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Effectiveness of a home-based physical exercise intervention in patients with fragility fractures on functional independence and hospital readmissions: a protocol for a randomised controlled trial

Rocío Segura-Ruiz,[1,2,3] Macarena Ruiz-Cañete,[1,2] Adoración Muñoz-Alonso,[1] Claudia Rivas-Cruces,[1] Pilar Serrano-Lázaro,[4] Pedro José Armenteros-Ortiz,[3] Pedro Hidalgo-Lopezosa,[1,2,3] Nicola Lamberti,[5] Fabio Manfredini,[6,7] Pablo Jesús López-Soto [1,2,3]

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For numbered affiliations see end of article.

Correspondence to
Professor Pablo Jesús López-Soto; pablo.lopez@imibic.org and
Dr Nicola Lamberti; lmbncl@unife.it

ABSTRACT

Introduction Patients with fragility fractures are two times as likely to suffer future fractures as their peers who have not suffered a fracture. In addition, 40% of those who suffer fragility fractures do not recover their level of functioning in terms of activities of daily living after 1 year. The present study aims to verify the hypothesis that a semipersonalised home-based exercise intervention may improve patients' independence and reduce the number of hospital admissions compared with usual care for a population that suffers fragility fractures.

Methods and analysis This parallel-arm single-blinded randomised-controlled trial will take place at the University of Cordoba (Spain) between September 2022 and September 2024. Patients aged >50 years old who have undergone surgery for a fragility hip fracture and who were prefracture independent (Barthel index (BI)>60) will be invited to participate. Patients will be excluded if they present a different type of fracture, mild or greater cognitive impairment or contraindication to exercise training. Patients will then be randomised into exercise or usual care group. The former will receive a daily walking appointment (number of steps to be completed inside home, interspersed with sit-to-stand movements) with the total volume increasing weekly. The latter will receive the usual care. The outcomes, collected at baseline, at the end of training (3 months) and at follow-up (6 months) by blinded operators will include the BI and number of readmissions (primary outcomes) and quality of life, exercise capacity, strength, cognitive status, bone mineral density and laboratory biomarkers (secondary outcomes). Variables related to quality of life, cognitive status, laboratory markers and densitometry will also be analysed.

Ethics and dissemination The research ethics committee of the province of Cordoba approved the project (number 326; date 28 July 2021). Patients who meet the eligibility criteria will receive a patient information document and the consent form and will be encouraged to ask any questions. The proposed research respects the fundamental principles of the Declaration of Helsinki, the Council of Europe Declaration on Human Rights and Biomedicine, the UNESCO Universal Declaration on the Human Genome and Human Rights, and the Oviedo Council on Human Rights and Biomedicine. The data obtained in this study will be confidential. They will be treated by the Organic Law 3/2018, of 5 December, on the Protection of Personal Data and Guarantee of Digital Rights, keeping it strictly confidential and not accessible to unauthorised third parties, and the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on Data Protection (RGPD). Written informed consent will be obtained from all the participants. The study's results will be published in peer-reviewed journals and presented at scientific congresses worldwide. The results will also be disseminated through patient advocacy group newsletters and social media platforms. Patient partners will help select the appropriate channels and develop plain-language summaries tailored to their communities' needs.

Trial registration number ClinicalTrials.gov ID: NCT04934358 (registration date: 14 June 2021).

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The proposed intervention uses a patient-centred model with home-based exercise routine reinforced by a motivational approach.
⇒ A semipersonalised exercise approach based on actual patient exercise capacity may improve adherence and both short-term and long-term outcomes.
⇒ Home-based exercise is designed to overcome most of the physical and psychological barriers to execution.
⇒ The very specific type and location of fractures may limit the external validity of the results.
⇒ This single-centre trial may limit generalisability due to potential dropouts.

INTRODUCTION

Population ageing increases the risk of non-communicable diseases and the demand for acute and chronic care and services.[1] Among the numerous conditions affecting older adults, osteoporosis plays an important role, affecting more than half a billion individuals worldwide[1 2] and increasing the risk of fragility fractures. Fragility fractures, which are caused by low-impact trauma, such as a fall from a standing height and influence mainly the humerus, wrist, vertebrae and hip,[3] usually affect females and individuals older than 55 years.[4–7]

Unfortunately, although osteoporosis is responsible for fragility fractures in one out of three women and one out of five men over 50 years of age,[8–10] there is a poor awareness of the risk of this condition and of treatments to avoid it.[11]

Moreover, fragility fractures are accompanied by physical and psychological complications, such as pain, reduced mobility, quality of life, autonomy and independence.[12–14] In addition, fear of falling, anxiety and depression[15–18] is often reported. Finally, fractures are also associated with increased hospitalisation morbidity and mortality,[3 19] and it has been reported that only 40% of fractured patients regain their previous level of independence, autonomy and quality of life.[13 14] The annual cost of osteoporosis fractures to healthcare systems worldwide is 400 billion dollars, accounting for approximately 3% of total healthcare costs.[20]

In this complex scenario, all interventions aimed at preventing fragility fractures or reducing the risk of falls and possible refractures are crucial.

First, pharmacological interventions can improve bone strength and be effective in reducing refractures.[21] Second, interventions in primary care after the postfracture interval, that is, the timespan where the highest risk of refracture occurs,[22–24] have been tested. In particular, the use of behaviour change interventions has increased in this context, where printed educational materials are advised to support brief interventions, even though no outcome improvement has been demonstrated.[25] Physical exercise may provide better muscle control, balance and coordination, reducing fall risk and increasing muscle strength and bone mineral density (BMD).[26–32] However, the majority of these programmes are carried out in clinical settings for fixed periods after bone reconstruction, and patients are unlikely to continue exercising at home.[33] Therefore, considering that home-based exercise has the potential to be beneficial and effective in this context,[34] there is an urgent need to identify effective home-based exercise programmes possibly empowered by fall prevention.[25 35–38] Previous studies by our research team have demonstrated the feasibility and effectiveness of home-based low-intensity progressive exercise programmes to improve the functional capacity of severely dependent populations (peripheral arterial disease, dialysis, etc),[39–42] as well as positive long-term outcomes.[43–45] Therefore, we hypothesise that a similar in-home intervention may be safe, highly adherent and effective in this frail population that has experienced fragility fractures.

Aims

This trial aims to test the effectiveness of a simple home-based exercise programme in patients discharged from the hospital after hip reconstruction and early rehabilitation treatment on functional independence and the number of hospital readmissions compared with usual care. Moreover, this study aimed to verify whether home-based training is both safe and feasible (in terms of adherence) and whether it impacts other outcomes, such as quality of life, mobility, strength, BMD and circulating biomarkers of bone function.

Design

A single-blinded randomised-controlled parallel arms clinical trial will be conducted.

METHODS

Participants and setting

Patients operated on for fragility hip fractures between September 2022 and September 2024 in a tertiary hospital in southern Spain. The estimated number of fragility hip fractures treated in the study hospital complex in 2020 was 650–700.

Inclusion and exclusion criteria

The inclusion criteria are as follows: (1) people presenting with a hip fracture (including a cervical or trochanteric fracture), which is classified in the 10th version of the International Classification of Diseases (ICD-10-ES) with codes S72-S72. 26X; (2) the fracture must be fragility fracture (due to low energy trauma or not proportional to the consequences (Hermoso de Mendoza, 2003[45])); (3) have received surgical repair by replacement arthroplasty or internal fixation (ICD-10-ES procedures: 0SU and 0SR) within less than 1 week; (4) be recovering in a trauma and orthopaedic unit and/or be transferred to a rehabilitation unit or discharged; (5) before fracture, independent or mildly dependent for activities of daily living (Barthel index (BI)>60) and living at home; (6) have the cognitive capacity to give informed consent; (7) live and be domiciled in a primary health area covered by the study hospital complex; and (8) be over 50 years of age.

The exclusion criteria will be as follows: (1) the presence of an impaired cognitive level (scores below 23 points in the Lobo Mini-Cognitive Test); (2) patients with pathological fractures due to skeletal alterations other than osteoporosis; (3) the presence of more than one fall (other than the cause of hospital admission) in the previous year; (4) the presence of uncorrected anaemia (haemoglobin concentration 10 mg/L); and (5) the presence of severe cardiorespiratory disease: unstable angina; severe heart failure (identified by the New York Heart Association as class III–IV), musculoskeletal or

neurological diseases (eg, major lower limb amputation) that preclude safe participation in physical exercise.

The investigator will check patients' interest in participating in the study; if a positive response is given, a screening visit (at the hospital) will be conducted to verify compliance with the inclusion criteria. Patients who meet the eligibility criteria will receive a patient information document and consent form and will be encouraged to ask any questions. Within 7 days, patients will be asked to return a signed copy of the consent form; if patients have yet to decide, they will be given sufficient time (approximately another week) to consider their participation. At any time, patients who choose to participate may opt out if they feel it is appropriate. Baseline outcome measurement sessions will be scheduled within 2 weeks for those who consent to participate in the study.

For the calculation of the sample size, considering the clinical data previously mentioned and the fact that only 25% would meet the inclusion criteria, the equivalent sample size is 175 patients. On the other hand, the study by[38] is considered, indicating that it hypothesises a 25% acceptance rate, which can be progressively increased. According to a power calculation based on a theoretical response rate of 25% and considering a margin of error equal to 5% and a confidence level of 90%, 100 patients would be required to be representative of the population. A loss to follow-up rate of 15% has been estimated. Therefore, the distribution would be 50 persons per group (control and intervention).[38]

Randomisation

Randomisation will be performed by dynamic allocation,[46] ensuring a 1:1 allocation ratio within each stratification variable and throughout the clinical trial. The participants will be stratified by their baseline physical activity capacity, as shown in table 1. Randomisation will be performed via a secure computer system. The system will be established, maintained and monitored independently of the investigators involved in the study. There will be a 3-month follow-up with three monthly visits (the first 3 months) and a closing visit at 6 months.

Interventions

A motivational and progressive physical exercise intervention tailored to functional capacity will be compared with usual rehabilitation care. In both cases, multidisciplinary teams with advanced clinical and research experience from the following disciplines will be involved: orthopaedic surgery and traumatology, rheumatology, hospital and community nursing, sports medicine and physiotherapy. All patients will receive a follow-up logbook, prepared by all members of the working team, which records the physical activity carried out and/or possible events that may occur (positive or negative), as well as an information leaflet related to the study and containing information on services of the Public Health Service of Andalucia and resources to be used. Information will be provided on different integrated care programmes (prevention and action in the event of falls). The two study arms will be: (1) usual care: based on multidisciplinary rehabilitation provided by professionals from hospitals and primary care, according to the individual needs of patients at different stages of their recovery and the accessibility and availability of services in the different care settings (online supplemental information); (2) exercise programme agreed on the patient/family and

Table 1 Proposed interventions by baseline exercise capacity

Exercise capacity	6MWT<200 m		6MWT≥200<400 m		6MWT≥400 m	
Week	Walking (steps per day)	Sit and stand (reps/set)	Walking (steps per day)	Sit and stand (reps/set)	Walking (steps per day)	Sit and stand (reps/set)
1	1000	3×2	2000	5×3	4000	4×4
2	1000	3×2	2000	5×3	4000	4×4
3	1250	3×3	2000	5×3	5000	5×4
4	1250	3×3	2500	4×4	5000	5×4
5	1500	4×3	2500	4×4	6000	5×4
6	1500	4×3	2500	4×4	6000	5×5
7	1750	5×3	3000	5×4	7000	5×5
8	1750	5×3	3000	5×4	7000	6×5
9	2000	4×4	4000	5×4	8000	6×5
10	2000	4×4	4000	5×5	8000	7×5
11	2250	5×4	4500	5×5	9000	7×5
12	2250	5×4	4500	5×5	9000	8×5
13	2500	6×4	5000	5×5	10 000	8×5

6MWT, 6 min walk test; reps/set, repetitions per set.

according to their functional status (based on the 6 min walk test) and motivational intervention. In addition to the care provided in usual care, a progressive physical exercise programme based on baseline functional capacity is prescribed. The exercise will be carried out inside a corridor in the home setting. In this sense, primary care professionals (essentially nurse case managers) will make scheduled home visits to detect barriers to mobility and advise on their removal or change of arrangement. Patients will be asked to walk at a low-to-moderate speed inside home, completing the number of daily steps and chair-raising movements as reported in table 1. Rest breaks of at least 1 min are allowed and recommended in case of fatigue>6/10 when walking. Walking should be performed at least 5 days a week. The rest time between movements from sitting to standing is set at least 1 min.

Each individual will be followed up to update the exercise prescription and verify adherence. Motivational interventions (eg, meetings with nurses, physiotherapists and team) will also be provided to the patients/families to increase adherence. Potential modifications to the exercise regimen reported in table 1 are possible (eg, for an intercurrent disease) but they will be discussed within the research team. The number of daily steps shall be calculated as additional walking time, excluding usual daily activities. Activity data, energy expenditure, steps taken, intensity of physical activity, body position and exposure to ambient light will be recorded using an actigraph (ActiGraph wGT3X-BT, Amertis Medical Devices). For this intervention, the diary will record the daily scheduled activity, possible related symptoms and all other physical activities performed during the day (eg, gardening, vacuuming, etc). An exercise facilitator will be based in a clinical research unit/consultancy on the motivational and progressive exercise intervention. This will be an experienced physiotherapy professional and/or qualified exercise specialist who will be active in the unit for a specified number of hours per day to advise patients on their concerns and answer questions about physical activity. The research team professionals will appropriately train the facilitator in managing frail patients, as the investigators have extensive experience in prescribing physical exercise to severely affected patients with different conditions before starting the study.

Variables

Blinded assessors will collect outcomes for patients' allocation groups.

The primary outcome variables will be independence in activities of daily living (individual ability to care for oneself) and the number of hospital readmissions (reasons and consequences).

In particular, independence will be tested through the Spanish version of the BI).[47] The BI is a scale ranging from 0 to 100 and assesses a patient's independence in terms of feeding, bathing, grooming, dressing, bowel and bladder control, transfer, mobility and climbing stairs. A higher value corresponds to greater independence.

The number of hospital readmissions, along with the reasons, dates and lengths of stay, will be collected within 6 months of recruitment. The data will be gathered from the regional hospital database and eventually censored at the date of death. The secondary outcome variables will include the following:

- Sociodemographic variables: age, sex, weight, height, postfracture family role, primary caregiver, previous/habitual physical activity, type of fracture, type of surgery, housing (and if there were structural modifications/arrangements), place of residence before admission and place of residence after hospital discharge.
- Variables related to osteoporosis: intake of calcium, alcohol, coffee and tobacco; sun exposure; previous diagnosis of osteoporosis; T-score; personal or family history of fragility fractures; and knowledge of osteoporosis.
- Variables related to comorbidities: concomitant diseases, cognitive status, treatments (especially analgesics and altering bone mineral metabolism), visual or auditory disturbances, blood pressure, heart rate, blood glucose and previous falls.
- Functional capacity will be assessed via the 6 min walking test.[48] Patients will be asked to walk back and forth on a 10 m corridor, aiming to cover the longest distance possible, which was recorded as the 6 min walking distance. They were allowed to stop if needed due to fatigue or symptoms and restart as soon as possible. In addition, lower limb strength will be measured by the 5-time sit-to-stand test. Patients with their arms folded across the chest will be asked to raise five consecutive times from a standard-height chair and sit back to the starting position as quickly as possible.[49]
- Quality of life: health-related quality of life will be measured through the European Quality of Life 5 Dimensions 5 Level Version (EQ-5D-5L) Questionnaire,[50] which assesses a person's health through questions on mobility, self-care, activities of daily living, pain and anxiety/depression and a numerical scale of general health.
- Cognitive capacity will be assessed via the Lobo Cognitive Mini-examination.[51] This test has a maximum score of 35 points and covers five cognitive areas: spatial–temporal orientation, immediate memory, concentration and calculation, memory and language.
- Depression will be measured via the 15-item Yesavage Depression Scale.[52]
- Physical activity levels will be measured through the Spanish reduced version of the Minnesota Leisure Time Physical Activity Questionnaire.[53] This questionnaire consists of six questions, provides information on energy expenditure during leisure time and allows individuals to be classified into activity categories.
- BMD will be assessed via dual-energy X-ray absorptiometry according to standard published methods.[54] For each patient, both the t-score and z-score at both the lumbar vertebrae and the femur will be assessed.

Table 2 Flow chart of variable measurements during the study

	Inclusion	Allocation	Post allocation			Closure
Time point	−15 days (maximum)	0 Baseline	1° month	2° month	3° month	6° month
Eligibility criteria	X					
Informed consent	X					
Allocation		X				
Intervention						
Exercise-based intervention					X	X
Usual care		X			X	X
Results						
Primary outcomes						
Barthel index		X			X	X
Rehospitalisations		X			X	X
Secondary outcomes						
Lobo Mini-Cognitive Test		X			X	X
VREM		X			X	X
Yesavage scale		X			X	X
VAS		X			X	X
FES-I		X			X	X
EQ-5D-5L		X			X	X
PC6M, 5STS		X			X	X
Osteoporosis-related variables (densitometry and risk factors)		X			X	X
Therapeutic adherence (% of completed sessions)			X	X	X	X
Biochemical/laboratory markers		X			X	X
Long-term results					X	X

EQ-5D-5L, European Quality of Life 5 Dimensions 5 Level Version; FES-I, Falls Efficacy Scale International; PC6M, 6 min walk test; 5STS, 5-time sit-to-stand test; VAS, Visual Analogue Scale; VREM, Minnesota Leisure Time Physical Activity Questionnaire.

- Laboratory parameters: blood samples will be collected by standard methods in the morning while the patient is in a fasting state. In particular, blood glucose, serum creatinine, serum calcium and phosphorus, 25-hydroxyvitamin D, parathyroid hormone and the calcium/creatinine ratio will be analysed via standard laboratory methods at the University Hospital Laboratory Unit.

Data collection: procedure

The data collection procedure is specified in table 2. The follow-up time points will be structured as follows: inclusion, allocation/baseline, post allocation and closure (6 months after starting the intervention for each individual):

- Inclusion (conducted at the hospital site): considering the eligibility criteria, study information will be provided to those individuals who meet the inclusion criteria. If they give their written consent to participate in the study, an independent research unit will randomly assign participants to one of the two groups.
- Assignment: participants will be asked to complete several questionnaires related to physical activity, functional and cognitive capacity, osteoporosis risk factors, pain and quality of life. Biochemical/laboratory tests and densitometry will also be performed. All participants will receive a diary and a debriefing document.
- Post-assignment and closure: For the control group (usual activity), there will be a needs-based follow-up, with two follow-up points (at 3 and 6 months). For the physical exercise group, there will be a monthly follow-up, with four follow-up points (at 1, 2, 3 and 6 months). In all cases, the variables recorded in the assignment period will be collected again at 3 and at 6 months. Specifically, treatment adherence will

be assessed monthly in the physical exercise group. Long-term outcomes will also be recorded in the 3rd and 6th months.

Statistical analysis

Descriptive statistics (measures of frequency, central tendency and dispersion according to the type of variable (quantitative or qualitative)) will be used. Normality will be calculated via the Shapiro-Wilk test, and homogeneity will be calculated via the Levene test. The χ^2 test was used to compare the proportions of categorical variables for contingency tables. In the case of 2×2 tables, this test will be used with Yates' correction and Fisher's exact test if the expected frequency is ≤5. The Student's t-test for independent samples or the non-parametric Wilcoxon test will be used to compare mean values between quantitative variables between intervention groups. The one-factor Analysis of Variance (ANOVA) test and its post-tests with GT2 Hochberg correction (if variances were homogeneous) or Games Howell (if unequal) will be used to determine differences between quantitative variables. For correlations between quantitative variables, Pearson's correlation coefficient will be used. Multivariate analysis will be performed to assess the effect of the intervention. In addition, Kaplan-Meier analysis and Cox regression will be used to model the incidence rates of long-term clinical outcomes (hospitalisation rate and refractures). A posthoc power analysis will also be performed to determine the clinical impact of the findings. All analyses will be performed using intention to treat. Although we will try to reduce their incidence, missing values will be treated via the multiple imputation procedure. In addition, a per-protocol analysis will also be conducted to assess the stability of the study findings. Appropriate gender-oriented analyses will be performed for most of the results. A p value of 0.05 will be considered statistically significant.

Validity and reliability/rigour

The study demonstrates intense rigour through its randomised, controlled, single-masked design, enhancing validity by minimising biases and confounding variables. The consistent single-centre approach and defined inclusion criteria bolster reliability. Regular follow-ups at 3 and 6 months enable thorough monitoring of changes in functional status and health outcomes. The study comprehensively evaluates the intervention effects by examining various outcomes, including functional status or long-term variables. External monitoring and an insurance policy further ensure ethical standards and data integrity. Overall, these elements collectively strengthen the study's validity and reliability.

Author affiliations
[1]Instituto Maimónides de Investigación Biomédica de Córdoba (IMIBIC), Córdoba, Spain
[2]Department of Nursing, Pharmacology and Physiotherapy, Universidad de Córdoba, Córdoba, Spain
[3]Department of Nursing, Hospital Universitario Reina Sofía, Córdoba, Spain
[4]Department of Orthopaedic Surgery and Traumatology, Hospital Universitario Reina Sofía, Córdoba, Spain
[5]Department of Neuroscience and Rehabilitation, University of Ferrara, Ferrara, Italy
[6]Biomedical and Surgical Specialties Sciences, University of Ferrara, Ferrara, Ferrara, Italy
[7]Unit of Physical Medicine and Rehabilitation, University Hospital Arcispedale Sant'Anna of Ferrara, Ferrara, Emilia-Romagna, Italy

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Competing interests None declared.

Patient and public involvement A patient representative will interpret the study results. The results will be disseminated through patient advocacy group newsletters and social media platforms. Patient partners will help select the appropriate channels and develop plain-language summaries tailored to their communities' needs

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ORCID iD
Pablo Jesús López-Soto https://orcid.org/0000-0002-1046-6686

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