Sarcopenia and Physical fRailty IN older people: multi-componenT Treatment strategies

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

Summary

ID

NL-OMON44113

Source
ToetsingOnline

Brief title
SPRINTT

Condition

- Muscle disorders

Synonym
Physical frailty; Physical debility

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: IMI,Innovative Medicines Initiative

Intervention

Keyword: Intervention, Multi-component treatment strategies, Physical frailty, Sarcopenia

Outcome measures

Primary outcome

The primaire efficacy endpoint is the Incidence of mobility disability defined as incident inability of the participant to complete a 400-m walk within 15 min without sitting, help of another person, use of a walker, or stopping for more than 1 minute at a time.

Secondary outcome

The secondary efficacy endpoint are: changes in physical performance measures, body composition, anthropometric parameters, nutritional status, quality of life, cognitive function and mood, incidence of falls, differences in use of healthcare services and mortality rate.

Study description

Background summary

The demographic transition Europe has experienced over the last several decades poses an unprecedented challenge for both a societal and healthcare perspective. The existing healthcare systems built around the traditional medical paradigm of patients suffering from a single acute illness are largely unprepared to face the increasing demands for health services that can specifically address the medical needs of older, multi-morbid people 18. It follows that, on the one hand, a large and growing segment of the older European population is currently suffering from medical conditions that cannot be efficiently managed by the existing healthcare services. On the other hand, although prolongation of life remains an important public health goal, of even greater significance is that extended life includes preservation of the capacity to live independently and function well. Indeed, disabling conditions have shown to be extremely burdening for the individual as well as for the sustainability of healthcare systems 19. In this scenario, the geriatric

syndrome of frailty gains special interest and importance.

The recognition of sarcopenia as a major component of PF implies that interventions specifically targeting the skeletal muscle may provide therapeutic and preventive advantages against frailty and its clinical correlates. However, although observational studies and some RCTs have suggested a positive effect of regular physical activity (PA) and nutritional interventions on improving physical function and/or reducing symptoms of disability in healthy older individuals and those at risk for mobility disability, definite evidence from high-quality, large-scale clinical trials is still lacking. In this regard, it is important to recognise that short-term gains in intermediate outcomes of PA programmes, such as strength and aerobic capacity, are insufficient to prove that such programmes can truly prevent frailty and disability.

The SPRINTT long-term clinical trial is part of a larger a project being conducted under the auspices of IMI, and will focus on PF&S in older persons. The SPRINTT project is geared to produce significant advancements in the management of frail elders by promoting a consensus among academia, regulators, industry, and patients* representatives. The SPRINTT project will produce novel and meaningful data on a large sample of *real-practice* older adults to define reference values specific for the European population to be potentially used in the future for regulatory and research purposes.

Study objective

The primaire objective is to evaluate the effectiveness of a multicomponent intervention (MCI) programme (physical activity [PA], nutritional counselling/dietary intervention, and information & communication technology [ICT] intervention) compared with a healthy aging lifestyle education (HALE) programme on the hazard rate of mobility disability, in non-disabled older people with physical frailty and sarcopenia (PF&S). The secondary objectives are: to compare and evaluate the MCI and the HALE programme on relevant health-related outcomes, predicting outcomes, safety and tolerability; to refine the definition of PF&S and evaluate and qualify the role of the different variables and biomarkers in predicting outcomes and to develop a health economic model for the clinical take-in-charge of PF&S.

Study design

International, multicentre, single-blind, 2 parallel groups, randomised trial.

Intervention

: Duration of the intervention will be 24 months; an extension up to 36 months may be proposed based on study power consideration. Participants will be

randomly divided into two intervention groups: the Multi-Component Intervention (MCI) groups or the Healthy Aging Lifestyle Education (HALE) group. During the study, participants in both groups could be prescribed vitamin D supplementation in case of insufficiency or deficiency, in accordance with their primary care physician. The MCI programme will consist of following elements: a PA program (including aerobic, strength, flexibility and balance training);a full nutritional assessment and dietary counselling; an ICT intervention. The HALE programme will consist of: regular meetings in small groups; short (5-10 min) instructor-led program of upper extremity stretching exercises at the end of the meeting.

Study burden and risks

Each participant will benefit from the supplementary clinical measurements performed during the study. Participants of the movement intervention group will exercise with guidance of a professional. The participants of the education group will receive relevant information regarding healthy aging lifestyle.The main burden of the study is it*s duration of minimal 2 and maximal 3 years and compliance to the research protocol. The risks of the study are comparable with those of regular health care.

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

- Participants have to be willing to be randomised to either intervention group and to follow study protocol
- Men and women
- Aged 70 years and older
- SPPB score ranging between 3 (included) and 9 (included)
- Ability to complete 400-m walk test within 15 minutes without sitting down, the help of another person or the use of a walker
- Presence of low muscle mass according to results from a DXA scan and in agreement with the Foundation for the National Institutes of Health Sarcopenia Project (FNIH) reports.

Exclusion criteria

- Unable or unwilling to provide informed consent or accept randomisation in either study group
- Plans to relocate out of the study area within the next 2 years or plans to be out of the study area for more than 6 consecutive weeks in the next year
- Nursing-home residence
- Household member enrolled in the study
- Current diagnosis of schizophrenia, other psychotic or bipolar disorder
- Consumption of more than 14 alcoholic drinks per week
- Difficulty communicating with the study personnel due to speech, language, or (non-corrected) hearing problems
- MMSE lower than 24/30
- Severe arthritis (e.g., awaiting joint replacement) that would interfere with the ability to participate fully in either study arm
- Cancer requiring treatment in the past 3 years, except for non-melanoma skin cancers or cancers that have an excellent prognosis (e.g., early stage breast or prostate cancer)
- Lung disease requiring regular use of supplemental oxygen
- Inflammatory conditions requiring regular use of oral or parenteral corticosteroid agents
- Severe cardiovascular disease (including New York Heart Association [NYHA] class III or IV congestive heart failure, clinically significant valvular disease, history of cardiac arrest, presence of an implantable defibrillator, or uncontrolled angina)
- Upper and/or lower extremity amputation
- Peripheral arterial disease Lériche-Fontaine 3 or 4
- Parkinson*s disease or other progressive neurological disorder

- Renal disease requiring dialysis
- Chest pain, severe shortness of breath, or occurrence of other safety concerns during the baseline 400-metre walk test
- Current participation in a structured PA program, physical therapy or cardiopulmonary rehabilitation
- Current enrolment in another RCT involving lifestyle, nutrition, or pharmaceutical interventions
- Other medical, psychiatric, or behavioural factors that in the judgment of the principal investigator may interfere with the study participation or the ability to autonomously follow either the MCI or the HALE programmes
- Other illness of such severity that life expectancy is expected to be less than 12 months
- Clinical judgment concerning safety or non-compliance

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-08-2016
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	30-03-2016
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit

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	NCT02582138
CCMO	NL54645.068.15