ISRCTN65882886 https://doi.org/10.1186/ISRCTN65882886

The effect of a mobile safety alarm on going outside, feeling safe, fear of falling and quality of life in community living older persons.

Submission date 20/07/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 02/09/2010	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 02/09/2010	**Condition category** Other	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Sophia de Rooij

Contact details
Academic Medical Center
Department of Internal Medicine, F4-159.1
section of Geriatric Medicine
Meibergdreef 9
Amsterdam
Netherlands
1105 AZ
s.e.derooij@amc.uva.nl

Additional identifiers

Study information

Scientific Title
The effect of a mobile safety alarm on going outside, feeling safe, fear of falling and quality of life in community living older persons: A randomised controlled trial

Study objectives
What is the effectiveness of a mobile alarm in changing the frequency of going outside of older people and what are their experiences about safety, fear of falling and quality of life?

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Medical Ethical Committee of University of Amsterdam/Academic Medical Centre Amsterdam reviewed this study and confirmed that as a social study, it did not require ethics approval.

Primary study design
Interventional

Study design
2 armed randomised controlled trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
New communication technology and services for older persons

Interventions
The intervention consisted of a mobile safety alarm with an inbuilt drop sensor. The mobile alarm was a prototype in development and uses a positioning system patented Europe-wide. The alarm went off by pressing a button. An integrated hand free function allowed the user to speak to personnel of an emergency call centre, even if the user didnt hold the device at their ear. If the user had fallen, the system automatically registered this and independently made a voice call to the emergency call centre. The Butler used a new kind of positioning system. The user of the alarm was located in 3 steps: their rough location was found via the cell phone network: from close-range, their position was pinpointed via an integrated tracking device and a beeping sound emitted from the device. This procedure allowed first-aiders to reliably find someone, even where conventional positioning systems such as GPS fail, such as in buildings or underground garages.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Primary outcome measure was change in the frequency of going outside. The frequency of going outside will be assessed in a telephone interviews at baseline and at 1, 2, 4 and 6 months follow-up.

Key secondary outcome(s)
The following secondary outcomes will be assessed in a telephone interview at baseline, and at 1, 2, 4 and 6 months follow-up:

1. Fear of Falling (Visual Analogue Scale [VAS]-FOF)
2. Unsafe feelings (VAS for Feeling Unsafe)
3. Quality of Life (VAS-EQ-5D).
4. Falls (data on falls were collected prospectively with use of fall calendars)

Completion date
31/03/2010

Eligibility

Key inclusion criteria
1. Having a home-based alarm
2. Community-dwelling
3. Being able to go outside alone
4. Willingness to participate

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
Confined to bed

Date of first enrolment
16/07/2009

Date of final enrolment
31/03/2010

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Center
Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation
City council Amsterdam (Netherlands)

Funder(s)

Funder type
Government

Funder Name
City council of Amsterdam (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration