ISRCTN68655887 https://doi.org/10.1186/ISRCTN68655887

Comparing different strategies for chronic patients self-control in dependent patients living at home

Submission date
07/06/2017

Recruitment status
No longer recruiting

Registration date
04/08/2017

Overall study status
Completed

Last Edited
04/08/2017

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Since 2005 a set of interventions aimed at patients with chronic (long-term) diseases were introduced in order to reduce the re-admission rate and improve quality of life. The aim of this study is to assess whether these questionnaire-based interventions are also effective in home-based frail patients at detecting exacerbation (worsening) of chronic conditions.

Who can participate?
Frail patients who are living at home

What does the study involve?
Participating Primary Health-Care Centers are randomly allocated to either the experimental group or the control group. Within the experimental group, participants are randomly allocated to phone follow-up or follow-up using the mobile phone application. Participants in the phone group call the case nurse every 2 weeks or any time the patient has any alarm signs or symptoms. Participants in the app group answer a short questionnaire every morning and the app compares the situation with the previous one to see if the patient has worsened or stayed the same, then suggests either a change in treatment (sent to the doctor to confirm it) or to stay with the previous treatment. Mortality (death rate), emergency department visits, consultations, phone calls, number of visits, quality of life and quality of care are compared between the two groups.

What are the possible benefits and risks of participating?
Participants may benefit from better care and better perceived quality of life. No risks are anticipated because this is not a treatment intervention, it is a different way of providing care to these patients.

Where is the study run from?
Hospital Universitario Donostia (Spain)

When is the study starting and how long is it expected to run for?
January 2017 to March 2018

Who is funding the study?
CIBER Centro de Investigación Biomédica en Red (Spain)

Who is the main contact?
Dr Jose Ignacio Emparanza
joseignacio.emparanza@osakidetza.eus

Contact information

Type(s)
Scientific

Contact name
Dr jose ignacio Emparanza

Contact details
Paseo Begiristain 115-117
San Sebastián
Spain
20014
+34 (0)943 007 147
joseignacio.emparanza@osakidetza.eus

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
EAP2016

Study information

Scientific Title
Self-control strategies in chronic diseases (at home chronic and dependent patients): a randomized controlled trial

Study objectives
The use of an app (web based) or a mobile phone can diminish the need for physical consultation and visits to the emergency department, improving perceived quality of care as compared with the conventional care in chronic patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Gipuzkoa ethics review board, 24/05/2016, ref: 05/2016

Study design
Cluster randomized trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Chronic diseases in frail patients (at-home dependent patients)

Interventions
Five Primary Health-Care Centers (PHCs) from the OSI Donostialdea are randomised to the experimental group and five PHCs to the control group. Within the experimental group (five PHCs), individuals will be randomized to telephone follow-up or follow-up using the mobile phone application. The control group receive usual care.

Phone group: Phone call every 2 weeks from the patient to the case nurse or any time the patient has any of the alarm signs or symptoms established
App group: The patient answers a short questionnaire every morning. The app compares the situation with the previous one to see if the patient has worsened or remains at the basal situation. Then suggest an action: change in treatment (send to the doctor to confirm it) or stick to the previous treatment

Mortality, emergency department visits and physical consultations in relation to the chronic process, telephone calls, number of visits and quality of life (EuroQol) and the quality of care are collected via questionnaire. The total intervention duration is 1 year, the same as the follow-up.

Intervention Type
Other

Primary outcome measure
1. Number of physical consultations, taken from information systems during the 1-year follow up
2. Number of visits to ED, taken from information systems during the 1-year follow up
3. Mortality, taken from mortality registry at the end of the 1-year follow-up

Secondary outcome measures
1. Number of admissions, registered by information systems during the 1-year follow up
2. Length of stay, the mean number of days if the patients suffers more than one admission, registered by information systems during the 1-year follow up
3. Perceived quality of care, measured using standard questionnaire at the end of the 1-year follow-up

Overall study start date
01/01/2017

Completion date
31/03/2018

Eligibility

Key inclusion criteria
1. Frail patients
2. Living at home
3. Barthel Index score lower than 60
4. Agree to participate
5. No age limits

Participant type(s)
Patient

Age group
All

Sex
Both

Target number of participants
60

Key exclusion criteria
Do not agree to participate

Date of first enrolment
01/02/2017

Date of final enrolment
31/03/2018

Locations

Countries of recruitment
Spain

Study participating centre
OSI Donostialdea. Hospital Universitario Donostia
Paseo Begiristain 115-117
San Sebastián
Spain
20014

Sponsor information

Organisation
Hospital Universitario Donostia

Sponsor details
Paseo Begiristain 115-117
San Sebastián
Spain
20014
+34 (0)943 007 147
joseignacio.emparanza@osakidetza.eus

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04fkwzm96

Funder(s)

Funder type
Research organisation

Funder Name
CIBER Centro de Investigación Biomédica en Red

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Jose Artetxe (josemaria.artecheocasar@osakidetza.eus).

IPD sharing plan summary

Available on request