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A multicomponent frailty intervention in community-dwelling elderly persons

Submission date 04/06/2019	**Recruitment status** Suspended	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 02/08/2019	**Overall study status** Completed	
Last Edited 06/09/2023	**Condition category** Musculoskeletal Diseases	

Plain English summary of protocol

Background and study aims

Frailty is defined as a progressive, age-related decline of physiological systems. It results in a loss of reserve of intrinsic functional capacity, producing extreme vulnerability to stressors and increasing the risk of adverse events, such as dependency, institutionalisation and death. Frailty is an independent risk factor for the occurrence of adverse health events, but it is potentially reversible. However, this condition is not systematically addressed within the primary care network of the public health system, for reasons including the lack of consensus on adequate instruments with which to identify frailty among persons treated in primary care, and inadequate evidence on the effectiveness of treatment. Moreover, interventions are often performed in areas other than primary health care, or demand resources that are not readily accessible, such as nutritionists or physical trainers.

The aim of this project is to advance our understanding of how frailty should be approached in primary care. This goal will be addressed by evaluating the effectiveness of a multicomponent intervention (concerning the adequacy of pharmaceutical prescriptions, nutritional care and exercise) carried out in subjects with frailty, seeking to improve their functional capacity and to reduce the incidence of frailty-related adverse events.

Who can participate?

Subjects aged over 70 years living in the community, who met the criteria for frailty and who are autonomous.

What does the study involve?

The project is based on the outcomes obtained from a multicentre randomised clinical trial of subjects aged over 70 years, who present frailty, are autonomous and live in one of the two Autonomous Communities in which the trial be held. The intervention will consist of two arms: multifactorial intervention in primary health care versus usual follow-up. The unit of randomisation is the physician's patient quota and the analysis unit is the patient. The patients' condition will be followed up for twelve months. Finally, the efficiency of the intervention and its viability and adequacy will be evaluated.

What are the possible benefits and risks of participating?

All participants will be followed up in primary care, at the baseline evaluation, and after six and

twelve months. In the experimental group, we expect the patients to obtain an improvement in functional capacity and in preventing adverse events that may impair the quality of life. The study involves no risks beyond the discomfort derived from the extraction of blood at the three time points established for evaluation.

Where is the study run from?
1. Unidad de investigación de AP-OSIs Gipuzkoa, Spain
2. Hospital Costa del Sol

When is the study starting and how long is it expected to run for?
January 2019 to March 2020

Who is funding the study?
1. Instituto de Salud Carlos III, Spain
2. European Fund for Regional Development – FEDER

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
PI18/01558

Study information

Scientific Title
Tackling frailty at primary care: evaluation of the effectiveness of a multicomponent intervention through a randomized controlled trial

Acronym
InFrAP

Study objectives
The functional capacity of people with frailty can be improved and their progression to dependency reduced by applying a multicomponent intervention, developed by the primary care teams referred to.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 22/05/2019, CEI Euskadi (Ethical committee of clinical research of Euskadi, Departamento de Salud del Gobierno Vasco. C/ Donostia-San Sebastián, nº 1. 01010 Vitoria-Gasteiz, Spain; ceic.eeaa@euskadi.eus; +34 945 019 296), ref: CEIm-E_ Versión DEF 25.03.2019_ Acta 07/2019_22/05/2019
2. Approved 28/03/2019, CEI Costa del Sol (Hospital Costa del Sol. Autovía A-7 Km 187 - 29603 Marbella ,Spain; ceics.ephcs@hcs.es; +34 951 976 620) ref: 007_mar19_PI - Intervención Fragilidad

Study design
Two-arm pragmatic cluster randomized trial

Primary study design

Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Frailty

Interventions
The clinical trial will have two study arms: an experimental group receiving a multicomponent intervention and a control group receiving usual care and follow-up at a primary health care centre.
The randomisation unit will be the patient quota and the analysis unit will be composed of persons aged over 70 years presenting frailty. The patient quotas corresponding to 40 family doctors who have expressed interest in participating in the study will be identified. These quotas will be assigned to the intervention or the control group by simple random assignment, and in each one a cluster of five patients will be recruited. Thus, for each quota, all patients who meet the criteria of age (over 70 years) and level of autonomy (Barthel index > 90 points) will be systematically screened, consecutively, when they attend the health centre. These patients will be seen by the nurses taking part in the study and their compliance with the frailty criterion (SBBP) will be assessed. When frailty is established, the patient’s informed consent will be requested, and if granted, the baseline assessment will be made. If consent is refused, the patient will be excluded from the study.

The randomisation procedure will be performed as follows: the patient quotas will be allocated to the control or intervention group, randomly, once the medical professionals responsible for each quota have agreed to their participation in the project. The allocation will be carried out as randomisation by "blocks". By means of the "sample" function of the R program of statistical analysis, in each region, half of the quotas will be assigned randomly to the intervention group and the other half to the control group, simultaneously. A cluster size of 5 patients per quota will be adopted, making it necessary to recruit 100 patients per study branch (in 20 clusters of 5), to be divided equally between the two study areas.

The scheduled inclusion period is six months with follow-ups at six and twelve months after the baseline assessment. The baseline assessment and the two follow-up assessments will be made both for the intervention group and for the control group. For this purpose, the patients will be asked to attend the health centre. The nurses responsible for this operation will be trained accordingly and will be blind to the group assignment. These assessments will include questionnaires, anthropometric measurements and blood sampling. During the follow-up

period, each patient's electronic clinical history will be obtained, to extract information on prescriptions (at baseline and any changes during follow up), institutionalisation and hospitalisations.

The multicomponent intervention will be composed of the following elements:
a) Physical exercise: based on WHO recommendations for physical activity by the elderly. This component is based on the relevant indications and on the individual's level of fitness for the exercise proposed. It consists of a set of twelve muscle-strengthening exercises that are appropriate for the subject and can be performed without supervision. The patient will be advised of the number of repetitions that should be made and the frequency of performance. In addition, a follow-up plan will be provided. The patient will be evaluated by their primary health care physician who will provide and describe the use of a table of recommended exercises. In addition, a follow-up plan will be provided. The patient will be advised to perform the exercise programme five times per week, and also to take three 30-minute walks at moderate intensity every week. As no supervision is needed, the physical exercise programme is to be performed throughout the year of patient follow-up.
b) Review of polypharmacy: the patient's primary health care doctor will review the medication prescribed to each participant and give instructions for appropriate changes, if needed, according to the STOPP criteria. The Spanish version of the 2014 criteria will be used to detect potentially inappropriate prescriptions recorded on the baseline assessment of the patients in the experimental arm. Using the electronic medical record, data on all the drugs prescribed to each patient in the intervention group will be compiled, together with the dose, on the referral date. Drugs will be registered according to the name of the active ingredient. The clinical history of each patient assigned to the experimental group will be consulted to ensure compliance with the treatment criteria, according to the patient's clinical condition and the dose prescribed. The primary care physicians will then take the appropriate treatment decision, which will be recorded for subsequent evaluation. The medication prescribed to each participant will be reviewed at the beginning, after six months and at the end of the study.
c) Nutritional care: this component focuses on evaluating the quality of the patient's habitual diet and on detecting any risk of malnutrition (or its presence, and in this case, prescribing appropriate treatment), taking into account expert recommendations and following established nutritional guidelines for this population group. At baseline, the presence or absence of the risk of malnutrition and the quality of the habitual diet will be evaluated. The scores obtained by application of the MNA-SF questionnaire will be used to classify patients as "not at nutritional risk" (and given recommendations on healthy eating), "at risk of malnutrition" (and given specific advice on nutrients that should be included in the daily intake of food) or "malnourished" (and given a personalised nutrition plan, which may include texture modification and monthly monitoring in primary care will be recommended). The patient's nutritional status and the introduction of corrective measures if malnutrition (or risk of malnutrition) is detected, will be determined in the baseline evaluation.

The doctors and nurses collaborating in the field work for this project will take a specialised training course accredited by the corresponding quality agency in each Autonomous Community, after they have been randomised and before the recruitment of subjects begins. This training will only be received by the doctors and nurses assigned to the intervention group. The course will consist of four sessions. The first will be a face-to-face session to present the study and the tools that will be used to detect frailty among the elderly, based on the Barthel index of autonomy and the SPPB tests of frailty. The remaining three sessions will be offered in e-learning format and will focus, in turn, on each of the elements of the intervention (physical exercise, review of polypharmacy and nutritional intervention). The training modules will be imparted by a member of the research team who has expert knowledge of the corresponding area (i.e., by a physiotherapist, a pharmacist and a nutritionist, respectively). The e-learning

format ensures consistency of instruction in each of the Autonomous Communities in which the intervention will take place.

Intervention Type
Mixed

Primary outcome measure
At baseline and twelve months' follow-up:
1. Functional capacity measured by the stand up and walk test. A cut-off point of 12 seconds will be applied to identify subjects with low functional capacity.
2. The incidence of adverse events, a score less than or equal to 90 points in the Barthel test will be considered to represent dependency. Other adverse events assessed during the follow-up year will be institutionalisation and hospitalisations (by number, hospital service required, type – programmed or urgent – and duration).

Secondary outcome measures
1. Incidence of transitions from frailty to robustness, at six and twelve months. Patients will be classed as robust if they obtain a score greater than or equal to 10 in the SPPB test
2. Incidence of dependency at six and twelve months
3. Incidence of institutionalisation at six and twelve months
4. New hospitalisations at six and twelve months
5. Level of physical activity at six and twelve months. This parameter will be evaluated using a scale adapted from the WHO recommendations on physical activity for elderly people
6. Prevalence of polypharmacy and potentially inadequate prescriptions at six and twelve months. The number of STOPP criteria met will be determined, for the three time points (baseline and at six and twelve months of follow-up)
7. Prevalence of nutritional alterations at six and twelve months. Alteration is defined as a nutritional score of 17-23.5 points, and malnutrition as a score lower than 17 points in the Mini Nutritional Assessment (MNA)
8. Health-related quality of life at six and twelve months evaluated using EuroQuol 5D 5L.
9. Depression at six and twelve months
10. Validate the expression of the molecular pattern associated with frailty after the proposed intervention and determine the complete transcriptome of each participant
11. Evaluate the efficiency of the intervention (cost-effectiveness)
12. Evaluate the feasibility and adequacy of the intervention (exploration of barriers and facilitators, using a qualitative approach)

Overall study start date
01/01/2019

Completion date
31/12/2021

Eligibility

Key inclusion criteria
Subjects aged over 70 years, presenting frailty (SPPB <10), who are autonomous (Barthel > 90 points), resident in the autonomous community in question and agree to participate.

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
200

Key exclusion criteria
1. Subjects who are terminally ill (as defined in the guidelines published by the Spanish Society of Palliative Care)
2. Subjects who do not habitually reside in the study area (i.e. those who reside for more than six months per year elsewhere)
3. Those who have difficulty in communication in Spanish or Basque (the latter language, for subjects resident in Gipuzkoa)

Date of first enrolment
01/01/2020

Date of final enrolment
31/03/2020

Locations

Countries of recruitment
Spain

Study participating centre
Unidad de investigación de AP-OSIs Gipuzkoa
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Study participating centre
Hospital Costa del Sol
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Sponsor information

Organisation
AP-OSIs Gipuzkoa

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Sponsor type
Research organisation

Organisation
Hospital Costa del Sol

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Research organisation

Funder Name
Instituto de Salud Carlos III

Funder Name
European Fund for Regional Development – FEDER

Results and Publications

Publication and dissemination plan
Plan to publish
1. Study protocol
2. Trial findings
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/12/2021

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		20/02/2020	06/09/2023	Yes	No