Developing an effective method of determining circadian phase in humans for clinical applications

Published: 09-09-2014
Last updated: 20-04-2024

The objective of this research is to develop a reliable and efficient method of determining the phase of the biological (circadian) clock in humans.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON42265

Source
ToetsingOnline

Brief title
Improving biological clock measurements

Condition

- Other condition

Synonym
biological rhythm, circadian clock

Health condition

individuele variatie in 24-uurs ritmiek

Research involving
Human

Sponsors and support

Primary sponsor: Rijksuniversiteit Groningen
Source(s) of monetary or material Support: STW grant "On Time"

Intervention

Keyword: At home measurements, Biological clock, Clinic, Melatonin

Outcome measures

Primary outcome

The primary study parameters are the model parameter-estimates of the daily profile of skin temperature, light exposure, core body temperature, activity, heart rate, sleep parameters (EEG and self-reported) and salivary melatonin profile for each participant. The outcome measures will be the different model parameter estimates required for late/early chronotypes, both sexes and the two age groups to best estimate the phase determined by the salivary melatonin sampling.

Secondary outcome

Differences between working days an free days will also be analysed, but this is not determinant for the size of the study population.

Study description

Background summary

Circadian rhythms control the daily cycle of sleep and wake, a disruption of this control can effect an individual's health. Some treatments, for example chemotherapy for cancer, appear to be more efficient at a certain phase of the circadian rhythm of the patient. Unfortunately, despite the growing attention of these modified treatments, the methods to determine the circadian rhythm of the patient are not optimal. The standard method to determine circadian phase in people is the measurement of the timing of the nightly rise of the hormone

melatonin. These measurements cost a lot of money and time and requires specialist expertise. This research is designed in order to develop a way of measuring circadian phase of people in an efficient, practical way that is suitable for use in the clinic. Different methods to determine circadian phase will be combined and modeled to determine an optimal combination of measurements, devices and software algorithms to find a system that can be used by non-circadian researchers to determine the circadian rhythm of a patient for clinically relevant applications.

Study objective

The objective of this research is to develop a reliable and efficient method of determining the phase of the biological (circadian) clock in humans.

Study design

In this observational study measurements on working days and free days will be used to develop algorithms, based on the daily pattern of activity, core body temperature, light exposure, skin temperature, heart rate frequency and EEG-derived sleep parameters, comparable to the phase of the individual's melatonin rhythm. In week 1, activity, skin temperature and heart rate will be continuous measured. Core body temperature will be measured 2x24h. At the end of the week, salivary melatonin secretion will be measured in the lab. Week 2 is a rest week. In week 3, there will be two nights of EEG measurements. A sleep diary will be completed during week 1 and week 3. The wrist activity meter will be worn on all days that the other sensors are worn and at the same time a light sensor will be worn around the participant's neck and placed at the bedside during the sleep period. Before the study begins participants will complete some questionnaires, further details are given in the protocol.

Study burden and risks

The burden for the participants during the study consists of the wearing of lightweight data loggers for a week and two days. Also the completion of the sleep diary is necessary. Participants do not have to complete questionnaires or other tasks that would affect their daily functioning. In order to measure core body temperature a pill needs to be swallowed to obtain the temperature measurements (for more information see the structure risk analysis in the protocol). The measurement of skin temperature will be conducted by attaching 6 temperature loggers to the skin (for 7 days). For heart rate measurements, 2 standard ECG electrodes will be attached to the chest (for 7 days). The EEG measurements will consist of 9 electrodes attached to the head (2 non-consecutive nights). For the activity measurements an accelerometer about the size of a watch will be worn on the wrist (for 7 days). The light sensor is the size of a USB stick and will be worn around the participant's neck (at the same time as the accelerometer is worn on the wrist). Also, 8 saliva samples

will be taken (1 an hour) one night in the laboratory, beginning 7h before habitual sleep onset. Participants have the option of sleeping in the facility so that their sleep onset will not be altered.

Contacts

Public
Rijksuniversiteit Groningen

Nijenborgh 7
Groningen 9747 AG
NL
Scientific
Rijksuniversiteit Groningen

Nijenborgh 7
Groningen 9747 AG
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

healthy men and women, aged 20-30 or 50-60
early/late/normal chronotype

Exclusion criteria

Bad sleepers (PSQI >10)
Depressive tendencies (BDI >8) (HADS >8)
Anxiety problems (HADS >8)
Chronotype of relatively late (20-30 year olds MSF 5.63-6.29-60 year olds MSF 4.5-5.08) or relatively early (20-30 year olds MSF 4.29-5.044, 50-60 year olds MSF 3.27-4.0)
Chronic (psychiatric or somatic) disease
Smokers
Recreational drug use (e.g. cannabis, ectasy, GHB etc.)
Past head injury or epileptic fits
Medically diagnosed sleep disorders
Eye complaints or eye surgery in the past (not including contact lenses or glasses)
Use of chronic (photosensitizing) medication in 3 months prior to the start of the study
Regular use of sleep medication or stimulating drugs
Colour blindness
More than 3 glasses of alcohol per day
More than 8 caffeinated drinks per day
Shiftwork in 3 months prior to the start of the study
Travelled across more than 1 timezone in the month prior to the start of the study
People with a BMI lower than 18 and higher than 27, or weighing below 36kg.
Actual or suspected gastrointestinal obstructive disease
Having a disorder or impairment of the gag reflex
Previous gastrointestinal surgery
Felinization of the oesophagus
Hypo-motility disorders of the gastrointestinal tract
Cardio pacemaker or any other implanted electro-medical device
People who work with or plan to come in contact with Magnetic devices during the study (hospital or scientific grade only)

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2014

Enrollment:	72
Type:	Actual

Ethics review

Approved WMO Date:	09-09-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	18-12-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	15-04-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	12-02-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL48468.042.14