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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 [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 02/09/2010	**Overall study status** Completed	
Last Edited 02/09/2010	**Condition category** Other	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

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.

Study design
2 armed randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet.

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 measure
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.

Secondary outcome measures
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)

Overall study start date
16/07/2009

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

Age group
Senior

Sex
Both

Target number of participants
100 participants in the intervention group and 100 participants in the control group

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)

Sponsor details
c/o Mrs. N. Siemonsma
Department of Housing, Health and Society (Dienst Wonen, Zorg en Samenleven)
PO Box 1900
Amsterdam
Netherlands
1000 BX

Sponsor type
Government

Website
http://www.wzs.amsterdam.nl

Funder(s)

Funder type
Government

Funder Name
City council of Amsterdam (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration