# Fitness training and movement efficiency and quality of sleep with increasing age

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To assess the effect of fitness training on movement efficiency, fitness level, physical activity and quality of sleep in ageing subjects

Ethical review	Approved WMO
Status	Pending
Health condition type	Age related factors
Study type	Interventional

# Summary

## ID

NL-OMON36979

**Source** ToetsingOnline

**Brief title** Fitness training, health and age

## Condition

• Age related factors

#### **Synonym** energy spent during standardized movements, Movement efficiency

# Research involving

Human

## **Sponsors and support**

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

## Intervention

Keyword: Age, Fitness training, Movement efficiency, Quality of sleep

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## **Outcome measures**

#### **Primary outcome**

Movement efficiency . Movement efficiency is derived from activity energy expenditure during specific activities at a fixed workload, measured with indirect calorimetry.

#### Secondary outcome

Fitness level, as derived by indirect calorimetry during maximal exercise, measured at the beginning and at the end of the intervention in order to determine the effect of fitness training.

Physical activity, as derived by accelerometry during 2 weeks in daily life,

measured at the beginning, after six months and at the end of the intervention

in order to determine the effect of fitness training.

Quality of sleep, as assessed with a polysomnogram and by comparing deep sleep

energy expenditure to overnight energy expenditure during one night in a

respiration chamber, measured at the beginning and at the end of the

intervention in order to determine the effect of fitness training.

# **Study description**

#### **Background summary**

Ageing is associated with a reduction of movement efficiency, fitness level, physical activity and quality of sleep. This leads to reduced health and well being in elderly subjects. Fitness training can increase movement efficiency, fitness level, physical activity and quality of sleep.

#### Study objective

To assess the effect of fitness training on movement efficiency, fitness level, physical activity and quality of sleep in ageing subjects

## Study design

The study consists of an intervention study on the efficacy of fitness training on movement efficiency fitness level, physical activity and and quality of sleep.

#### Intervention

Subjects in the intervention group will have subscribed for a group fitness training schedule of moderate intensity, at 50% of heart rate reserve, as available for the specific age group in a fitness centre (Topfit, Maastricht). Control subjects are not interested in subscribing to any fitness program during the study.

#### Study burden and risks

Subjects interested in the study will receive the information letter and a copy of the informed consent and they will be given at least one week to decide whether to participate. Subjects that decide to participate and signed the informed consent will visit the university four times: a screening visit (1 hour) a visit to assess fitness level (1 hour) and two visits to perform initial and final measurements (11 and 13 hours respectively). During the screening visit, (1 hour) subjects will visit our physician. The visit will include an ECG (examined by a cardiologist), blood pressure and auscultation (0.5 hours), an anamnesis to be recorded in a questionnaire concerning personal and family health condition, personal lifestyle and measurements of height, weight and body composition (0.5 hours). Fitness level is assessed during the second and the fourth visit with maximal oxygen consumption as measured on a cycle ergometer (1 hour each). The visit for initial measurements at the university includes, movement efficiency, i.e. energy expenditure during four standardised activities (1 hour), and the assessment of sleep guality with polysomnography in a respiration chamber (10 hours overnight). Measurements of body characteristics, fitness level (maximal test), movement efficiency, and sleep quality will be repeated during the final visit. Subjects from both groups will wear a tri-axial accelerometer for movement registration (DirectLife active monitor) for two weeks at baseline, after 6 months and after 12 months. A diary will be used to report when one gets up in the morning, goes to bed at night, and to report periods when not wearing the device during the day.

There are no risks associated with the tests and measurements, except for the maximal test. This test can cause fatigue. The medical screening will minimize risks of injuries. Participation to the training is a requisite for the participation as intervention subject. Risks of injuries during this training

will be also minimized by the supervision during all sessions by a training instructor.

Subjects will receive 40 euro for every night spent at the university, 30 euro for every assessment of fitness level, and 10 euro for each measurement of movement efficiency (40  $\times 2 + 30 \times 2 + 10 \times 2 = 160 \times$ ). Transport allowances will also be provided to both groups for each visit.

# Contacts

**Public** Universiteit Maastricht

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# **Trial sites**

# **Listed location countries**

Netherlands

# **Eligibility criteria**

#### Age

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

## **Inclusion criteria**

No fitness activity in the previous year, to amplify training effects on movement efficiency and quality of sleep.

Body mass index between 20 and 30 kg/m2, obesity limits the training capacity of subjects. Signed informed consent by the participants.

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# **Exclusion criteria**

Age below 50 years;

Body mass index below 20 kg/m2 or above 30 kg/m2;

Cardiologic issues (Cardiac insufficiency, myocardial infection, angina pectoris, hyperhypotension), orthopaedic issues (arthrosis, prosthesis or reduced functionality of lower limbs) or neurologic diseases (Alzheimer, Parkinson, epilepsy, history of strokes) as evaluated by our physician. If any abnormality is revealed, our physician will evaluate the possibility of inclusion. An ECG at rest will be screend by a researcher experienced in reading ECG\*s. In case of any abnormal reading in the ECG the subject will be excluded. Both the subject and his general practitioner will be informed in case of health issues, with the agreement of the subject (informed consent);

Pregnancy or lactation.

# Study design

## Design

Primary purpose: Basic science	
Masking:	Open (masking not used)
Allocation:	Non-randomized controlled trial
Intervention model:	Other
Study type:	Interventional

## Recruitment

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NL	
Recruitment status:	Pending
Start date (anticipated):	01-11-2012
Enrollment:	60
Туре:	Anticipated

# **Ethics review**

Approved WMO	
Date:	22-10-2012
Application type:	First submission

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Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO	07 11 2012
Date:	07-11-2012
Application type:	Amendment
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** ClinicalTrials.gov CCMO ID NCT01609764 NL41052.068.12