Older adults exercising on time

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Primary:To examine the effect of physical activity timing on insomnia severity in older adults with self-reported sleep problems.Secondary:To examine the effect of physical activity timing on exploratory rhythmic parameters of biological clock...

Ethical review	Approved WMO
Status	Completed
Health condition type	Sleep disorders and disturbances
Study type	Interventional

Summary

ID

NL-OMON56414

Source
ToetsingOnline

Brief title
ON TIME study

Condition

- Sleep disorders and disturbances

Synonym
Insomnia, Sleep problems

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: NWO

Intervention

Keyword: Biological clock, Chronoactivity, Healthy ageing, Timing

Outcome measures

Primary outcome

The main outcome of this study will be insomnia severity which will be measured by the Dutch version of the ISI ranging from 0-28 (0-7: no clinically significant insomnia; 8-14: subthreshold insomnia; 15-21: moderate severity clinical insomnia; 22-28: severe clinical insomnia).

Secondary outcome

Secondary and exploratory endpoints include:

Biological clock function

• Clockgene expression

• Core body temperature (°C)

o Diurnal pattern

o Time of lowest temperature

• Melatonin

o Dim light melatonin onset (DLMO)

Physiological parameters

• Heart rate

o Diurnal pattern

o Average

o Resting heart rate

o Minimum/peak heart rate (5 and 95 percentile)

• Heart rate variability (HRV)

• Breathing rate

• Oxygen saturation (SpO2)

Mental health

• Subjective mood

o Diurnal pattern of:

* Positive affectivity

* Negative affectivity

* Energy

* Fatigue

* Cognition

• (objective) Electrodermal activity (emotional arousal and stress)

Behavioural factors

• Food intake

o Frequency

o Timing

• Habitual sleep (Table 8.1)

o Sleep latency (min)

o Duration (min)

o Efficiency (%)

o Sleep phases (%, min)

o Awakenings at night (x, min)

o Rested feeling (subjective, 0-7)

o General satisfaction with sleep (subjective, 0-7)

Biochemistry

• Glucose metabolism*

• Inflammatory markers

• Liver function

• Kidney function

• Thyroid function

• White blood cell count

Study description

Background summary

There are indications based on epidemiological cohort studies and animal experiments that timing of physical activity (also referred as *chronoactivity*), irrespective of intensity, impacts health and disease. In view of the detrimental effects of circadian misalignment, the large group of older people suffering from sleep problems, and the seeming importance of chronoactivity, we will perform a randomised cross-over study that aims to uncover the effect of timing of physical activity on insomnia severity and related (circadian) health parameters in older adults with self-reported sleep problems. Here, we hypothesize that timing of physical activity has a beneficial impact on insomnia symptoms and on circadian rhythms of additional health parameters (e.g., metabolic, psychosocial) in older people.

Study objective

Primary:
To examine the effect of physical activity timing on insomnia severity in older adults with self-reported sleep problems.

Secondary:
To examine the effect of physical activity timing on exploratory rhythmic

parameters of biological clock function, physiology and metabolism, mental health, behavioural factors, and immune and cell signalling functions.

Study design

This study will be a two-armed randomised cross-over study. This means that all participants will go through all interventions.

Intervention

The intervention will comprise one sedentary period and two period of increased physical activity with different daily patterns: 1) active morning; 2) active evening with a duration of 14 days each. In both active intervention arms, participants will follow an exercise program containing outdoor physical exercise sessions (Vitality Club) containing endurance and strength exercises, relative restdays of 30 minutes light intensity physical activity, and one Active@Home program; a 1-hour training session of various moderate to vigorous activities. The training sessions will be held either in the morning or evening (depending on the intervention arm) and will be one hour long. Since this will be a cross-over study, all participants will follow the sedentary period as well as both exercise timing interventions consecutively with a 7-day wash-out period between all interventions.

Study burden and risks

The chance of harm is small, because it is largely non-invasive research. The 5 blood draws are the only invasive procedures of the study. The procedures performed in this study are frequently performed in clinical practice and clinical research. In addition, the exercise interventions are supervised by a physiotherapist specialized in elderly care. There is therefore a lot of experience with the risks and possible adverse effects of the intervention and all other procedures. For this reason, there is great predictability that risks are negligible.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Aged between 60 and 80 years old
• Retired
• Long lasting sleep problems (as assessed by a the screening questionnaire administered telephonically and by the ISI which will be filled out during the screening visit)
• Access to and ability to use a smart phone (Android or Apple)

Exclusion criteria

• Currently employed or working
• Participation in any sort of fasting regimen (e.g. intermitted fasting or Ramadan)
• Experienced recent (<6 months) adverse life events (e.g., death of partner)
• Abnormal/extreme values in glucose metabolism, thyroid, liver or kidney function, or inflammation markers that after examination of the study doctor need immediate attention of a general practitioner or specialist.
• Diagnosed clinical depression
• Diagnosed neurodegenerative diseases (e.g. dementia or Parkinson*s disease)
• Diagnosed sleep apnoea
• Diagnosed restless legs syndrome
• Use of beta-adrenergic blocking agents
• Use of sleep medication
• Injuries or other severe physical conditions (such as active arthrosis) that

inhibits physical activity
• Travelled across time zones one week prior to start of study

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	08-02-2024
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	08-06-2023
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	20-11-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	18-12-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	23-02-2024
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL82335.058.22