

AMersfoort COhort Study on functional decline, Healthy ageing and Frailty (AMCOHF): *Identification of physical predictors for healthy ageing and early stages of frailty in people from the age of 55 years: a prospective 10-year follow-up cohort study'

Published: 19-09-2019

Last updated: 12-10-2024

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON55250

Source

ToetsingOnline

Brief title

AMersfoort COhort study on Healthy ageing and Frailty

Condition

- Other condition

Synonym

Frailty

Health condition

Kwetsbaarheid (zie s.v.p. paragraaf 6.1.1 (Primary endpoints) voor de definitie.

Research involving

Human

Sponsors and support

Primary sponsor: SOMT University of Physiotherapy

Source(s) of monetary or material Support: Eigen financiering door SOMT University of Physiotherapy. Opties voor andere bronnen zijn in overweging.

Intervention

Keyword: Frailty, Functional decline, Healthy ageing, Physical predictors

Outcome measures

Primary outcome

Variables: Factors related to trajectories of intrinsic capacity covering 7 physiological systems. Please see sections 6.1.2.1 to 6.1.2.7 of the research protocol for a description of the physiological systems, the factors and the measurements.

Primary outcome: Staying robust or the occurrence of frailty when positive on at least one of three instruments (Fried Phenotype, Rockwood Frailty Index, Groningen Frailty Indicator). Please see section 6.1.1 of the research protocol for a description of these instruments for measuring frailty.

Secondary outcome

Additional explanatory variables: Factors related to functional ability and/or (neuro)physiological factors that can explain changes in trajectories of intrinsic capacity. Please see sections 6.1.3.1 to 6.1.3.6 of the research

protocol for descriptions of these variables and their measurements.

Study description

Background summary

It is a well-known fact that the world population is ageing. This demographic shift brings along many health challenges. One of the ways to overcome these challenges is to promote healthy ageing. The World Health Organisation (WHO) considers Healthy Ageing in a holistic sense, one that is based on life-course and functional perspectives (WHO 2015). Hence, health is considered from the perspective of an adult's longitudinal trajectory of intrinsic capacity and functional ability. However, frailty is the ultimate obstacle hindering healthy ageing. Predictive models of future trajectories of functional decline and healthy aging could provide the opportunity to intervene in specific ways to counter frailty and to promote Healthy Ageing.

Study objective

The aim of this research project is to investigate whether time-related trajectories of intrinsic capacity can predict maintenance of robustness (healthy ageing) or the onset of frailty in persons aged 55 to 75 over a period of 10 years. In the long term, the results of this project will allow (clinicians, policy makers) to differentiate proactively those persons who will remain fit and independent from those who are apparently fit but who are at risk of becoming frail.

Study design

Prospective cohort study with reassessment every 2.5 years for a total follow-up of 10-years.

Study burden and risks

Based on our previous experiences from a similar research, we estimate the medical screening by the physician, the filling out of the questionnaires and the physical measurements to last approximately 3 hours. These measurements take place every 2.5 years, in total 4 times over a period of 10 years. The questionnaires will be filled in every year (30 minutes). The medical screening only takes place at baseline.

To our knowledge, the literature does not indicate that risks are associated with the measurements. A venepuncture can sometimes be accompanied by a

sensation of inconvenience and/or a small hematoma. The irradiation related to a DXA scan is extremely low (corresponding to a few days walking in open air). Exercise tolerance tests and muscle performance tests can give rise to feelings of tiredness and muscle soreness.

Contacts

Public

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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 aged between 55 and 75 years, who are living independently in the city of Amersfoort (the Netherlands) and who understand spoken and written are eligible to participate. All participants will provide written informed consent. After signing informed consent, each participant will first undergo a medical screening by a physician in order to exclude any contra-indications for participation to the test battery. Those who are non-frail at baseline (i.e.

robust on three frailty scales: score=0/5 for the Fried phenotype, score<0.25 for the Rockwood Frailty Index as operationalised by Collerton et al. and score<4/15 for the Groningen Frailty Indicator) will be included in the longitudinal study and invited to be reassessed for potential early markers of frailty every 2.5 years for 10 years.

Exclusion criteria

Subjects who are at baseline unable to participate in the assessments due to physical (e.g. unable to stand up or walk) or cognitive impairments (e.g. unable to understand the test instructions and/or Mini Mental State Examination score < 23/30), will be excluded as well as those with a recent (past 6 months) diagnosis of cancer and/or who had surgery, chemotherapy or radiotherapy within the past 6 months or scheduled for the near future.

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 23-06-2022

Enrollment: 3000

Type: Actual

Ethics review

Approved WMO

Date: 19-09-2019

Application type: First submission

Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO	
Date:	09-12-2021
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO	
Date:	29-08-2022
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO	
Date:	30-09-2024
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL70141.096.19