (Baseline and after 6, 12, and 26 weeks)]

Self-reported control over eating [Time Frame: Changes from baseline. Assessed at all four visits (Baseline and after 6, 12, and 26 weeks)]

Self-reported eating behavior [Time Frame: Changes from baseline. Assessed at all four visits (Baseline and after 6, 12, and 26 weeks)]

Self-reported gastrointestinal symptoms (part 1) [Time Frame: Changes from baseline. Assessed at all four visits (Baseline and after 6, 12, and 26 weeks)]

Self-reported gastrointestinal symptoms (part 2) [Time Frame: Changes from baseline. Assessed at all four visits (Baseline and after 6, 12, and 26 weeks)]

Self-reported gastrointestinal symptoms (part 3) [Time Frame: Changes from baseline. Registered 7 days after the test days at baseline and after 12 weeks]

Self-reported night eating [Time Frame: Changes from baseline. Assessed at all four visits (Baseline and after 6, 12, and 26 weeks)]

Self-reported overall health and wellbeing [Time Frame: Changes from baseline. Assessed at all four visits (Baseline and after 6, 12, and 26 weeks)]

Self-reported physical activity [Time Frame: Changes from baseline. Assessed at all four visits (Baseline and after 6, 12, and 26 weeks)]

Self-reported sleep quality [Time Frame: Changes from baseline. Assessed at all four visits (Baseline and after 6, 12, and 26 weeks)]

Self-reported sleepiness [Time Frame: Changes from baseline. Assessed at all four visits (Baseline and after 6, 12, and 26 weeks)]

Sleep duration (min) [Time Frame: Changes from baseline. Registered and measured for 7 days after the test days at baseline and after 6 and 12 weeks]

Sleep efficiency (%) [Time Frame: Changes from baseline. Measured for 7 days after the test days at baseline and after 6 and 12 weeks]

Sleep onset latency (min) [Time Frame: Changes from baseline. Registered and measured for 7 days after the test days at baseline and after 6 and 12 weeks]

Sleep timing (hh:mm) [Time Frame: Changes from baseline. Registered and measured for 7 days after the test days at baseline and after 6 and 12 weeks]

Sleep variability (min) [Time Frame: Changes from baseline. Registered and measured for 7 days after the test days at baseline and after 6 and 12 weeks]

Small bowel transit time (hours and minutes) [Time Frame: Changes from baseline. Time after consumption of the standard mixed meal at baseline and end of the intervention (after 12 weeks).]

Standard deviation of glucose concentrations [Time Frame: Changes from baseline. Measured 7 days after the test days at baseline and after 6 and 12 weeks]

Subjective appetite [Time Frame: Changes from baseline. Fasted state at all four visits (Baseline and after 6, 12, and 26 weeks) and during a mixed meal test at baseline and end of the intervention (after 12 weeks)]

Substrate oxidation (respiratory exchange ratio) [Time Frame: Changes from baseline. Measured at visits at baseline and after 12 weeks]

Systolic blood pressure (mmHg) [Time Frame: Changes from baseline. Measured at all four visits (Baseline and after 6, 12, and 26 weeks)]

Timing of dietary intake (hh:mm) [Time Frame: Changes from baseline. Registered 3 days after the test days at baseline and after 6 and 12 weeks]

Timing of physical activity (hh:mm) [Time Frame: Changes from baseline. Measured 7 days after the test days at baseline and after 6 and 12 weeks]

Total gastrointestinal transit time (hours and minutes) [Time Frame: Changes from baseline. Time after consumption of the standard mixed meal at baseline and end of the intervention (after 12 weeks).]

Variation coefficients of glucose concentrations [Time Frame: Changes from baseline. Measured 7 days after the test days at baseline and after 6 and 12 weeks]

Waist circumference (cm) [Time Frame: Changes from baseline. Fasted state at all four visits (Baseline and after 6, 12, and 26 weeks)]

Wakefulness (min) [Time Frame: Changes from baseline. Measured for 7 days after the test days at baseline and after 6 and 12 weeks]

Secondary ID(s)

NNF17OC0027822

Source(s) of Monetary Support

Please refer to primary and secondary sponsors

Secondary Sponsor(s)

Aalborg University Hospital

iMotions A/S

Salk Institute for Biological Studies

University of Copenhagen

University of Leeds

Ethics review

Results

Results available:

Date Posted:

Date Completed:

URL: