

Tele-care II Generation

Submission date 09/09/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 18/12/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 18/12/2013	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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)

Study design

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

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 the contact details below to request a patient information sheet

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 measure

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

Secondary outcome measures

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)

Overall study start date

01/07/2011

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

Age group

Senior

Sex

Both

Target number of participants

3764

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
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Sponsor information

Organisation
Spanish Red Cross (Spain)

Sponsor details
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Sponsor type
Charity

Website
<http://www.cuzroja.es>

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

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