Old and well-functioning; Determinants of PReservation Of Function in ELderly

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The aim of this project is to gain insight in which somatic, cognitive and psychosocialfactors contribute to preservation of functioning, in order to identify older people with potentialrisk of functional decline in an early stage and develop...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cognitive and attention disorders and disturbances
Study type	Observational invasive

Summary

ID

NL-OMON37951

Source
ToetsingOnline

Brief title
PROFIEL

Condition

- Cognitive and attention disorders and disturbances
- Age related factors
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
decrease in functioning

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: elderly/ older people, preservation of function

Outcome measures

Primary outcome

The main outcome parameter will be functional status (being able to function independently). It will be measured using the instrument prescribed in the minimal dataset. i.e. KATZ-15, and the physical performance score by Guralnik.

Secondary outcome

Use of care which was not planned will also be an important outcome parameter. Characteristics of somatic, functional, cognitive and psychosocial status will be assessed as potential determinants. Somatic status will be characterized with vascular status (large artery stiffness and carotid intima-media thickness) and bone and body fat status (bone mineral density, lean and fat mass, intra-abdominal and peripheral fat). Functional status will be further characterized by hand grip strength, peak flow measurement, six minute walking test and physical activity. Cognitive status will be assessed in the domains of memory, processing capacity and speed, and executive functions. Psychosocial status will be characterized by quality of life, depression, anxiety and panic disorder, and self management ability questionnaires. As much as possible we will not only assess what people are capable of doing, but also what they actually do. Whenever possible we will use similar tests or measurements as were used at the baseline visit, to maximize the potential to study changes

over time in addition to the current status.

Study description

Background summary

According to the majority of older people preservation of physical and psychosocial functioning is important in their live. However, two third of older people have one or more chronic disease, with a mean number of conditions of 2.5. For older people these chronic conditions become problematic as soon as these conditions threat daily live activities and vitality. Functional decline and loss of vitality can change the balance in daily living negatively with the risk of a cascade breakdown. This group of older people is vulnerable; this vulnerability is often defined as *frailty*. Although frailty is studied in a growing number of studies, the pathway to frailty is almost unknown. Age, disease, loss of muscle mass and bone mineral density are considered as key factors in the process of frailty. The lack of understanding of the physiology and etiology of frailty causes a problem in the development of effective preventive interventions. Preventive interventions could enable people, even in old age and with chronic conditions, to live independently the life they choose to live. Cardiovascular diseases (CVD) such as coronary ischemic disease, heart failure and cerebrovascular accidents are prominent among the chronic conditions that predispose elderly people to functional limitations and disability. Because of the aging of the population, the number of people with functional limitations and disability will only increase.

Many elderly develop one or more eye conditions threatening that independency. A decline in visual functioning and eye disease change the balance in daily life with potential drastically consequences: increased dependency on others and potential admission to a nursing home.

Several aspects of visual functioning are affected by geriatric (old age) disease or ocular complications of chronic disease, such as visual acuity, visual field, contrast sensitivity, refraction, or glare. Exact numbers of visual challenges of independent living elderly are lacking as ocular changes are not routinely registered in physician*s registries and patients are not routinely screened nor do they seek medical care as they consider visual decline a normal deterioration with age. The impact of visual impairment and effects of even *normal* age-related functional decline may therefore be underestimated.

To our knowledge, no study addressed the effect or combined effect of several visual aspects including straylight (glare) and ocular health on activities of

daily living in independently living elderly.

Study objective

The aim of this project is to gain insight in which somatic, cognitive and psychosocial
factors contribute to preservation of functioning, in order to identify older people with potential
risk of functional decline in an early stage and develop interventions to prevent or delay
functional decline to enable older people to stay independent and able to take care of themselves.

The aim of the additional study is to gain insight in which factors (i.e. somatic, psychosocial) contribute to the preservation of visual functioning and in which aspects of vision influence the individual*s well being with respect to physical, social and mental functioning. The knowledge will enable the development of preventive interventions in older people to stay independent and take care of themselves.

Study design

a longitudinal population-based study

Study burden and risks

The participants will be invited for 3 visits, because the program (measurements, tests and questionnaires) will be too intensive for 1 day. The third visit will be at a different location. Fasting bloodsamples will be collected and the six minute walking test will be performed. No serious adverse events were reported in numerous of studies. In only a small percentage of the participants dizziness and nausea were reported.
During the third visit pupillary dilation eye drops will be administered. Due to that, participants may experience photophobia (1-4 hours). Therefore, all participants will receive free transportation to and from the research center.

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

Participation in Hamlet or Frailty-study
Informed Consent

Exclusion criteria

not applicable

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-02-2010
Enrollment:	600
Type:	Actual

Ethics review

Approved WMO Date:	12-01-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	10-02-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	20-09-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	29-03-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL28151.041.09
Other	TC 1864