# Effects of timing of food intake on glucose metabolism and the brain during a hypocaloric diet in obese subjects

No registrations found.

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

# **Summary**

## ID

NL-OMON22981

Source NTR

Brief title TIME

Health condition

obesity, type 2 diabetes

## **Sponsors and support**

Primary sponsor: AMC Source(s) of monetary or material Support: STW

#### Intervention

#### **Outcome measures**

#### **Primary outcome**

- 1. Insulin sensitivity (hyperinsulinemic euglycemic clamp)
- 2. Diencephalic SERT ([123I]FP-CIT SPECT)
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3. Brain 5-HT neurotransmission (pharmacological MRI (phMRI) using citalopram).

#### Secondary outcome

Motivation and impulse control

Abdominal and liver fat

Circulating hormones and substrates: blood drawing

Sleep duration

Resting energy expenditure

Sympathetic and parasympathetic activity

Feeding behaviour

# **Study description**

#### **Study objective**

Consuming most calories at breakfast compared to at dinner leads to more suppression of appetite and craving and enhances insulin sensitivity.

#### Study design

before and after diet

#### Intervention

Subjects will reduce their daily caloric intake with 50% for 4 weeks. Subjects will be randomized into either a hypocaloric diet group where 15% of total kcal have to be consumed with breakfast, 35% kcal with lunch and 50% kcal with dinner or a hypocaloric diet group where 50% of kcal have to be consumed with breakfast, 35% kcal with lunch and 15% kcal with dinner.

# Contacts

**Public** Ruth Versteeg

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Amsterdam The Netherlands **Scientific** Ruth Versteeg Amsterdam The Netherlands

# **Eligibility criteria**

## **Inclusion criteria**

men

>50 y

BMI >30

fasting glucose > 5.6 and/or insulin > 74

Stable weight three months prior to study inclusion

## **Exclusion criteria**

Use of any medication except for those related to treatment of components of the metabolic syndrome (excluding insulin, oral glucose lowering drugs, beta-blockers)

Any actual medical condition except for treated hypothyroidism and the metabolic syndrome

History of any psychiatric disorder

Shift work

Irregular sleep pattern

Intensive sports (>3/week)

**Restrained eaters** 

History of eating disorders (anorexia, binge eating, bulimia)

Smoking, XTC, amphetamine or cocaine abuse

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Alcohol abuse (>3/day)

**Contraindication MRI** 

Lactose intolerance

# 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):	01-11-2014
Enrollment:	25
Туре:	Anticipated

# **Ethics review**

Positive opinion	
Date:	07-07-2015
Application type:	First submission

# **Study registrations**

## Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

## In other registers

Register	ID
NTR-new	NL4822
NTR-old	NTR5399
Other	METC : 2014_200

# **Study results**