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Tele-care II Generation

Submission date 09/09/2013	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 18/12/2013	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 18/12/2013	**Condition category** Other	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
The aim of the study is to see how useful it is to have a technically-based assistance system in the houses of older people in order to decrease morbidity and the economic and social consequences of non-intentional lesions at home (home accidents).

Who can participate? :
People who are 75 years old or more, either sexes, with full mental faculties and able to move about by themselves, who are users of the Tele-health service (1st generation) residing in selected regions in Spain and who have accepted to participate in the study.

What does the study involve?
Participants are randomly allocated to one of two groups: intervention group or control group. All participants attend an interview which includes completing a questionnaire about accident rates and home conditions in the 12 months before inclusion in the study/
For the intervention group, a number of devices are installed such as smoke and gas detector, fall detector, bed and armchair pressure detector and presence detector. No devices are installed for the control group.
There is a follow-up visit 6 months in the study and a final visit (same questionnaires).

What are the possible benefits and risks of participating?
Benefits include the early detection of events (falls, burns, etc.) in the home that would lead to the intervention of a provider and/or entry in a healthcare centre.

Where is the study run from?
In 6 regions (autonomous communities) in Spain: Andalucía, Aragón, Cantabria, Castilla y León, Ceuta, Galicia y Murcia.

When is the study starting and how long is it expected to run for?
The study started in July 2011 and is expected to complete in July 2014.

Who is funding the study?
Ministry of Health and Social Affairs (Ministerio de Sanidad y Asuntos Sociales), Spain

Who is the main contact?
Spanish Red Cross (Cruz Roja Española)

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
23

Study information

Scientific Title
Care system in older and disabled peoples' homes based on new technologies: Tele-care II Generation

Acronym
TAD II Generation

Study objectives
To evaluate the efficiency of installing a techno-care system in elderly peoples' homes in order to minimise morbidity and also the economic and social costs derived from non-intentioned lesions at home (domestic accidents).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee and Animal Welfare Research (Comité de Ética de la Investigación y de Bienestar Animal)

Primary study design
Interventional

Study design
Prospective controlled randomized open two parallel arms (1:1) study

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Not applicable

Interventions
Randomization with four stratification criteria in order to select the two groups

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Mean number of hospitalizations in each group
2. Mean time of stay in hospital.
The number of hospitalizations and the mean time of stay in hospital will be provided by monitoring and interviewing users and will be corroborated by obtained from Health Records from the healthcare information systems.
3. The quality of life will also be measured from the interviews.
4. The rate of events resulting in the provider going to the house, the stay and use of day centers will be measured from the platform of the social care provider

Key secondary outcome(s)
1. Mean total cost per person, including health and social care costs
2. Global rate of events (falls, burns, etc) resulting in the provider going to the house or the entry in a healthcare center
3. The entry rate in residences or socio-sanitary centers
4. The rate of use of day centers
5. Quality of life of users and quality of life of (usual) carers
6. The mean time of attention (formal and informal care)

Completion date
30/06/2012

Eligibility

Key inclusion criteria
1. 75 or more years old, both sexes with good mental faculties
2. Users of Tele-care service 1st generation residing in the community
3. Who accepted to participate in the study (written informed consent)
4. Able to move on and get around by themselves

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
1. People who refuse to participate
2. People with terminal condition, immobilized patients, people with psychiatric diseases and / or cognitive deterioration that prevents them from participating in the research (according to the research team in charge in the area)
3. Displaced or institutionalized people
4. People who cannot change position without help and without supervision
5. People who cannot walk or move in their home without help and without supervision
6. People who spend long time periods (more than 3 months) out of their usual residence (e.g. in relatives' houses)

Date of first enrolment
01/07/2011

Date of final enrolment
30/06/2012

Locations

Countries of recruitment
Spain

Study participating centre
Avenida Reina Victoria 26
Madrid
Spain
28003

Sponsor information

Organisation
Spanish Red Cross (Spain)

Funder(s)

Funder type
Government

Funder Name
Project funded by Ministry of Health and Social Affairs (Ministerio de Sanidad y Asuntos Sociales), Spain

Funder Name
The installed devices belong to the company Tunstal, Spain

Funder Name
The project provider is the Spanish Red Cross (Cruz Roja Española), Spain

Funder Name
Several provincial delegations belonging to the 6 autonomous communities participate, Spain

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration