

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

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 04/08/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 04/08/2017	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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  
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## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
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

## **Study type(s)**

Prevention

## **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(s)**

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

## **Key secondary outcome(s)**

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

## **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

**Healthy volunteers allowed**

No

**Age group**

All

**Sex**

All

**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

**ROR**

<https://ror.org/04fkwzm96>

## **Funder(s)**

### **Funder type**

Research organisation

### **Funder Name**

CIBER Centro de Investigación Biomédica en Red

## **Results and Publications**

### **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](mailto:josemaria.artecheocasar@osakidetza.eus)).

### **IPD sharing plan summary**

Available on request