FRAGICOR Study Protocol –

Impact of a Program Aimed at Improving Frailty in Patients with Stable Ischemic Heart Disease in Primary Care: Fragicor Study

Brief title: Improving Frailty in Patients with Stable Ischemic Heart Disease

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SUMMARY

The progressive aging of the population leads to an increase in frailty, with the consequent risk of falls, hospitalization, and institutionalization. Frailty has been described as an important predictor of falls, disability, and mortality in older adults. People with frailty have a higher prevalence of coronary heart disease, which is especially relevant given the greater risk of bleeding associated with falls in these patients.

Lifestyle-based interventions — such as physical exercise and nutrition — as well as the management of chronic diseases, may be effective in preventing adverse events.

Objectives: We propose a multimodal before-and-after interventional study in a population aged 70 years and older with stable ischemic heart disease, aiming to improve frailty and reduce the risk of falls. The study will be conducted in five primary care centers in Barcelona. Patients will be selected by the healthcare professionals responsible for their care, and the intervention will be delivered by their physicians, nurses, and physiotherapists.

After verifying inclusion and exclusion criteria, patients will sign the informed consent and participate in twelve physiotherapy sessions, being assigned to specific frailty groups. Sociodemographic and clinical variables will be recorded, and specific frailty tests will be administered at baseline and at the end of the study. Measurements will be compared after twelve sessions. At the end of the intervention, a recommendation sheet will be provided to participants. Three months after completing the intervention, frailty-related variables will be reassessed, and adherence to recommendations. The research team will have access to clinical records for up to 6 months to ensure all

variables are documented. Descriptive statistics will be performed, and pre-post values will be compared using the paired t-test for normally distributed data and the Wilcoxon signed-rank test for non-parametric data. Qualitative variables will be expressed as absolute frequencies and percentages, and compared using McNemar's test.
The protocol has been submitted for approval to the Ethics Committee of the IDIAP Jordi Gol Research Institute and has been agreed upon by the research team and the management of all participating centers.

INTRODUCTION

The population attended in primary care is increasingly older and presents greater comorbidity. This situation leads to an increase in frailty and its associated risks: falls, hospitalization, and institutionalization (1). Frailty has been identified as an important predictor of falls, disability, and mortality in older adults (2). Its prevalence increases with age and ranges between 12% and 45% among individuals over 65 years, depending on whether they live in the community or in institutionalized settings (3,4).

The World Health Organization defines frailty as "an age-related decline in physiological systems that results in decreased intrinsic capacity reserves, conferring greater vulnerability to stressors and increasing the risk of adverse health outcomes" (5). Early detection has proven effective in achieving reversibility in its initial stages. The ADVANTAGE Joint Action, involving 22 EU member states and 38 organizations, recommends the Short Physical Performance Battery (SPPB) for early diagnosis (6).

The Spanish National Health System's consensus on frailty and fall prevention recommends opportunistic screening for frailty in individuals over 70 years old who are not dependent (Barthel ≥ 90 points) in primary care (7).

Lifestyle-based interventions — such as physical exercise and nutrition — along with optimal management of chronic diseases, have proven effective in preventing adverse outcomes (8). Among these, exercise-based interventions focusing on strength training show the best results, outperforming aerobic training, with superior benefits when performed in group settings rather than individually (1).

The SPRINTT study concluded that in patients with SPPB scores between 3 and 7, a complete multimodal intervention reduced disability, particularly in women (9).

Additionally, it is known that frail older adults have a higher prevalence of coronary heart disease (10). The EPESE study demonstrated a two-fold higher risk of coronary mortality when coronary disease coexisted with impaired mobility (11).

One of the pillars of secondary prevention in ischemic heart disease is low-dose antiplatelet therapy (12), yet this treatment carries bleeding risks (13), making falls particularly severe. Furthermore, dual antiplatelet therapy with aspirin and clopidogrel should not extend beyond one year after the acute episode (14).

Frailty also increases the risk of bleeding in patients with acute coronary syndrome (15). The clinical picture becomes even more complex when atrial fibrillation coexists with ischemic heart disease. Atrial Fibrillation (AF) incidence among patients with ischemic heart disease ranges from 6–21% (16), while 20–30% of AF patients will develop

ischemic heart disease (17), often requiring concurrent anticoagulant and antithrombotic therapy, increasing bleeding risk.

Therefore, it is essential to identify patients with ischemic heart disease at high risk for frailty and to implement strategies to prevent or improve frailty when already present — both due to the intrinsic consequences of frailty and its specific prognostic impact in this population.

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HYPOTHESIS

1. The application of a multimodal frailty-prevention program may be effective in reducing frailty in patients with stable coronary artery disease.
2. The application of a multimodal frailty-prevention program may be effective in reducing the risk of falls in patients with stable coronary artery disease.
3. The application of a multimodal frailty-prevention program may improve muscle strength in patients with stable coronary artery disease.
4. The application of a multimodal frailty-prevention program may improve quality of life in patients with stable coronary artery disease.
5. The application of a multimodal frailty-prevention program may improve clinical and laboratory parameters in patients with stable coronary artery disease.
6. The improvements obtained may be maintained three months after completion of the in-person intervention.

OBJECTIVES

General Objective

To evaluate the effect of a multimodal preventive intervention consisting of group physiotherapy sessions, nutritional recommendations, and medication review on frailty parameters in a group of patients aged 70 years and older with stable ischemic heart disease.

Specific Objectives

1. To analyze whether the application of an intensive group program to address frailty in patients with stable ischemic heart disease leads to a lower risk of falls.
2. To determine whether this program is accompanied by an improvement in muscle strength.
3. To evaluate changes in quality of life perceived by patients as a result of the program.
4. To assess changes in clinical and laboratory parameters in these patients.
5. To determine whether the results obtained are maintained three months after completion of the in-person intervention.

DESIGN

Experimental before-and-after study in which the effect of a multimodal preventive intervention on frailty parameters will be evaluated in a group of patients with stable ischemic heart disease.

INCLUSION CRITERIA

- Age ≥ 70 years
- Diagnosis of coronary artery disease (International Classification Diseases (ICD)-10 I20–I25)
- Canadian Cardiovascular Society Class I
- Low cardiovascular risk according to exclusion criteria

- Barthel Index ≥ 90

EXCLUSION CRITERIA

(adapted from the SPRINTT study)

- Inability or refusal to provide informed consent (advanced dementia, severe psychiatric illness)
- Inability to perform protocol procedures
- Severe mobility-limiting conditions (Parkinson's disease, progressive neurological disorders, disabling joint disease)
- Recent (<6 months) unstable angina, myocardial infarction, coronary revascularization or angioplasty
- Deep venous thrombosis or pulmonary embolism in the last 6 months
- Recent stroke (<6 months)
- Heart failure in New York Heart Assocaition functional status (NYHA) III-IV
- Left ventricular ejection fraction < 50%
- Symptomatic valvular heart disease

SAMPLE SIZE (BEFORE–AFTER, MATCHED MEANS IN A SINGLE GROUP)

Accepting an alpha risk of 0.05 and a statistical power >0.8 in a two-sided test, at least 63 subjects are required to detect as statistically significant a difference ≥1 point on the SPPB scale. A common standard deviation of 2.7 is estimated. A 10% loss to follow-up is assumed. (Pandey A et al. JAMA Cardiol. 2023) (21–23).

SETTING AND SAMPLE SELECTION

The physician responsible for the patient will generate a list of potential participants based on the diagnosis (ICD-10 I20–I25) and age (≥70 years).

The physiotherapist may also identify patients from lists of individuals with ischemic heart disease who have already been treated.

The family physician or the physiotherapist at the reference Primary Care Center (CAP), if the physician delegates, will call the patient by phone for the inclusion visit, informing them about the study. Participants will be selected using consecutive sampling from the lists until the required sample size is reached.

Distribution of sample size among centers:

- Primary Healthcare Center (PHC) Adrià: 16 patients (2 physiotherapists)
- (PHC) Pare Claret: 16 patients (2 physiotherapists)
- (PHC) Passeig de Sant Joan: 12 patients (1 physiotherapist)
- (PHC) Sant Martí de Provençals: 24 patients (3 physiotherapists)
- (PHC) La Mina: 16 patients (2 physiotherapists)

The physician will evaluate the patient, verify inclusion and exclusion criteria, and request any complementary tests needed to complete baseline data.

Patients who meet the inclusion criteria and sign the informed consent will be referred to the physiotherapist. It will be recorded in the patient's medical record that they have signed the consent.

The consent forms will be centralized at the Barcelona Research Support Unit.

The physiotherapist will arrange a first appointment at which they will assess each participant's frailty parameters. Once the required number of patients has been reached for each group, they will schedule the group sessions.

The physiotherapist will inform the physician about the results of the tests for their patients, in case the physician considers it appropriate to intervene.

OUTCOME VARIABLES

Variable name	Type	Instrument / scale	Time points (visits)	Coding / units
Gerontopole score	Quantitative	Gerontopole Frailty Screening Tool (seven questions)	Baseline, post-intervention, 3 months	1 or more questions means frailty
SPPB total score	Quantitative	Short Physical Performance Battery	Baseline, post-intervention, 3 months	<10 points means frailty
SPPB components	Quantitative	SPPB subtests	Same as above	0–4 points

Variable name	Type	Instrument / scale	Time points (visits)	Coding / units
(balance, gait speed, chair rise)		measured in seconds to perform the prove		each
Handgrip strength	Quantitative	GRIPX digital hand dynamometer	Baseline, post-intervention, 3 months	kg (best of 2 attempts)
Goldberg anxiety score	Quantitative	Goldberg Anxiety and Depression Scale (9 questions)	Baseline, post-intervention, 3 months	>=4 afirmative questions means anxiety
Goldberg depression score	Quantitative	Goldberg Anxiety and Depression Scale (9 questions)	Baseline, post-intervention, 3 months	>=4 afirmative questions means depression
EuroQol Visual Analogic Scale	Quantitative	EQ-5D VAS	Baseline, post-intervention, 3 months	0–100
Number of falls	Count	Patient report / calendar	During intervention, 3-month follow-up	Count
Major Adverse Cardiovascular Events (MACE) / angina	Binary	Clinical record	Throughout study	0 = no, 1 = yes (withdrawal)
Adherence to home program	Quantitative	Exercise calendar	3-month follow-up	Number of sessions attended

Changes in the following variables will be evaluated with respect to their baseline values:

Gerontopole Frailty Screening Tool (first and last visit)

This is a tool designed to identify frail older people in primary care, allowing early detection and the implementation of preventive and personalized care strategies.

It assesses 6 parameters: weight loss, fatigue, gait speed, loss of mobility, memory complaints, and living alone. It also includes a subjective question for the healthcare professional.

- Record the score for each item.
- Calculate the total score.

SPPB Scale (Short Physical Performance Battery) – First and last visit

It measures balance, gait speed, and lower-limb strength.

- Record the total number of seconds in each exercise and categorize it according to the validated instructions of the test.

Balance test:

If the patient maintains the position for more than 10 seconds, record up to a maximum of 20 seconds.

Gait speed and chair-stand tests:

If the patient exceeds the maximum times (>8.70 and >60 seconds, respectively), do not insist on continuing the test and assign the corresponding score according to the scale.

Hand Grip Strength (Dynamometer)

Recorded at the first and last visit (best of two attempts). Measures isometric handgrip strength in kilograms.

Goldberg Anxiety and Depression Scale

First and last visit.

Number of falls throughout the study

EuroQol-5D

First and last visit.

Major Adverse Cardiovascular Events (MACE) or angina

(Reason for withdrawal from the study).

INDEPENDENT VARIABLES

Variable name	Type	Source	Time point	Coding / units
Age	Quantitative	Clinical record / interview	Baseline	Years
Sex	Categorical	Clinical record	Baseline	Female / Male / Non-binary
Sistolic blood pressure /	Quantitative	Blood pressure measurement	Baseline, 3 months	mmHg

Variable name	Type	Source	Time point	Coding / units
Diastolic blood Pressure				
Heart rate	Quantitative	Clinical record	Baseline	bpm
Hemoglobin	Quantitative	Laboratory	Baseline, 3 months	g/dL
Red blood cell count	Quantitative	Laboratory	Baseline, 3 months	10^6/µL
Glucose	Quantitative	Laboratory	Baseline, 3 months	mg/dL
Glycated haemoglobin	Quantitative	Laboratory	Baseline, 3 months	%
Total cholesterol	Quantitative	Laboratory	Baseline, 3 months	mg/dL
Low density Lipoprotein cholesterol	Quantitative	Laboratory	Baseline, 3 months	mg/dL
High density Lipoprotein cholesterol	Quantitative	Laboratory	Baseline, 3 months	mg/dL
Transaminases	Quantitative	Laboratory	Baseline, 3 months	U/L
Glomerular	Quantitative	Laboratory	Baseline, 3	mL/min/1.73m²

Variable name	Type	Source	Time point	Coding / units
filtration			months	
Comorbidities	Categorical	Clinical record	Baseline	(yes/no)
Medication	Categorical	Medication list	Baseline	Betablockers, renne/angiotensine inhibitors, Calcium cannel blockers, diuretics, antiplatelets,

ETHICAL ASPECTS

Eligible candidates will sign the informed consent form. All procedures will be explained to participants in detail.

The informed consent form includes a statement allowing the investigating physicians on the team to review participants' medical records throughout the study to identify clinical events and extract data relevant to this research. All personal data collected for the study will always be used in anonymized form (see below).

There is no potential ethical conflict regarding confidentiality when identifying suitable candidates or reviewing medical records, since these tasks are exclusively assigned to the physicians responsible for the participants' care.

There are no potential conflicts of interest among the members of the research team.

Data recorded, both from the medical record and from face-to-face visits, will be entered in coded form into a data collection sheet stored at each participating center, which will be sent regularly to the Barcelona Research Support Unit, where the information will be centralized. When a participant meets criteria compatible with those for exclusion, they will be immediately withdrawn from the study and their physician will be informed. If they present chest pain or symptoms compatible with acute coronary syndrome, urgent clinical protocols will be activated and their physician will be informed as soon as possible. In that case, the participant will be withdrawn from the study.

When the project is completed, all collected information will be destroyed five years later. The results will be presented in aggregate form in reports and written publications, always anonymously, so their name or any other identifying information will be removed.

Physiotherapists will inform the physicians responsible for the patients of any issues that may influence therapeutic management during the study.

The principal investigators will assess the outcome variables at the end of the study.

The reference healthcare professionals are responsible for proposing participation in the study to selected individuals, explaining the type of study that is to be carried out, and obtaining their written informed consent. All data will be obtained through interview, physical examination, and review of the medical record.

The study will be conducted in accordance with the latest revision of the Declaration of Helsinki (2013):

https://www.idiapjgol.org/images/investigacion/declaracion_helsinki_2013.pdf

Likewise, the Code of Good Research Practice in Primary Care Research of IDIAP Jordi Gol (2015) will be followed. The protocol has been approved by the IDIAP Jordi Gol Research Ethics Committee (CEI) (Reference Number: 25/198-P).

The investigators undertake to maintain data confidentiality and not to use the data for any other purpose.

Confidentiality of Data

The European Union legislation on personal data will be observed, in particular Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on data protection, as well as Spanish Organic Law 3/2018 of 5 December on Personal Data Protection and guarantee of digital rights.

Information will be recorded in coded form and stored in a password-protected Excel database on computers belonging to the Catalan Health Institute (ICS). The data required to decode the information will be kept in a separate, password-protected file accessible only to the investigators.

Use of Data

- **Identification of data and individuals processing them.**

  The variables needed for the study come from interviews conducted with informed consent, which includes access to the data recorded in the electronic medical record (e-CAP). Information will be recorded in coded form and stored in a protected Excel database on ICS computers, and the data required for

decoding will be in another password-protected file accessible only to the investigators. The Catalan Health Institute will act as the data controller in the context of this study, and the project database will be hosted on ICS servers.

- **Identification of uses and legal basis.**

  The variables necessary to carry out the study will be obtained directly from project participants and from review of their clinical records with their consent.

- **Tools used for data processing.**

  Project data will be stored on the institution's servers.

- **International data transfers.**

  No international transfer of data is planned.

- **High-risk data processing.**

  The project does not meet the conditions that would require a specific Data Protection Impact Assessment.

- **Information sheet and consent form content.**

  The participant information sheet and consent form will include a section on data processing (see Annex).

POTENTIAL HEALTH RISKS FOR PARTICIPANTS

The activities planned in the group sessions are not expected to increase participants' risk, nor do they differ from those already carried out in existing frailty groups. Health, physical strength, balance, and quality of life are expected to improve during the intervention. As participants are in a stable phase of their disease, no adverse effects related to the intervention are expected.

This is not a cardiac rehabilitation project, as it will only include clinically stable patients who have not experienced a cardiovascular event in the previous six months.

STATISTICAL ANALYSIS

A before-and-after design will be used to evaluate changes in the variables of interest after the intervention.

Quantitative variables will be summarized using means and standard deviations when normally distributed, and medians and interquartile ranges when they are not. The normality of the variables will be assessed using the Shapiro–Wilk test.

To compare the values before and after the intervention, the paired t-test will be used for normally distributed data, and the Wilcoxon signed-rank test for non-parametric data. Qualitative variables will be expressed as absolute frequencies and percentages, and compared using McNemar's test.

A statistical significance level of $p < 0.05$ will be adopted.

A difference of 1 point on the SPPB scale will be considered clinically significant. A common standard deviation of 2.7 and a 10% loss to follow-up are assumed (Pandey A et al. JAMA Cardiol. 2023) (21–23).

Data analysis will be performed using the R statistical software package.

BUDGET

The project starts without an assigned budget.

However, during its development, the team plans to apply for competitive calls.

This is a pilot project. Depending on the results obtained, the research team will consider applying for calls from the Instituto de Salud Carlos III and similar funding bodies.

TIMELINE OF INTERVENTIONS

Visit	Responsible professional	Timing	Main activities / assessments
Screening / Inclusion visit	Family physician	before intervention	Eligibility, inclusion/exclusion, clinical history, consent, Barthel, ECG, labs
Baseline physiotherapy visit	Physiotherapist	Week 0	Gerontopole, SPPB, handgrip, Goldberg, EQ-5D, walking test, fall risk

Visit	Responsible professional	Timing	Main activities / assessments
Group sessions 1–12	Physiotherapist	Weeks 1–12 (1 session/week)	Warm-up, aerobic training, strength, balance, cool-down
Post-intervention physiotherapy visit	Physiotherapist	Week 12–13	Gerontopole, SPPB, handgrip, Goldberg, EuroQool-5D, walking test; home program
3-month follow-up physiotherapy visit	Physiotherapist	3 months after last session	Adherence, falls, SPPB, handgrip, Goldberg, walking test, EuroQool-5D -5D
3-month follow-up physician visit	Family physician	3 months after last session	Clinical parameters (BP), labs, review of events
Continuous follow-up (medical record review)	Research team physicians	Up to 6 months after intervention	Recording MACE, angina, other relevant events

BASELINE FAMILY PHYSICIAN VISIT

After explaining the reason for the appointment, the physician will inform the patient about the objective of the study.

They will verify that all variables required to start the study are available and request those not updated (older than six months).

Medication review:

Evaluate the appropriateness of chronic use of benzodiazepines, neuroleptics, first-

generation antihistamines, vasodilators, and opioids. Review cardiovascular treatments, including antiplatelets.

Barthel Index (see Annex; https://www.samiuc.es/indice-de-barthel/)

The physician will question the patient regarding exclusion criteria.

Patients who meet all inclusion criteria and none of the exclusion criteria will receive the informed consent form and will be referred to the physiotherapist, who will conduct an interview and schedule the intervention sessions.

PHYSICIAN RESPONSIBLE: _____ ID: _____

VERIFY INCLUSION CRITERIA (all three must be met)

- Age ≥ 70 years – YES / NO
- ICD-10 diagnosis (I20–I25) – YES / NO
- Barthel Index > 90 – YES / NO

VERIFY EXCLUSION CRITERIA

(Exclusion if any criterion is present)

Recent cardiovascular disease < 6 months – YES / NO

- Unstable angina – YES / NO

- Myocardial infarction – YES / NO
- Coronary revascularization surgery / angioplasty – YES / NO
- Venous thrombosis / pulmonary thromboembolism – YES / NO
- Stroke – YES / NO
- Heart failure NYHA III–IV – YES / NO
- Documented ejection fraction < 50% – YES / NO
- Symptomatic valvular disease – YES / NO
- Uncontrolled severe arrhythmias – YES / NO
- Advanced peripheral arterial disease – YES / NO
- Advanced renal insufficiency (eGFR < 30) – YES / NO
- Severe depression or mental illness – YES / NO
- Institutionalized patients – YES / NO
- Life expectancy < 12 months – YES / NO
- Inability to participate in the study – YES / NO

Biological sex

- Female / Male / Non-binary

Check comorbidities:

- Ischemic heart disease I20–I25:
    - Record specific ICD-10 diagnosis (AMI, chronic ischemic heart disease, etc.)
    - Date of diagnosis (dd/mm/yyyy)
    - Date of last hospital admission or emergency visit (if not recorded, ask the patient)

- Previous stroke – YES / NO
    - If YES: date of diagnosis and date of last admission
- Peripheral arterial disease – YES / NO
- Hypertension – YES / NO
- Atrial fibrillation – YES / NO
- Chronic Obstructive Pulmonary Disease – YES / NO
- Diabetes mellitus – YES / NO

Check if there is a laboratory test within the last 6 months

(if not, request):

Complete blood count, glucose, Glycosilated haemoglobine, transaminases, lipids, glomerular filtration rate

Check if there are BP and BMI measurements within the last 6 months

(if not, obtain them during the visit):

- Systolic blood pressure
- Diastolic blood pressure
- Body Mass Index

Check if there is an Electrocardiogram from the last year (if not, request one):

- Present: YES / NO
- Severe arrhythmia: YES / NO
- Acute ischemia: YES / NO

Medication review:

Mark YES / NO for:

- Beta-blockers
- Antiplatelet agents
- Anticoagulants
- Calcium antagonists
- Renine-angiotensine inhibitors
- Diuretics (thiazide/loop)
- Sodium-glucose co-transporter 2 inhibitors
- Neuroleptics
- Benzodiazepines

DIETARY RECOMMENDATIONS

Provide dietary recommendations from the Spanish Heart Foundation (Fundación Española del Corazón):

Available at:

https://fundaciondelcorazon.com/phocadownload/recursos-didacticos/dietas/Nuevas2021/DIETA%20ENFERMEDAD%20CORONARIA.pdf

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FIRST VISIT WITH THE PHYSIOTHERAPIST

The first visit will focus on four areas: frailty, fall risk assessment, quality of life, and psychological distress.

FRAILTY ASSESSMENT

The physiotherapist will schedule the appointment, reinform the patient about the purpose of the study, and perform frailty screening.

Actions:

- Gerontopole Frailty Screening Tool
- Short Physical Performance Battery (SPPB)

During this visit, the time (in seconds) required to perform each activity will be recorded on a data collection sheet.

- Determination of grip strength using the GRIPX Digital Hand Dynamometer (automatic handgrip force meter).

FALL RISK ASSESSMENT

Falls Risk Scale (Spanish Consensus).

According to the Spanish consensus guidelines for fall prevention (27), the patient will be asked:

- Have you had any fall in the last year that required healthcare attention?
- Have you had two or more falls in the last year?

- Do you have any gait disorder considered significant?

  (This question will be considered positive if the performance test used for frailty screening is abnormal; frailty according to SPPB).

Interpretation:

- Negative answers to all three questions: **Low risk**
- Positive answer to any of the three questions: **High risk**

Home fall risk factors will also be reviewed.

QUALITY OF LIFE ASSESSMENT

- EuroQol-5D

ANXIETY-DEPRESSION ASSESSMENT

- Goldberg Scale (see Annex)

FACE-TO-FACE VISIT (INDIVIDUAL) – (INITIAL PHYSIOTHERAPY VISIT)

- Gerontopole Frailty Screening Tool
- SPPB scale (record seconds with stopwatch as well as the categorical score)
- Goldberg anxiety/depression scale
- EuroQol-5D
- Walking Test (time in seconds)
- Handgrip strength (record numerically the best of two attempts)

Structure and content of group physiotherapy sessions

Session	Duration	Components	Description / examples	Target intensity (Borg)
1	50 min	Introduction, education	Group introduction, objectives, rules, therapeutic exercise principles, Borg scale	–
2–12	50 min	Warm-up	Global mobility, joint range-of-motion exercises	3–4
		Aerobic component	Walking, side steps, stepping up/down, adapted to patient characteristics	3–4
		Interval training	20″ work / 15″ rest × 8 sets	3–4
		Balance	Static and dynamic balance exercises	3–4
		Strength	Upper and lower limb strengthening (with/without resistance)	3–4
		Cool-down	Stretching, breathing, relaxation ± simple game	2–3

INDIVIDUAL PHYSIOTHERAPY VISIT (FINAL)

- Gerontopole Frailty Screening Tool
- SPPB scale (record seconds and categorical score)
- Goldberg anxiety/depression scale
- EuroQol-5D
- Walking test (seconds)
- Handgrip strength (best of two attempts)

Participants will be invited to continue an exercise program at home.

They will receive recommendation sheets and will be asked to carry out the exercises twice a week. They will also be invited to record on a calendar the days on which they perform the activities and to bring it to the visit three months later.

VISIT 3 MONTHS AFTER COMPLETING THE INTERVENTION

PHYSIOTHERAPIST

Will assess adherence to the program three months after the end of the intervention:

- Measure: number of days the agreed exercises were performed according to the calendar provided.
- Ask about number of falls.

The following variables will be assessed:

- SPPB
- Hand dynamometry (handgrip)
- Goldberg scale
- Walking test
- EuroQol-5D

FAMILY PHYSICIAN

Clinical parameters:

- Systolic blood pressure (SBP)
- Diastolic blood pressure (DBP)

Laboratory test

ANNEXES

- SPPB scoring system:

  Balance (0–4 points), gait speed (0–4 points), chair-rise test (0–4 points); total (0–12 points).

  https://www.revespcardiol.org/es-recomendaciones-seccion-cardiologia-geri-articulo-S0300893218303579
- Barthel Index
- Goldberg Anxiety and Depression Scale:

  https://www.redpal.es/wp-content/uploads/2018/12/AnsiedadDepresio%CC%81nGoldberg.pdf
- EuroQol-5D
- Exercise scheme:
  - Warm-up
  - Balance
  - Strength work without resistance
  - Strength work with resistance
- Model of patient information sheet: including all paragraphs describing aims, voluntary participation, confidentiality, data protection, rights of access/rectification/erasure, and contact with investigators and Data Protection Officer, as per the original Spanish document.
- Informed consent model, including all YES/NO items about:
  - Having read the information sheet
  - Understanding risks and benefits
  - Voluntary nature of participation
  - Nature of physiotherapist-led visits

- Confidentiality
- Access to the clinical record by investigators
- Communication of clinically relevant findings
- Authorization for access to the clinical record for 6 additional months after the intervention

  With fields for:
- Participant name and signature
- Investigator name and signature
- Date and place

- National falls prevention leaflet: https://www.sanidad.gob.es/areas/promocionPrevencion/lesiones/ocioHogar/documentosTecnicos/docs/Prevenir_caidas_en_el_hogar.pdf

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INVESTIGATORS AND PARTICIPATING CENTERS

GRECAP (PRIMARY CARE CARDIOVASCULAR RESEARCH GROUP)

Name	Role in the project	Affiliation
Mercè López Grau	Principal Investigator	PHC Passeig de Sant Joan – GRECAP, ICS–IDIAP
Miguel Angel Muñoz	Co-Principal Investigator / Protocol lead	PHC Joanic (Pare Claret) – GRECAP, ICS–IDIAP
Jose María Verdú	Co-investigator	PHC Sant Martí de Provençals
Ernest Vinyoles	Co-investigator	PHC La Mina
Nuria Soldevila	Co-investigator	PHC La Mina
Victoria Cendrós	Co-investigator	PHC Adrià
José Luis del Val	Methodology advisor	Primary Care Management Deapartment, ICS Barcelona
Elena Navas	Statistician	Priamry Care Research Unit Barcelona
Miquel Gual Santandreu	Cardiology advisor	Hospital Sant Pau

PHYSIOTHERAPISTS:

(names and centers)

- Víctor Quartim Nobre – Passeig de Sant Joan
- Gema Duño Escagedo – Sant Martí
- Olga Bernat Rubio – Sant Martí
- Mercedes Orive Romero – Sant Martí
- Víctor Arias Alvarín – Adrià
- Mireia Fernández Meseguer – Adrià
- Natalia Blanco García – Joanic / Pare Claret
- Sergio García González – Joanic / Pare Claret
- Ferran Guitart Clermont – La Mina
- Marc Trujillo Pérez – La Mina

Steering Committee:

- Mercè López
- Miguel Angel Muñoz

PUBLICATION POLICY

The publication of three articles in peer-reviewed journals is envisaged.

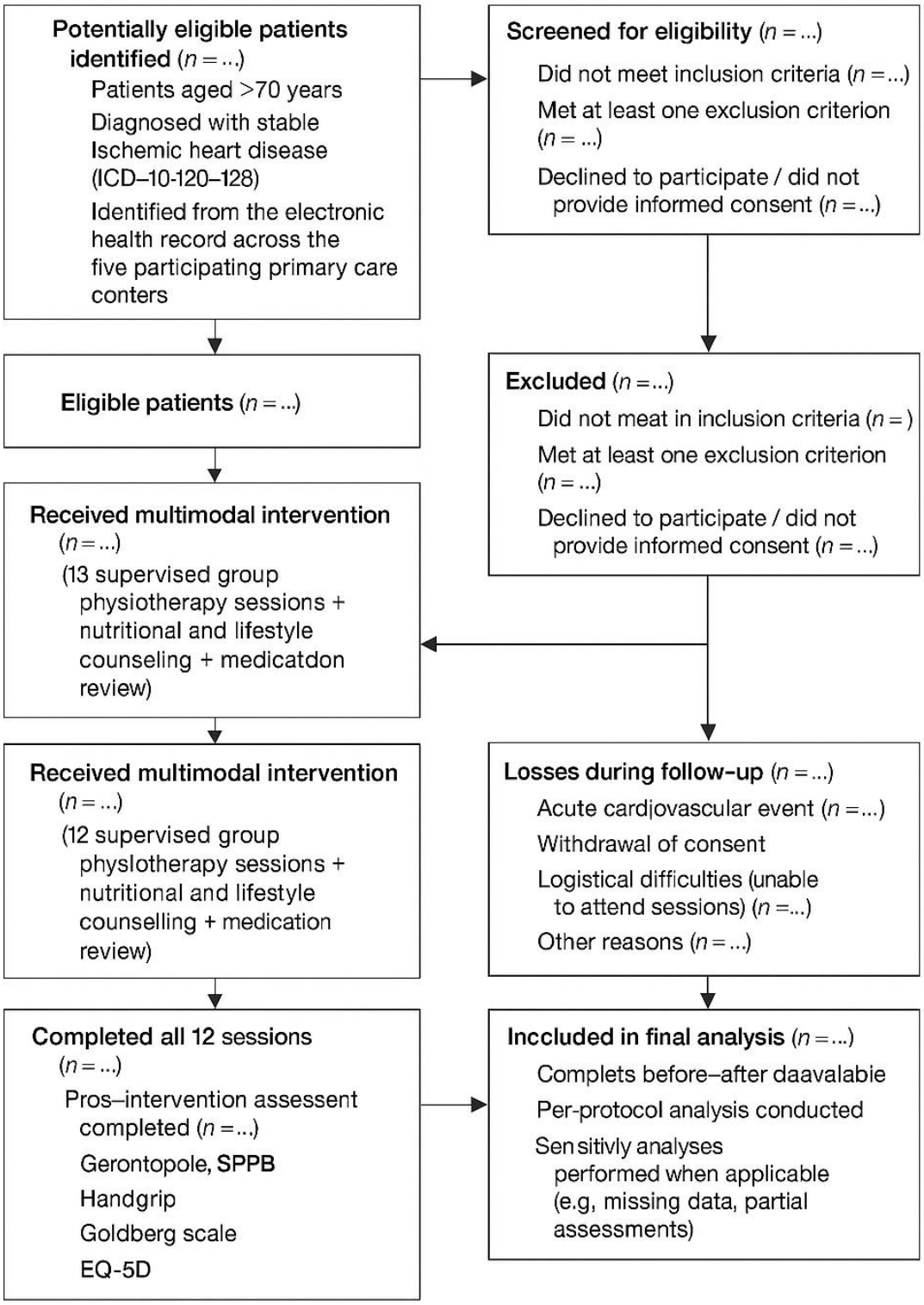
The main article will analyze the effect of the intervention.

Mercè López and Miguel Angel Muñoz are the originators of the project and have developed the protocol; therefore, they will appear as first and last authors, and

corresponding author respectively, in all publications and communications derived from the study.

In addition, three further GRECAP members will be listed as co-authors in the articles submitted for publication. If the journal allows it, four physiotherapists will be included as co-authors; if not, they will all be acknowledged in the Acknowledgments section.

Figure 1. Flow diagram of participants in the FRAGICOR before–after intervention study



INFORMED CONSENT

NAME AND SURNAME:

ID Number:....

Postal Address...

Email (if applicable)…

Who informed you:

Participant's Doctor:....

Please select YES or NO in the following qüestions:

I have read the Patient Information Sheet, I understand the risks and benefits involved, that my participation is voluntary, and that I can withdraw or request the removal of my data and/or samples at any time.

YES NO

I understand that my participation in the study consists of visits by the physiotherapist at my health center to improve frailty.

YES NO

I understand that the study information will be confidential and that no unauthorized person will have access to the data or samples.

YES NO

I know how to contact the researchers if needed.

YES NO

I authorize the study doctors (unless there are any objections, this will be my doctor, who invited me to participate) to access my medical records for the duration of the study intervention and the analysis of the results. I authorize the research team to communicate to me any clinical data obtained during the study that is relevant to my health.

YES NO

I authorize the study physicians (unless there are any objections, this will be my own physician, who invited me to participate) to access my medical records annually for an additional six years after the study intervention has ended.

YES NO

Participant: Name and signature

Researcher: Name and signature

Date and Place