# Het effect van diepe slaap op het onstaan van obesitas.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

## **Summary**

## ID

NL-OMON21595

Source

Brief title Slow-wave sleep and obesity

**Health condition** 

Obesity

## **Sponsors and support**

Primary sponsor: No sponsors Source(s) of monetary or material Support: Self-funding

## Intervention

## **Outcome measures**

#### **Primary outcome**

1. Effect of spontaneous sleep duration cq sleep alteration on: total energy expenditure, AEE (physical activity is measured with a Doppler radar and Tracmor system) and substrate oxidation in the respiration chamber;

2. Feelings of hunger, satiety and rewarding values of food: food intake;

3. The endocrinological parameters: melatonin, cortisol, ghrelin, leptin, growth hormone, insulin, glucose, adrenalin and noradrenalin and orexin A;

4. Body temperature (measured with a CorTemp<sup>™</sup> Data Recorder).

#### Secondary outcome

No secondary outcomes.

# **Study description**

#### **Background summary**

Sleep duration and sleep quality are associated with obesity in longitudinal studies. To evaluate what the influence is of the most important stage of the sleep, the slow-wave sleep, on the onset of obesity an intervention is necessary. Therefore, disturbing the slow-wave sleep without waking the subjects and in the meanwhile investigating the endocrinological parameters, energy expenditure, fat oxidation, body temperature, its effect on feelings of reward and feelings of hunger and satiety will give us insight in the etiology of obesity with respect to sleep.

#### **Study objective**

Suppression of SWS, without changing total sleep time, may affect total energy expenditure (TEE), activity induced energy expenditure (AEE), non-exercise activity thermogenesis (NEAT), endocrinological parameters and energy intake.

#### Study design

Subjects spent 2 x 48 hrs in the respiration chamber. Each hour between 07.00 AM and 11.00 PM they have to fill in several questionnaires. Furthermore their urine will be collected every 12 hrs for analysis of nitrogen and palmitic acid.

#### Intervention

Subjects will visit the university twice and during each visit they will stay in the respiration chamber for two days and nights (48hrs). During one of these visits subjects will sleep normally; during the other visit SWS will be suppressed. Subjects will be asked for their usual bedtimes during the week. They will be in a partly time-blinded surrounding and told to go to sleep or get out of bed as they are used to. The time, when they switch off the lights, is recorded. Suppression of SWS sleep will be done with acoustic tones varying in frequency from 500 – 2000 Hz, produced by speakers near the bed. When the EEG records indicate that the subject is in the SWS sleep, two delta waves (?4 Hz, >75 ?V) appearing within 15s, acoustic

sounds starting from 40 dB are delivered. If no response occurs, the sound will be increased with 10dB per step till 110 dB maximum. When the maximum tone does not cause any response the subjects name will be spoken over the intercom. Subjects are not supposed to wake up, they only have to skip the SWS sleep. During the day subjects spend their time freely in the chamber, yet are not allowed to sleep.

# Contacts

Public Maastricht University Dept. Humane Biology PO Box 616

Rick Hursel Maastricht 6200 MD The Netherlands +31 43 3882123 **Scientific** Maastricht University Dept. Humane Biology PO Box 616

Rick Hursel Maastricht 6200 MD The Netherlands +31 43 3882123

# **Eligibility criteria**

## **Inclusion criteria**

- 1. Healthy men and women;
- 2. A Body Mass Index (BMI) between 24-27 kg/m2;
- 3. Age of 20-30 years;
- 4. Short sleepers (les than 7 hours) and normal sleepers (7 to 8 hours) are included.

## **Exclusion criteria**

Exclusion criteria for subjects are apart from age, BMI and sleep duration:

- 1. Smoking;
- 2. Being on medication (except the use of contraception);
- 3. Excessive alcohol consumption;
- 4. Excessive exercise;
- 5. Not being weight stable;
- 6. Being dietary restraint (assessed by the Three Eating Questionnaire (TFEQ));

# Study design

## Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo

## Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2009
Enrollment:	16
Туре:	Actual

# **Ethics review**

Positive opinion Date:

21-07-2009

# **Study registrations**

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

No registrations found.

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

No registrations found.

#### In other registers

Register	ID
NTR-new	NL1809
NTR-old	NTR1919
Other	MEC Unimaas : MEC 08-3-060
ISRCTN	ISRCTN wordt niet meer aangevraagd.

# **Study results**

Summary results N/A