Identification and characterization of community-dwelling older people with sarcopenia.

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The objective of this study is to obtain insight in the characteristics of sarcopenic versus non-sarcopenic community-dwelling older people.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Muscle disorders
Study type	Observational invasive

Summary

ID

NL-OMON39890

Source
ToetsingOnline

Brief title
MaSS - Maastricht Sarcopenia Study

Condition

- Muscle disorders

Synonym
Loss of muscle mass and function - Sarcopenia

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Danone Research,Danone Research;Wageningen;Nederland.

Intervention

Keyword: Economic outcomes, Health outcomes, Prevalence, Sarcopenia

Outcome measures

Primary outcome

Characteristics (nutritional status, physical activity) of sarcopenic versus

non-sarcopenic community-dwelling older people.

Secondary outcome

Prevalence of sarcopenia, falls, frailty, activities of daily living, quality

of life, care use (health care costs).

Study description

Background summary

Sarcopenia is an age-related decline in muscle mass, strength and physical performance, and is recognized as a geriatric syndrome. Sarcopenia by itself or as a major component of frailty is associated with a risk of adverse outcomes e.g. physical disability, increased risk of falls and fractures, poor quality of life, loss of autonomy and independence, and death. Depending on the diagnostic criteria, it is estimated that the prevalence of sarcopenia in community-dwelling people above the age of 60 years varies between 10 and 50%. As sarcopenia is relatively prevalent and because it increases the risk of disability and the use of healthcare resources and institutionalization, the economic burden for the healthcare system is great. Considerable evidence suggests that sarcopenia is a partially reversible cause of disability and can benefit from intervention, particularly at its early stages.

Study objective

The objective of this study is to obtain insight in the characteristics of sarcopenic versus non-sarcopenic community-dwelling older people.

Study design

This study will be a cross-sectional study in the following settings: community-dwelling persons (n=252), including people living at home without

home care, with home care, in an assisted living facility or in a home for older people. Inclusion will last 1,5 year, or in case the preferred number of participants is met, shorter. There is one measurement moment and measurements will take place at the participant*s home.

During the home visit demographic data of participants will be collected. This includes age, gender, ethnicity, living situation, presence of chronic diseases, smoking, falls, BMI (height and weight) and cognitive function (Mini-Mental State Examination, MMSE; Kok & Verhey, 2002). Co-morbidity will not be an exclusion criterion per se, but participants with acute and/or uncontrolled conditions, judged by the investigator, will be excluded. Identification of sarcopenia will be done by measuring muscle mass, strength and physical performance, by respectively an bioelectrical impedance analyzer , hand-held dynamometer and the Short Physical Performance Battery (including a balance test, gait speed over a four meter course and by five chair stands). Nutritional status will be assessed by a food frequency questionnaire, the Mini Nutritional Assessment tool and a blood sample. Other questionnaires used are: Minnesota Leisure Time Physical Activity Questionnaire (level of physical activity), FRAIL scale and Fried criteria (physical frailty), GARS (activities of daily living), EQ-5D-5L (quality of life) and health care use (developed in cooperation with a professor in the field of Health Economics and HTA/economic evaluation).

Study burden and risks

In this study, serious adverse events are unlikely, since previous studies using the same battery of instruments have reported no or only few events (mainly muscle soreness). Most of the individual tests are used in clinical practice already.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Subjects must meet all of the following criteria: * 65 years old, have given informed consent, understand Dutch language and are able to perform a walk test. Subjects from both sexes will be included.

Exclusion criteria

Older people living in a nursing home, older people with active rheumatoid arthritis, post stroke status with evident lingering symptoms (paralysis, loss of motor functions), diseases of the nervous system like Parkinson and MS, active angina pectoris, dementia, older people in a wheelchair, with ICD or pacemaker and subjects unable to perform the tests, as judged by the investigator.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-05-2013
Enrollment:	252
Type:	Actual

Ethics review

Approved WMO Date:	22-04-2013
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	07-08-2013
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	ID
ClinicalTrials.gov	NCT01820988
CCMO	NL42626.068.13