Monitoring of physical frailty in older people: a feasibility study

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

Summary

ID

NL-OMON37305

Source
ToetsingOnline

Brief title
Monitoring of physical frailty in older people: a feasibility study

Condition

- Other condition

Synonym
difficulty in activities of daily living, disability, frailty, physical functioning, vulnerability

Health condition

kwetsbaarheid & beperkingen in het dagelijks leven

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Elderly people, Frailty, Monitoring, Self-Management

Outcome measures

Primary outcome

The primary outcomes of the feasibility study will be technical functioning, acceptability and usability and added value of the monitoring system as experienced by elderly people and professionals. Technical functioning will be measured by recording the number of errors, technical failures, defects and their causes in a logbook. Information regarding the acceptability and usability and added value of the system will be collected during semi-structured interviews with the researcher and in logbooks that the physiotherapist will keep.

Secondary outcome

The study will provide insight into the development of parameters of physical functioning over time. Measurements of weight, balance, grip strength, and physical activity are collected for 6 months. These data will be compared to information that was collected by the physiotherapist and a questionnaire regarding health, functioning, quality of life, and care consumption. This will provide more insight into how relevant changes in the physical functioning of participants can be detected with the three devices.

Study description

Background summary

As society ages the prevalence of frailty and its adverse outcomes increases. Disability is an adverse outcome of frailty that places a strain on frail individuals and their caregivers. As a consequence, the demand for care and the use of community services increases. Combined with a decreasing number of caregivers this causes frailty to be a burden on health care systems. Technological innovations can contribute to bridging the gap between demand and supply of care in frail elderly people. During our research project, an innovative system for monitoring physical frailty indicators (weight, balance, grip strength, and physical activity) in community-dwelling older people was developed. The system gives feedback to the user about (changes in) his/her physical functioning and warns the user and/or care providers if a change in the indicators occurs. A small scale pilot-study has already been conducted with the monitoring and feedback system. The results from the pilot-study were used to optimize the monitoring and feedback system.

Study objective

The primary objectives of this feasibility study are to provide insight into the usability, acceptability, technical functioning, and long-term added value of the system as experienced by elderly people and professionals. The secondary objective is to gain more insight into how relevant changes in the physical functioning of participants can be detected with the three devices.

Study design

The feasibility study will be a 12-month follow-up study with 50 elderly participants who will be recruited via the expertise centre for elderly care of the Orbis Medical Centre in Sittard. At baseline, the researcher will visit the participants in their home to install the system and to explain how the devices should be used. During the same visit, the participants will receive a questionnaire containing questions regarding their health, functioning, quality of life, and care consumption. After 1, 3 and 6 months, the researcher will have a face-to-face semi-structured interview with the participants regarding their experiences with the monitoring and feedback system in the past period. The participants will use the monitoring and feedback system only during the first 6 months of the study. After 6 and 12 months follow-up the participants will be asked to complete the same questionnaire that was conducted at baseline.

Intervention

The system consists of three devices that will be used daily by the participants; a bathroom scale monitoring weight and balance, a Grip-ball monitoring grip strength and a mobile phone with a built-in accelerometer monitoring physical activity. The information about these physical indicators is sent to the mobile phone via blue-tooth. The users will receive feedback regarding their own physical functioning on the screen of the mobile phone using text and/or spoken messages. The mobile phone also sends the information to an online database that is accessible for the treating geriatrician from Orbis Medical Centre. Besides that, the physiotherapist who is involved in the study will also have access to the database. This physiotherapist will visit the participants after they have used the three devices for 2 weeks, 2, 4, and 6, months. During the visits the physiotherapist will examine the physical functioning of the participants. Besides that, the physiotherapist will discuss the measurements that were performed with the three devices in the previous weeks with the participant. Based on that, the physiotherapist and participant will collaborate to set realistic and personally relevant goals that relate to the improvement or maintenance of physical functioning. The physiotherapist will support the participant in achieving these goals by providing tailored advice. This advice in combination with the feedback that is provided via the mobile phone will support the participants in the self management of their own physical functioning.

Study burden and risks

The risk that is associated with participation is minimal because the current level of physical functioning will be the starting point of the therapy that participants receive from the physiotherapist. There is a small possibility that participants will focus too much on the measures of their physical functioning because they are asked to measure this daily during the study whereas they do not do this in their normal lives. However, during the pilot-study that was conducted earlier with the system, elderly participants indicated that the daily feedback did not scare them at all.
The benefit that opposes the burden mentioned above is that participants get a detailed insight into their own physical functioning. Because of this insight, they receive care and advice from a physiotherapist that is tailored to their own needs which might result in an improved physical functioning.

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

Inclusion criteria are: 70 years or older, community-dwelling, Mini Mental State Examination (MMSE) > 23, movement/mobility/functioning problems, sufficient mastery of Dutch language, and able to step onto a bathroom scale independently.
Besides that, people have to answer *yes* to at least one of the following questions:
- Have you unintentionally lost a lot of weight in the past 6 months (5 kg or more)?
- Do you usually have the feeling that everything takes a lot of effort?
- Do you usually have the feeling that you cannot get going?
- When crossing the street at a traffic light, do you have difficulty reaching the other side before the light turns red?
- Do you have problems in your daily life due to low grip strength?
- Do you walk less than 2 hours a week/or cycle less than 1.5 hours a week?

Exclusion criteria

Exclusion criteria are: planned admission to a nursing home/hospital during the period of the study, being confined to bed, serious visual or hearing impairments, contra-indication for exercise.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-07-2013
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	22-10-2012
Application type:	First submission
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	NL41986.096.12