Effects of circadian misalignment and sleep disturbance on feeding patterns, obesity and the metabolic syndrome

Published: 19-05-2010
Last updated: 02-05-2024

The objective of the first part of the study is to assess whether circadian misalignment: - decreases energy expenditure and activity induced energy expenditure - alters substrate oxidation- alters feelings of hunger and satiety - alters food choice...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Appetite and general nutritional disorders
Study type	Observational invasive

Summary

ID

NL-OMON34717

Source
ToetsingOnline

Brief title
Circadian misalignment and obesity

Condition

- Appetite and general nutritional disorders

Synonym
obesity overweight

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: circadian misalignment, feeding patterns, obesity, sleep disturbance

Outcome measures

Primary outcome

With the experimental approach the following outcome will appear:

1) Effects of light- and food-entrained circadian misalignment versus circadian-alignment on:

(i) circadian patterns of parameters associated with circadian rhythm, and of parameters associated with food intake patterns, namely patterns of concentrations of the following blood-parameters: melatonin, leptin, glucose, insulin, ghrelin, GLP-1; VAS-ratings on appetite sensations; VAS-ratings on the stress-related POMS- and STAI-questionnaires.

(ii) food choice, food reward, and energy intake.

(iii) circadian patterns of energy expenditure and its components;

(iv) substrate oxidation; macronutrient-balance;

(v) circadian patterns of body-temperature;

(vi) physical activity and its circadian patterns;

(vii) circadian patterns of heart rate

viii sleep quality

Secondary outcome

Not applicable

Study description

Background summary

The prevalence of obesity has increased worldwide to epidemic proportions. For long-term treatment success permanent lifestyle changes are necessary with regard to approach to food, physical activity patterns and behavior to emotional stress. Until now, recommendations for improving food choice, food intake patterns, and energy intake, as well as for normalizing physical activity, have not resulted in solutions for prevention and treatment of obesity. It may be that advices on the energy balance components energy intake and energy expenditure lack the interaction with the subjects* individual circadian alignment, or that circadian alignment is disturbed, due to environmental pressure. Only one study till now has studied the consequences of circadian misalignment in humans. Circadian misalignment, when subjects ate and slept about 12h of phase from their habitual times, systematically decreased leptin, increased glucose despite increased insulin, completely reversed the daily cortisol rhythms, and increased arterial pressure. These findings illustrate how circadian misalignment represents a high risk for overweight and obesity.

Study objective

The objective of the first part of the study is to assess whether circadian misalignment:

- decreases energy expenditure and activity induced energy expenditure
- alters substrate oxidation
- alters feelings of hunger and satiety
- alters food choice and energy intake
- alters the reward system (wanting and liking)
- affects the endocrinological system
- alters body temperature
- alters sleep quality

Study design

Partly randomized single-blinded cross-over design.

Intervention

Part I: subjects stay for each condition, for 3 circadian cycles, in the absence of time cues, in a controlled situation under controlled energy balance conditions in a respiration-chamber. In order to identify effects of circadian misalignment and its associated sleep disturbance, subjects undergo randomly:

- circadian alignment by a 27 hrs light- and food-entrained cycle
- circadian misalignment by a 21 hrs light- and food-entrained cycle

The second part of the experiment will be conducted after completion of the first part.

Part II: in order to assess two concepts of restoration of circadian misalignment, the men first will be misaligned during a week at home, by a short sleep duration, i.e. 6hrs sleep.
Each time thereafter they will follow the next two conditions in random order:
- 1 cycle of light-entrained circadian misalignment (21 hrs), followed by two cycles of light-entrained circadian re-alignment (27 hrs), with a feeding schedule on demand
- 1 cycle of light-entrained circadian misalignment (21 hrs), followed by two cycles of food-entrained circadian re-alignment (27 hrs), under dim light conditions of 1.8 lux.

During all testdays, subjects will stay time blinded in the respiration chamber to measure energy expenditure, substrate oxidation and physical activity, during three light-entrained circadian cycles of a 1:2 ratio. A short cycle will be 21 hrs (7/14), a long cycle 27 hrs (9/18). Light-entrainment will be achieved using day-light lamps during the waking hours and black-out curtains during the sleeping hours. During food-entrainment, light conditions will be dim light continuously, (about 1.8 lux), to minimize any light-entrained influence on the circadian system. During their stay in the chamber, subjects will be fed in energy balance in a food-entrained way, at time-points related to their cycle duration. EEG will be used to measure wake and sleep phases continuously. Heart rate will be monitored using a ECG and body temperature using a CorTemp* Data Recorder (HQInc., Palmetto (FL), USA). Appetite and mood profiles will be measured hourly and before and after each meal, by anchored 100 mm visual analogue scales and by POMS and STAI-state questionnaires. Also, the blood-parameters will be measured hourly, and growth hormone will be measured every 20 minutes. Finally, effects of on food reward and energy intake will be measured by means of a validated wanting and liking computer-test, before and during the evening meal before subjects leave the chamber. This evening meal consists of subjects* food choice, and will be given ad libitum. Food choice, rewarding characteristics, macronutrient composition, energy-density, and energy content will be calculated.

Study burden and risks

This study does not include any major risks for the subjects. During the time-blinded two researchers will always be present during the subjects stay in the respiration chamber. There are no risks for the subjects in using any of the meals because people with certain food allergies are excluded and all products are regular food items available at the local supermarket (AH). The *thermometer pill* that they have to swallow is completely harmless and runs

through the digestive system, where it eventually will exit the body via the feces. Blood sampling in this study is limited and without side effects, apart from its usual risks of minor bruising. Urine sampling is done in urine bottles with 10 ml of diluted HCl, which might pose a risk for the subjects, however they will be carefully instructed on how to sample the urine and handle the urine bottles. The subject does needs to follow our schedule on sleeping, filling in questionnaires and eating, however, the majority of the time the subject is awake he can fill in his own time. The experiment will cost about 144 hours of the subject*s time.

Contacts

Public
Universiteit Maastricht

Universiteitsingel 50
6200 MD
NL
Scientific
Universiteit Maastricht

Universiteitsingel 50
6200 MD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Subjects have to be in good health, weight stable, non-smokers, not using medication, not

have sleep problems, and at most moderate alcohol users. They have to be overweight, BMI 25-29 kg/m2, adolescent and young adult, age 18-30 yrs, men, who are evening people.

Exclusion criteria

BMI <25 and >30 kg/m2, women, morningpeople, age <18 and >30 year, using any kind of medication, smokers, sleep problems and excessive use of alcohol

Study design

Design

Study type:	Observational invasive
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-07-2010
Enrollment:	16
Type:	Actual

Ethics review

Approved WMO

Date:	19-05-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
CCMO	NL31568.068.10