Monitoring of physical frailty in older people; an innovative system supporting self management and care.

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

Summary

ID

NL-OMON36147

Source
ToetsingOnline

Brief title
Monitoring of physical frailty in older people

Condition

- Other condition

Synonym
disability, Frailty, impairment, vulnerability

Health condition

Frailty, disability

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Elderly, Frailty, Monitoring, Self management

Outcome measures

Primary outcome

The primary outcomes of the pilot study will be technical functioning, usability, acceptability, comprehensiveness, and feasibility of the monitoring and feedback & advisory system. Technical functioning will be measured by recording the number of errors, technical failures, defects and their causes in a logbook. Information regarding the usability, acceptability, comprehensiveness, and feasibility of the system will be collected during semi-structured interviews with the researcher and in logbooks that the physiotherapist will keep.

Secondary outcome

The pilot 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 3 months. These data will be compared to information that was collected by the physiotherapist regarding health events, periods of illness, and physical functioning. This will provide better 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, gait, muscle strength, and physical activity) in community-dwelling older people was be developed. The system gives feedback to the user about his/her functional status and warns the user and/or care providers if a change in the indicators occurs. Before the system can be evaluated it will be tested in a small scale pilot study.

Study objective

The primary objectives of the pilot study are to provide insight into the technical functioning, usability, acceptability, comprehensiveness, and feasibility of the monitoring and feedback & advisory system. Improvements will be made to the system based on the information that was obtained during the pilot study. 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

For the pilot study, 5 participants will be recruited from the falls clinic of the Orbis Medical Center in Sittard. The duration of the pilot study will be 3 months. At baseline, the researcher will visit the participants in their home to install the system and to explain how the devices should be used. At the end of every month, the researcher will have a face-to-face semi-structured interview with the participants.

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 and gait. The information about these physical indicators is sent to the mobile phone via blue-tooth. The users will receive feedback and advice regarding their own physical functioning on the screen of

the mobile phone using text and/or spoken messages. The tailored advices relate to individually relevant and realistic goals that aim to maintain or improve physical functioning. The mobile phone also sends the information to an online database that is accessible for the physiotherapist that is involved in the pilot study. The physiotherapist will visit the participants after they have used the three devices for 2, 6, and 10 weeks. 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 and advice 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 pilot study whereas they do not do this in their normally.
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 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

- Community-dwelling
- Age: 70 years and older
- Frailty symptoms: moderate to severely frail as mearured by a score of 6 or higher on the Groningen Frailty Index (GFI), participants should score on the physical element of the GFI.

Exclusion criteria

- On a waiting list for intramural care
- Serious cognitive impairments: Mini Mental State Examination (MMSE) < 20
- Insufficient mastery of Dutch language
- Suffering from a fast progressive disease
- Being confined to bed
- Suffering from severe visual or hearing impairments.

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):	07-02-2012
Enrollment:	5
Type:	Actual

Ethics review

Approved WMO

Date:	10-05-2011
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	NL35961.096.11