# Validation of the Mobility Monitor for detecting mobility related activities

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The aim of this study is to determine the technical validity (sensitivity and specificity) of the Mobility Monitor for detecting and monitoring postures and walking in a home-based setting with frail and non-frail older adults. The targeted...

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

## Summary

### ID

NL-OMON36479

**Source**
ToetsingOnline

**Brief title**
Mobility Monitor: technical validity and practical feasibility

### Condition

- Other condition

**Synonym**
Niet van toepassing

**Health condition**

Geen, in basis gezonde ouderen als proefpersonen.

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen
**Source(s) of monetary or material Support:** ZonMW

## Intervention

**Keyword:** Body-worn sensors, Elderly, Home-based monitoring (ADL), Mobility

## Outcome measures

### Primary outcome

The main endpoint is to determine whether the Mobility Monitor detects the mobility categories adequately, with a sensitivity and specificity of at least 90%.

### Secondary outcome

A secondary goal is to assess user acceptance and practical feasibility of the device, by means of a questionnaire. A third goal is to compare two subjective, self-report means of past physical activity (the SQUASH and PASE questionnaires) and objective measurement of physical activity with the Mobility Monitor.

# Study description

### Background summary

The percentage of elderly in our society grows in a relative as well as an absolute fashion. In The Netherlands, the group of people aged 65 comprised 14% of the population, and by 2040 this percentage will be 23%. In addition to this, due to for instance the more advancing health care, the average age of people keeps rising steadily. This trend enlarges the burden on health care further because older people generally are in need of more chronic care and monitoring, and that way the growing age problem accordingly brings on the issue of shortage of doctors, nurses and other resources in health care. Thus, efficiency in health care in financial respect as well as resources is

becoming a more and more relevant item in health research. Following from the expected trends marked above, one of the major areas in which progression can be accomplished is the area of chronic home-based care and monitoring for the elderly and several chronic patient groups.
A recent development in this area is the Mobility Monitor, a necklace-worn tool to measure activity, balance and power in detecting and monitoring postures and walking. This device is aimed to function in detection of functional decline and it's consequences in the elderly. It will also be used in activity monitoring and stimulation programs, as previous research indicates that physical activity has many beneficial effects on health and disease burden in older people and other chronic patient groups.
At this moment, the Mobility Monitor is being tested on technical characteristics. In this study, the technical validity (sensitivity and specificity) of the Mobility Monitor for detecting postures *sedentary* (sitting, lying) and *active* (standing and walking) in a home-based setting with frail and non-frail older adults will be assessed, as well as the user acceptability and practical feasibility of home monitoring with the device.

**Study objective**

The aim of this study is to determine the technical validity (sensitivity and specificity) of the Mobility Monitor for detecting and monitoring postures and walking in a home-based setting with frail and non-frail older adults. The targeted sensitivity and specificity values for the different postures and activities are > 90%. Secondary goals are to assess the practical feasibility and the user acceptance of the method, both in the direct use of the mobility monitor in the study and by means of a questionnaire filled in by the participants. A third objective is to compare two subjective, self-report means of past physical activity (the SQUASH and PASE questionnaires) and objective measurement of physical activity with the Mobility Monitor.

**Study design**

The study will be an observational validation study of the prototype monitoring device Mobility Monitor.
The measurements will take place in the subjects' home environment. The first measurement contact will consist of filling out several questionnaires on health status, fear of falling, and activities of daily living, and completing a standardized movement protocol and free movement period wearing the sensor. This meeting will last about 1,5 hours. The next part of the measurements will be an independent week long measurement wearing the sensor in their regular daily life. The last measurement contact will be to collect the sensor and checking of several additional questionnaires, which will concern the user's opinion about the device and his or her physical activity pattern during the week measurements and had to be completed before this contact. This will last

about 15 minutes.

**Study burden and risks**

Subjects will be monitored during a fixed protocol and semi-free movement in their home environment in one session while being simultaneously monitored by both video and our neck-worn Mobility Monitor. Afterwards the person will wear the monitor for a full week in daily life non-stop.
The two groups, frail and non-frail, will be regarded together, separately and in comparison to each other on abovementioned calculations of sensitivity and specificity of the device, as well as user acceptance and practical usability.
Is the device accurate and feasible in community-dwelling elderly, and are these features better in frail or in non-frail older persons? From these results, implications for further research and fine-tuning will be given.

# 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

- 70 up to and including 80 years of age
- Community-dwelling
- Be able to walk at least 10m, unsupported or using a walking device such as a cane or rollator

### Exclusion criteria

- Total hip replacement surgery in the previous 6 months
- Visual problems to a degree that makes it impossible for the subject to accurately read the questionnaires or walk around safely
- Having had a stroke within the last 6 months
- Parkinson*s disease stage 4 or 5
- Other neurologic diseases that can impair daily functioning (for instance dementia).

## Study design

### Design

**Study type:** Observational non invasive

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

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 17-06-2011 |
| Enrollment: | 20 |
| Type: | Actual |

## Ethics review

Approved WMO

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| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |

# 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 | NL35121.042.11 |