# RESEARCH PROJECT APPLICATION REPORT

**Title of the Project:** Effects of a Multimodal Program of Therapeutic Exercise and Functional Recovery With Follow-up in the Elderly After Hip Fracture Surgery Using a Digital Application. Observational Study.
(Code P-2020_007_v1).
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**Principal Investigator's identification details**
Surname, first name: Zambrano Martín, Joaquín
Professional category: Physiotherapist
Email: jzambrano@nebrija.es
Institution: Centro Universitario San Rafael Nebrija, Doctoral Programme in Health, Disability, Dependence and Welfare. International Doctoral School (EIDUM), University of Murcia.

**Collaborating researchers:**

- Surname, first name: Gómez Conesa, Antonia.
  Institution: University of Murcia.
- Surname, first name: Mendoza Puente, Miguel
  Institution: Centro Universitario San Rafael Nebrija.
- Surname, first name:Méndez Sánchez, Roberto
  Institution to which it belongs: University of Salamanca.
- Surname, first name: Chana Valero, Pedro
  Institution: Centro Universitario San Rafael Nebrija.
- Surname, first name: García García, Elena
  Institution to which it belongs: Fundación San Juan de Dios, Centro Universitario de CC de la Salud San Rafael Nebrija.
- Surname, first name: Saldaña Díaz, Andrés
  Institution to which he belongs: Hospital San Juan de Dios de León.

**Project type:** Individual ☒ Coordinated ☐ Multicentre ☐

**SUMMARY**

**Background**

In recent years, Western populations have experienced an increase in life expectancy and therefore an ageing population. This has led to an increase in the number of low-energy hip fractures, which have a major impact in terms of mortality, mobility and loss of function in activities of daily living in this segment of the population.

**Objectives**

To determine the impact in terms of functional recovery, return to pre-hip fracture functional status, of elderly patients treated with the new multimodal therapeutic exercise programme and follow-up for one year compared to patients treated with the previously developed standardised nursing care plan at the Hospital San Juan de Dios de León.

**Methodology**

Observational study of ambispective cohort with two groups, an exposed cohort (retrospective) and a non-exposed cohort (protective factor), made up of people over 65 years of age referred from the Emergency Department of the University Care Centre of León (CAULE) with a confirmed diagnosis of hip fracture, who underwent hip fracture surgery in theHospital San Juan de Dios de León during the years 2020 and 2021.

In order to carry out an analysis of the new care model proposed by the area oforthogeriatricsfor the year 2021: functional recovery programme and its follow-up through a digital application, the entire simple universe will be included (analysis of the complete cohort) with follow-up over a period of one year.

**Keywords (maximum 5)**

*Hip fractures, Physiotherapy, Functional capacity, Frail elderly,*

# BACKGROUND AND CURRENT STATUS OF THE ISSUE

**Introduction.**

Spain is one of the countries with the highest life expectancy at birth in the world, with a life expectancy of 80.0 years for men and 85.6 years for women in 2015 (1). This has led to a considerable increase in the population of elderly people over the last century (2).

This increase does not imply that this high life expectancy is accompanied by years of good health, as older people may suffer from diseases and health problems that lead to a loss of quality of life, without resulting in immediate death (3-5).

One of the most important problems associated with ageing is hip fractures, as it generates a significant impact in terms of morbidity, mortality and functional deterioration. In Spain, this problem causes an incidence of 103 cases per 100,000 inhabitants, with the rate increasing from the age of 75 onwards to 2,534 per 100,000 inhabitants (6.7).

Hip fractures have a very important impact on older people, since in addition to their functional impact on gait, they have an associated inability to perform other activities of daily living and a cognitive impact (8).

Following hip fractures, these patients require many modifications to their daily lives, ranging from increased assistance at home to the need for residential care. This leads to increased health care costs, not only during the hospital stay, but also after discharge (9).

Different clinical practice guidelines have been published in recent years with recommendations aimed at reaching a consensus and improving the care of patients with this pathology (10-13). Despite these recommendations, their implementation in Spanish hospitals has been irregular, generating great variability in the care provided in this process. This has led to differences in patient care depending on the hospital where the patient has been treated, such as: delays in the performance of surgeries, an increase in the number of days of hospitalisation, differences in the number of rehabilitation sessions and differences in the number of consultations (14,15).

What does seem clear is that every elderly person who suffers a hip fracture should undergo a comprehensive assessment including: the cause of the fall, assessment of comorbidity and clinical stability, previous medications, pain, nutritional and hydration status, continence, and cognitive, functional and social status (11).

According to clinical practice guidelines, rehabilitation should begin from the moment of admission, following a multidisciplinary approach, where all those involved are aware of the treatment plan and reasonable expectations of recovery (10-13,16). Early mobilisation, weight bearing and active recovery are the basis of rehabilitation treatment, resulting in lower mortality six months after the intervention and better ambulation (17).

It is estimated that 60-80% of elderly people with hip fractures were walking independently before the fracture. One of the most important goals is to achieve the same degree of ambulation as before the fracture. For this reason, it is important to use validated scales that can provide information on the patient's previous state and help to assess whether or not the objectives have been achieved. Despite this, only 50% manage to recover their pre-fracture state (10).

To achieve this goal, it is desirable that the patient be operated on as soon as possible and begin sitting up the day after surgery, thus facilitating early loading as soon as possible, provided that drains or other devices permit (10,11).

Specific rehabilitation treatment will aim to increase joint mobility; strengthening of the gluteal and quadriceps muscles; re-education of walking as soon as possible, first with the use of devices and progressively more and more independently (10).

In recent years, several reviews have studied the implementation of different rehabilitation programmes for the elderly after hip fracture, with the aim of increasing physical and psychosocial function (18-23).

Several of these reviews (18,19,21) have focused on comparing multidisciplinary rehabilitation with routine orthopaedic care after hip fracture. These studies found that multidisciplinary rehabilitation was associated with a modest but significant reduction in adverse outcomes such as death. These results were confirmed by Wang et al. (22) who found significant differences in terms of reduced mortality during hospitalisation or during subsequent follow-up.

While rapid surgery, early mobilisation and a multidisciplinary team-based approach to rehabilitation seem important for restoring the patient's previous function, there are discrepancies about the contribution of various components of this intensive approach to interventions specifically focused on improving independence such as dressing, shopping and interacting in the community (18,21,24).

Handoll et al. (20) in their review analysed different strategies focused on functional recovery of the elderly after hip fracture surgery, both in and out of the hospital setting.

Their findings highlight the lack of evidence to determine the most effective strategy to help people continue walking after surgery.

On the other hand, Handoll et al. (19) in another review, analysed the difference in costs between patients treated with a multidisciplinary rehabilitation team and regular orthopaedic care, being unable to establish which of the two interventions is more beneficial from an economic point of view. The study includes some recommendations suggesting the inclusion of direct and indirect cost evaluation including both economic and social criteria such as the burden on caregivers. These results contrast with those found by Sabharwal et al (23), who found that orthogeriatric care models in the treatment of frail patients with hip fractures demonstrate a reduction in mortality and morbidity rates, with a better cost-effectiveness of treatment.

Social and psychological factors such as fear of falling, self-efficacy, perceived control and coping strategies are considered important in hip fracture recovery. Positive affect" (e.g. optimistic outlook) appears to be an important predictor of recovery in activities of daily living in various clinical groups and has been associated with a significant reduction in the risk of frailty (25). Mastery or internal control has been shown to be associated with improved coping, adjustment and general mental health after hip fracture. However, strategies such as reorientation, cognitive behavioural therapy and intensive occupational therapy did not show changes in psychosocial outcomes, function and quality of life. This suggests that the transition between acute care, rehabilitation and community care requires further attention. Crotty et al. (18) who did address these social and psychological factors in their review, were unable to establish clear criteria for recommendation in practice because the design and sample size of the included studies were inadequate to draw clear and conclusive conclusions.

It appears that the concept of multidisciplinary treatment is not without certain limitations (26). This type of treatment has been implemented heterogeneously, which makes it difficult to interpret the results obtained and, therefore, to determine best practice (22,23).

Research has addressed the study of different functional parameters with multiple results, however, the aspect of patient participation has been less studied despite being described as the most important outcome for people with disabilities, their families and society (27). Encouraging patients to take an active role has been shown to lead to greater motivation and better outcomes. However, the way in which care after hip fracture is structured, despite the many benefits that can be found, has been described as a possible limiting factor for patient participation because staff are focused on the care of the patient and often do not focus on identifying the personal needs of patients (26).

Based on all of the above, the comprehensive treatment of patients with a hip fracture does not only include the surgical aspect, but is much more complex. It should aim to reduce mortality and recover the functional and psychosocial situation prior to the fracture, trying to achieve these objectives in the shortest possible time and at the lowest possible cost.

**Justification of the Study**

In recent years there has been an increase in the number of hip fractures and this is expected to continue until 2050. From 1.26 million in 1990 to 21.3 million in 2050 (28). Given the ageing of Western populations, the total number of hip fracture cases and their economic consequences are likely to increase considerably. This, coupled with the negative outcome for survivors, many of whom end up being more dependent than before the fracture, calls for studies that address the effectiveness of a functional recovery programme that addresses both the physical and psychosocial spheres of the patient, both in and out of hospital.

The target population of this study is an ageing population, living in a rural environment, far from relatives or people who can help them with daily tasks and with difficulties in accessing the different resources to achieve an optimal recovery. These people therefore need a level of functional recovery that can give them back the level of independence they had before the hip fracture.

# HYPOTHESES AND OBJECTIVES

## Overall objective

- To determine the impact in terms of functional recovery, return to pre-hip fracture functional status, of elderly patients treated with the new multimodal therapeutic exercise programme and follow-up for one year compared to patients treated with the previously developed standardised nursing care plan at the Hospital San Juan de Dios de León.

## Specific objectives

- To describe the improvement in gait ability in patients undergoing hip surgery after a functional recovery programme compared to the historical control group (exposed cohort).
- To describe the clinical and functional characteristics of the patients operated on for hip fracture in the SJD hospital in León who are being followed up by the new system of care implemented in comparison with the historical control group (exposed cohort).
- To analyse risk and protective factors related to the level of dependency and mortality at 30 days and one year of follow-up in patients operated on hipfractureat the SJD hospital in León.
- To describethe impact of a functional recovery programme on the prevention and treatmentof sarcopeniain the new unexposed cohort.
- To describe the quality of life and patient-reported outcomes in the new unexposed cohort.
- To analyse the impact of a functional recovery programme on the prevention of falls in elderly patients who have undergone hip fracture surgery.

## Hypothesis

Amultimodalfunctional recoveryprogrammeoftherapeutic exercisewith patient follow-upafter hip fracture surgery in older people can achieve better resultsthanstandard practice (standardised nursing care plan) in terms ofrecovery of functional status prior to hip fracture.

# METHODOLOGY

## Study design

Longitudinal analytical observational study ofambispectivecohortswith two groups, an exposed cohort (retrospective) and a non-exposed cohort (protective factor),made up of people over 65 years of age referred from the Emergency Department of the University Care Centre of León (CAULE) to theHospital San Juan de Dios de León (HSJD) with a confirmed diagnosis of hip fracture and whounderwent hip fracture surgery in the latter during the years 2020 and 2021, and who will be followed up during the year after surgery, in the latter, to undergo hip fracture surgeryduring the years 2020 and 2021 and who will be followed up during the year following the surgery.

Two groups:

- Non-exposed cohort (protective factor):group of patients operated on during the year 2021 in HSJD for hip fracture and to which the new programme implementing functional recovery and therapeutic exercise will be applied with follow-up for one year. The implementation of a functional recovery plan and subsequent follow-up is considered a protective factor in relation to the loss of functionality.
- Exposed cohort (retrospective): complete cohort of patients operated on during the year 2020 in HSJD for hip fracture and to whom no specific functional recovery plan was applied.

## Ethical aspects

The ethical considerations and good clinical practices set out in the Code of Good Practice in Research of the Fundación de la Orden Hospitalaria San Juan de Dios, following the latest version of the Declaration of Helsinki (2013) and the Taipei Declaration (2016) regarding the custody of health databases, will be taken into account.

1. **Clinical Research Ethics Committee and/or Institutional Review Board.** Documented approval will be obtained from the Fundación San Juan de Dios.
2. **Patient information and consent.** Informed consent (IC) will be requested from all individuals who voluntarily participate in this study. Participants will be informed of the purpose and objectives of the study and the type of participation that will be requested of them, by means of a patient information sheet (HIP). The decision to withdraw from the project during the course of the project will be respected at all times. Consent to participate may be revoked at any time without any detriment to the participant.

3. **Confidentiality. In accordance** with Organic Law 3/2018, of 5 December, on Personal Data Protection and guarantee of digital rights (29), only data that are strictly necessary for the purposes of the study will be obtained. All information will be stored in a computerised archive with access limited to authorised study personnel, with a double password for research purposes. No data that could reveal the personal identity of the participating subjects will appear in any of the study reports.

   The investigators undertake to preserve the confidentiality of the data as provided for in the Law on Patient Autonomy, Information and Clinical Documentation (Law 41/2002 of 14 November 2002) (30), and will inform patients that all data will be kept in computerised format and in a strictly confidential manner. All project investigators will ensure adherence to applicable personal data protection regulations. Data will be destroyed at the end of the study and only data necessary for the present research will be used.

   All data will be stored in an anonymised form. The patient will be informed, via the HIP, that his or her answers will be anonymised.

   The confidentiality and pseudo-anonymisation of the data obtained will be guaranteed by anonymisation through an alphanumeric code. A pseudo-anonymised database will be generated and collected on a technological platform that meets the highest security standards. Pseudo-anonymisation will be maintained in the exploitation of the data.

   Any personally identifiable information will be securely stored by computerised methods in the participating centres and by the PI of the project.

**Study subjects**

**Target population**

The target population will be made up of people over 65 years of age referred from the Emergency Department of the Centro Asistencial Universitario de León (CAULE) with a confirmed diagnosis of hip fracture, who are going to undergo hip fracture surgery at the HSJD.

**Eligibility criteria for the unexposed cohort (protective factor).**

Inclusion criteria:

- Patients referred from the Emergency Department of the Complejo Asistencial de León (CAULE), with confirmation of the medical diagnosis of hip fracture by means of anterior-posterior and lateral radiography.
- Be over 65 years of age.
- Ability to walk before the fracture with or without the aid of instruments or people.
- Have signed the informed consent to participate in the research project.
- With access to a smartphone mobile phone with the option of installing applications.

Exclusion criteria:

- Polytrauma patients will be excluded.
- Metastatic origin of the fracture.
- Periprosthetic fracture.
- Patients with cognitive impairment that makes it impossible for them to use the PPP and who are not accompanied by a responsible person during the recovery process.

Withdrawal criteria:

- Mortality at hospital discharge.
- Presentation of complications.
- Non-compliance with the therapeutic plan or assessment process.

**Eligibility criteria**for the exposed (retrospective) cohort.

Inclusion criteria:

- Patients referred from the Emergency Department of the Complejo Asistencial de León (CAULE), with confirmation of the medical diagnosis of hip fracture by means of antero-posterior and lateral radiography.
- Be over 65 years of age.
- Ability to walk before the fracture with or without the aid of instruments or people.

Exclusion criteria:

- Polytraumapatients will be excluded.
- Metastaticoriginof the fracture
- Periprostheticfracture.

**Sampling**

**Sample and procedure for inclusion of patients in the unexposed cohort.**

In order to carry out an analysis of the new care model (functional recovery programme and patient follow-up through a digital application), the entire simple universe will be included, a complete cohort analysis, with follow-up at 1, 3, 6 and 12 months using a digital toolFollow-up will be carried out at 6 weeks, 4 months and12afterdischargeaccording to the protocol of theorthogeriatricsunit.

The patient will be given instructions on how to download the application to their mobile device. The application is available in the open repository of mobile applications for public use. Once the app is installed, the patient will be provided with a personal access code that does not include recognisable personal data. This code will be used to connect to the therapeutic plan and to the questionnaires provided by the patient when registering with the Traumatology Service. Only the principal investigator (PI) will have a system of correlation between the code and the patient's personal data,be responsible for its safekeeping.

**Sample and procedure for inclusion of patients in the exposed cohort.**

Data will be collected from the medical register reported annually from the HSJD to the National Hip Fracture Registry as part of the active research project in which the project investigators linked to theHSJDare involved.

**Variables**

In the two groups that form part of this study, different variables specified in the database adapted from the National Hip Registry and the *International Fragility Fracture Network,* of which the HSJD is a member*,* will be collected.

Until now, data collection and patient follow-up was completed after one month and the data was transferred annually to the National Hip Fracture Register. In the new model proposed byorthogeriatricsunitof the HSJD, patients will be followed up in person at one and a half months, four months and one year, and at discharge, one month after discharge, three months, six months and one year, by means of a digital application.

The variables to be collected are described below:

**First group: variables established in the National Hip Fracture Registry, defined according to its protocol**

These scales will be administered to both groups:

- Cohort of unexposed patients:to be administered on the dates indicated.

- Cohort of exposed patients (retrospective): data will be retrieved from the Exceldata collection system that the medical management of the HSJD manages for the follow-up of these patients and the report to the national hip fracture registry.

These variables include socio-demographic, clinical and functional characteristics prior to surgery (Table I):

**Table I: Sociodemographic, clinical and functional characteristics prior to surgery.**

| Variables | Unit of measurement | Type |
|---|---|---|
| Age | Years | Independent quantitative |
| Genre | H- Male<br>M- Female | Independent qualitative |
| Caregiver | 1- Yes<br>2- No<br>3- Live alone | Independent qualitative |
| Preoperative mental assessment. Pfeiffer Test (SPMSQ-VE) | Points (0 to 10) | Qualitative |
| Mobility RNFC ladder | Levels (1 to 11) | Qualitative |
| Pre-fracture mobility. Gait assessment scale (mFAC). | Levels (0 to 6) | Qualitative |
| Side affected by the fracture | D- Law<br>I- Left | Qualitative |
| **Abbreviations:** SPMSQ-VE: *Short Portable Mental Status Questionnaire*, (mFAC): *ModifiedFunctionalAmbulatoryClassificator,*RNFC: Registro Nacional de Fractura de Cadera. | | |

- **Preoperative mental assessment. PfeifferTestor "*Short Portable MentalStatusQuestionnaire*" (SPMSQ-VE) (32)**

  It assesses the patient's cognitive status at the time of administration. It consists of 10 questions that are asked prior to surgery, inwhich errors are computed The test should be performed as close to the patient's baseline cognitive state as possible.

  The inter- andintra-observerreliabilityof the SPMSQ-VE is 0.738 and 0.925 respectively, with an internal consistency value of 0.82 (32)

Pfeiffertesttranslated and validated in Spanish

1. What day is today? (Month, day, year).
2. What day of the week is today?
3. Where are we now?
4. What is your telephone number? (If no telephone, street address).
5. How old are you?
6. What is your date of birth?
7. Who is the current Prime Minister?
8. Who was the previous Prime Minister?
9. Tell me your mother's first surname.
10. Starting at 20, subtract 3 by 3 successively until you reach 0.

Errors are scored, 1 point per error. A score of three or more indicates cognitive impairment. If the educational level is low (elementary education), one more error is allowed for each category. If the level of education is high (university), one level less is allowed.

This scale is only administered prior to surgery to assess the patient's cognitive status.

This scale is administered on entry.

- **Pre-fracture mobility, according to the national fragility hip fracture registry(33).**
  Gait is the parameter most strongly associated with frailty states, with gait speed being the parameter most commonlyassociated with frailty(34,36).This is why it is so important to recover functions and capacities in this area of movement. This scale is very easy to use and apply and is used by the national fracture registry, which allows us to make comparisons and statistical analyses with the results published with this registry.

  It assesses by ability levels ranging from 0 to 11. Its design allows firstly to determine gait ability and secondly to see the evolution and establish treatment guidelines.

Capacity levels:

- Level 1-Independent mobility inside and outside the home without technical aids
- Level 2- Independent mobility inside and outside the home, with technical assistance.
- Level 3- Independent mobility inside and outside the home with two technical aids or walker.
- Level 4- Independent mobility only indoors without technical assistance.
- Level 5- Independent mobility only indoors with a technical aid.
- Level 6- Independent mobility only indoors with two technical aids or walker.
- Level 7- Independent mobility only within the house under personal supervision.
- Level 8- Mobility only within the home with little assistance from a person.
- Level 9- Mobility only within the home with a lot of help from a person.
- Level 10- Mobility with two people or no mobility.
- Level 11- Unknown.

For simplicity this variable is summarised in these questions:

- Technical aids (yes/no).
- Outside/inside the home.
- And note the best situation, i.e. it is better with a cane outside than without help at home.

This scale is administered at admission, 6 weeks, 4 months and 1 year.

- ***ModifiedFunctionalAmbulatoryClassifier*(mFAC)(36).**

It is a scale that assesses different levels of ability by grading them between 0 and 6. Its design allows firstly to determine gait ability and secondly to see the evolution and establish treatment guidelines. The modified gait assessment scale has shown anintraclasscorrelation coefficient(ICC)= 0.960, with a 95% confidence interval: 0.942-0.972, an inter-observer agreement Cohen's kappa index of 0.83 (CI: 0.69-0.97) and a validity ρ= 0.814 (36-38)

The capacity levels for this scale are:

- Level 0: Patient who cannot remain seated for more than 1 minute without the help of the backrest and armrest.
- Level 1: Patient who can remain seated without the aid of the backrest and armrest for more than 1 minute.
- Level 2: non-functional ambulation. Walking with great physical assistance from a person,and/or walking is only possible within a therapy session at home, or in hospital, between parallel bars
- Level 3: ambulation in the home, walking with light physical contact with a person. Is able to walk only indoors, on flat, horizontal surfaces, usually within a defined area.
- Level 4: walks autonomously in the home or neighbourhood environment, but needs supervision by a person. They can walk on uneven surfaces and can climb an occasional step.
- Level 5: independent community walking. Can walk on uneven terrain, up and down steps, ramps, kerbs, etc. Can walk considerable distances, but with obvious limp.
- Level 6: walks normally both indoors and outdoors, in the absence of a limp or other abnormality.

This scale is administered at admission, 6 weeks, 4 months and 1 year.

**Second group: the variables collected in this second section form part of the new model of care established by theorthogeriatricsservice,whereby the hip fracture patient will be followed up for up to one year after the intervention, therefore, they are variables that can only be measured in the cohort of unexposed patients.**

Patient follow-up variables (Table II):

**Table II: Patient follow-up variables**

| Variables | Unit of measurement | Type |
|---|---|---|
| Mobility RNFC ladder | Levels (1 to 11) | Qualitative |
| The walking capacity assessment scale (mFAC). | Levels (0 to 5) | Qualitative |
| Level of physical dependency (Barthel Index) | Points (0 to 25) | Quantitative |
| SARCOPENIA (SARC-F Scale) | Points (or a10) | Qualitative |

**Table II (continuation): Patient follow-up variables**

| Variables | Unit of measurement | Type |
|---|---|---|
| Functional Capacity and Pain (Oxford Hip Score) | Points (0 to 48) | Quantitative and Qualitative |
| Falls Risk (STRATIFY Scale) | Points (0 to 5) | Quantitative and Qualitative |
| Medical complications | 0= Fall.<br>1= Pneumonia.<br>2= New fractures.<br>3= Dementia.<br>4= Acute Myocardial Infarction<br>5= Pulmonary embolism.<br>6=Deep vein thrombosis;<br>7=Death. | Qualitative |
| Quality of life analysis: questionnaire EQ-5D-5L | Levels (1 to 3125)<br>Points (0 to 100) | Qualitative<br>Quantitative |
| **Abbreviations: RNFC:** National Hip Fracture Registry, **mFAC:** *Modified Functional Ambulatory Classificator,* | | |

- **Level of dependency: the Spanish version of the *Barthel Index* will be used *(*Annex I). The "*Barthel Index"*** provides quantitative information on the level of dependence for activities of daily living by measuring ten activities that are considered basic (441,42). This scale has been used in other studies and shows a direct relationship between high levels of dependency and poor physical health (441). "The Barthel Index has demonstrated good inter-observer reliability, with Kappa indices between 0.47 and 1.00, intra-observer reliability with a Kappa index between 0.84 and 0.97 and internal consistency with a Cronbach's alpha of 0.86-0.92 (39-41).

  Test results:

  - Values: 0-20 total dependency.
  - Values: 21-60 severe dependence.

- Values: 61-90 moderate dependence.
- Values: 91-99 low dependency
- Values: 100 independence.

This scale is administered at 6 weeks, 4 months and 1 year.

- **Sarcopenia assessment: using the SARC-F scale (ANNEX II) (42).**

  It is an easily accessible questionnaire, validated in Spanish, which allows the identification of subjects at risk of sarcopenia. The maximum score is 10 points. A score of < 4 points after the test indicates an acceptable state of health, while any score higher than this indicates a risk of sarcopenia (43).

  This scale is administered at 6 weeks, 4 months and 1 year.

- **Assessment of functional capacity and specific hip pain: "*Oxford Hip Score (OHS)"* (ANNEX III)**

  It has high repeatability and reliability, with a Cronbach's Alpha value of 0.84 preoperatively, ICC=0.94, and 0.89 at six months and one year (44).

  It is a 12-item questionnaire, each item is answered on a five-level Likert-type scale where 4 is the minimum impact and 0 the most unfavourable (45).

  Results:

  0-19: Severe impact.

  20-29: Moderate to severe impact.

  30-39: Mild to moderate impact.

  40-48: Satisfactory condition.

  This scale is administered at 1, 3, 6 and 12 months.

- **Monitoring of adverse events.**

  During the follow-up period, information will be collected on variables derived from post-surgical and medical complications, and falls risk monitoring will be performed.

  - **Adverse events. Catalogued in:**

    0= Fall.

1= Pneumonia.

2= New fractures.

3= Dementia.

4= Acute Myocardial Infarction.

5= Pulmonary embolism.

6=Deep vein thrombosis.

7= Death.

This scale is administered at 6 weeks, 4 months and 1 year.

- **Falls risk scale: STRATIFY scale**.

  It can predict which patients are at high risk of falls, with sensitivity values of 92% and specificity of 68% for the elderly population (46).

  The total score of the STRATIFY scale is obtained based on the sum of the answers to the five questions, which can take values between zero and five. A score of 0 corresponds to a risk considered low, equal to 1 corresponds to a moderate risk and, finally, greater than or equal to 2 corresponds to a high risk (47).

  Question:

  1. Patient hospitalised for falls or with episodes of falls during hospitalisation?
  2. Restless patient?
  3. Are you a patient with visual impairment that affects your daily activity?
  4. Patient with a frequent need to use the toilet?
  5. Does the patient have a transfer or mobility score of 3 or 4?

  However, in the last question, the score is obtained by combining two answers from the modified Barthel index in relation to, respectively, the patient's ability to:

  - Transferring from bed to a chair

    0: incapable.

    1: needs significant assistance.

    2: Needs minimal assistance.

3: Independent.

- Level of mobility of the patient:
  0: Immobile.
  1: Independent with the help of a wheelchair.
  2: Use walking aids or walk with the help of a person.
  3: Independent.

This scale is administered at 6 weeks, 4 months and 1 year.

- **Quality of life analysis: EQ-5D-5L questionnaire (ANNEX IV) (48).**

  It is a self-administered questionnaire divided into two parts, the descriptive system and the Visual Analogue Scale (VAS).

  - The descriptive system EQ-5D-5L. describes health status along five dimensions:
    - Mobility.
    - Self-care.
    - Daily activities.
    - Pain/discomfort.
    - Anxiety/depression.

    Each of these dimensions has five possible responses or severity levels: no problems (1), mild problems (2), moderate problems (3), severe problems (4) and extreme problems/impossibility (5). The participant should indicate the level that best reflects his/her status for each of the dimensions, describing his/her status using five digits with values ranging from 1 to 5, with the best health status being 11111 and the worst 55555. The combination of these levels defines a total of 3125 ($5^5$) health states.
  - The Visual Analogue Scale (VAS). Assessment by means of a 20 cm millimetre scale in a vertical position. At the top of the scale is the message "the best state of health you can imagine" with a value of 100, at the bottom the message "the worst state of health you can imagine" with a value of 0.

  This scale is administered at 1, 3, 6 and 12 months.

**Data collection procedure.**

The clinical data of the exposed cohort corresponding to the patients operated on during the year 2020 will be extracted from the data collection records that the medical directorate manages for the follow-up of these patients and the report to the National Hip Fracture Registry.

The clinical and care data of the unexposed cohort of patients who will undergo surgery in 2021 will be collected by the trauma team during scheduled patient follow-up visits and by the patient or the patient's caregiver using a mobile application. This data will be recorded and the PI will be responsible for the safekeeping and processing of the data in accordance with current legislation.

The present study is part of a global project to monitor the cohort of patients with hip fractures operated on at the HSJD. This project is a *"real world data"* study in which all the variables of routine practice are collected through a technological application that allows the clinical situation of the patient to be known in real time. The information will be collected through the Caaring® app, developed by Persei Vivarium, with the specific programme for the care of hip fracture patients.

The patient, or the responsible person in patients with cognitive impairment, will receive instructions on how to download the mobile application to their device from an open repository of publicly available mobile applications. The patient will be provided with an access code in which no recognisable data is included. This code allows connection to the questionnaires and information provided by the HSJD trauma service. Only the PI will have a system of correlation between the code and the patient's personal data, and will be responsible for its safekeeping.

The app has two different profiles (doctor, patient), with the researchers being able to enter the data from the face-to-face assessments and the patient or main caregiver the follow-up data from home.

The specialist who monitors the patient has a control panel on the web-app, where he/she has access to risk alerts generated by the system based on the data collected and the clinical rules established for this purpose.

Content of the tool:

The tool has two types of content:

- Questionnaires for the collection of data on the clinical, functional and quality of life evolution of the patient as shown in table III.

**Table III. Summary of variables, assessment instruments and collection period**

| Variable | Questionnaire | Time of administration |
|---|---|---|
| March Capacity | RNFC scale | Entry, at 6 weeks, 4 months and 1 year. |
| | The walking capacity assessment scale (mFAC). | Entry, at 6 weeks, 4 months and 1 year. |
| Physical capacity | Barthel Index | At 6 weeks, 4 months and 1 year. |
| | Oxford Hip Score Scale | At the 1st, 3rd, 6th and 12th month. |
| Sarcopenia | SARC-F Scale | At 6 weeks, 4 months and 1 year. |
| Adverse Events | STRATIFY scale | At 6 weeks, 4 months and 1 year. |
| | Medical complications (ad hoc questionnaires) | At 6 weeks, 4 months and 1 year. |
| Quality of life | Questionnaire EQ-5D-5L | At the 1st, 3rd, 6th and 12th month. |

- The functional recovery programme designed and implemented as standard practice from 1 January 2021. This programme consists of a series of presentations and videos, in simple language with information and recommendations. It will provide answers to patients' most frequently asked questions and will also allow patients to receive reminders regarding their care (recommended exercises, precautions to take in certain circumstances, alerts, etc.).

It is the clinician and the patient, or family member if applicable, who enters the data directly into the application, prior to accepting the legal clauses to that effect.

The study variables collected in the project are included among the clinical variables included in the orthogeriatric protocol for the care of hip fracture patients at the HSJD. In order to analyse those established for this study, the variables will be extracted from the data collection platform, the PI being responsible for the storage and processing of the data in accordance with current legislation.

**Limitations of the study**

The project poses a number of constraints that need to be taken into consideration:

- The current pandemic situation affecting the hip fracture care process.

- The necessary involvement of the relative or the residence in the therapeutic process.
- Adherence to the application for data collection from the patient's experience.
- The use of a mobile application for data collection and the implementation of the recovery programme in an ageing population. A specific follow-up will be established by the research team to support participants who present any kind of difficulty.
- Thosederived from an observational study, which is not conducted under the control and randomisation conditions of a clinical trial

## WORK PLAN (ANNEX V)

This research project is intended to be carried out in the Functional Recovery Unit integrated in the Orthogeriatrics Service of the HSJD and has the following work plan:

- Administrative Phase.

  Complete development of the project in writing and submission for approval to the Doctoral Commission of the University of Murcia and the Research Commission of the Order of San Juan de Dios. Once the project has been approved, it will be submitted to the Clinical Research Ethics Committee (CEIC) as deemed appropriate.

- Initial Phase-Start-up. Duration 18 months.

  The programme will start when the patient is admitted to hospital for hip fracture. Participants who meet the eligibility criteria for the study will be recruited and data collectedParticipants will be informed of the purpose of the study (Annex VI) and their written informed consent will be requested (Annex VII).

  Description of the process:

  - Candidate selection: the patient will be cared for by orthogeriatricsunitaccording to its standard clinical practice protocol approved by the medical management, and based on the care model established by the National Hip Fracture Registry.
  - If the patientis admitted from the emergency department, a referral to geriatrics will be requested to assess the patient.
  - Explanation of the programme and request for informed consent (Annexes VI and VII): at the time of admission, an interview will be held between the patient or relative and the doctor in charge (traumatology service) explaining the process for patients withosteoporotichipfracturein the Hospital; which encompasses the set of coordinated medical decisions (Emergency, Traumatology, Geriatrics) with the aim of obtaining the highest quality care, shorter hospital stay with the maximum level of independence and avoiding a second fracture. In the same way and at the same time, the multimodal plan of therapeutic exercise and functional recovery that will help them during their recovery process will be explained to them.

Subsequently, the patient will be informedof the data collection process, mobile application and follow-up for 1 year, and signatures will be requested for informed consent for anaesthesia, surgery and participation in the study.If the patient accepts,Caaring®application.

Profiles of patients whose clinical circumstances permit, a corroborated history should be taken, including:

- Premorbid function and mobility.
- Available social support (including whether the patient already has a caregiver or whether someone is willing and able to provide such support)
- Relevant current clinical conditions
- State of mind.

- Hip Surgery.
- Recovery programme (protocol of action that replaces the usual practice developed previously):
  - Specific hip fracture recovery programme,restoring the mobility, strength and balance of the operated patient, in order to facilitate the return to a functional state as close as possible to the state prior to surgery and in the shortest possible time, as detailed in Annex VIII. This programme is part of the standard treatment protocol implemented since January 2021 by theOrthogeriatricsUnit of the HSJD.

    This programme is divided into 5 phases, each of these phases coincides with a level of the gait assessment scale. Each individual will start at the level assigned by the doctor and will only have access to the videos of the indicated level and the levels below it. As the patient meets the recovery goals, the physician will provide access to the higher level videos.The functional recovery plan begins the day after the hip fracture and continues after the patient has been discharged for a total of 16 weeks.

  - The therapeutic plan for the historical control group (standard practice until 31 December 2020) consisting of postural changes described in the standardised nursing care plan. Within this plan, the patient was moved to a sitting position prematurely (within the first 24 hours) and started to ambulate within the following 48

hours, provided that the patient's general condition allowed it. This group did not receive any specific functional recovery plan.

- The patient is discharged from hospital and will be assigned a link where he/she will be able to access the online platform to send information from the questionnaires sent during the established periods of 1, 3, 6 and 12 months and will also be sent videos illustrating the rehabilitation exercises that he/she will have to perform during this period. The patient and/or carer will be explained how the tool works, how to access the digital information content and how to access the questionnaires. A means of contact will be provided to resolve doubts, if any. The PI will have access through the web/app platformto a control panel where he/she will be able to detect a patient's lack of adherence, if any, or alerts related to clinical evolution, allowing for exhaustive monitoring of the patient.

- Analysis of results: The data collected will be analysed with the SPSS programme. The mean, median and standard deviation of each of the variables will be calculated. Based on the data obtained from the existing literature(31), having selected a sample of 67 patients, a normal distribution can be assumed for all variables

  For baseline demographic and clinical characteristics, a comparison of means for quantitative variables (t-Student), and of proportions (Chi-square) for qualitativewill be performed

  The statistical analysis will be carried out with a confidence level of 95%, so that statistically significant values will be considered to be those whose probability is $< 0.05$.
- Dissemination of results: the results of this study will be presented for dissemination in scientific journals and specialised conferences.

## BUDGET

| CONCEPT | | COST (€) | AVAILABLE |
|---|---|---|---|
| **Human resources** | Translation service | | NO |
| **Material resources** | Office supplies | | NO |
| | Hard disk (2 units) | 200 | NO |
| | Laptop (2 units) | | YES |
| *Subtotal 1* | | | *2600* |
| **Dissemination costs** | Publication of open access articles | | NO |
| | Attendance at national congress (2 congresses: registration, travel and subsistence. | | NO |
| | Attendance at international congress (2 congresses: registration, travel and per diem) | | NO |
| *Subtotal 2* | | | *3500* |
| **Other** | Travel to centres | | NO |
| | Acquisition of bibliography | | NO |
| | SPSS License | | NO |
| | Professional Office Package | 100 | NO |
| *Subtotal 3* | | | *2400* |
| ***TOTAL*** | | | **8500 (€)** |

## INSTITUTIONAL LINKAGE

The project will be carried out at the HSJD and will be carried out by staff from the centre itself, staff from the Centro Universitario San Rafael Nebrija and the Research Department of the Fundación San Juan de Dios.

All three centres belong to the Order of St. John of God.

## DISSEMINATION PLAN

This project is relevant because of its impact at the clinical and care level and adds value through the implementation of the functional recovery programme using a technological medium.

It is intended to present the results of this study in high impact scientific publications related to geriatrics, orthopaedics and physiotherapy.

The presence at national congresses of traumatology, geriatrics and physiotherapy of the respective scientific societies is an objective within the dissemination plan.

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# ANNEXES

**Annex I: *Barthel Index* Questionnaire (Spanish version) for the assessment of level of dependency.**

## BARTHEL INDEX

| |
|---|
| Patient's Name: ..... Date: .....<br>Initial: ..... |
| FEEDING<br>10 = Independent. Able to apply any necessary device. Feeds in reasonable time.<br>5 = Needs help (e.g; for cutting) ..... |
| BATHING<br>5 = Independent ..... |
| PERSONAL TOILET<br>5 = Independently washes face, combs hair, brushes teeth, shaves (manages plug, if electric) ..... |
| DRESSING<br>10 = Independent. Ties shoes, fastens fasteners, applies braces.<br>5 = Needs help, but does at least half of work in reasonable time. ..... |
| BOWELS<br>10 = No accidents. Able to use enema or suppository, if needed<br>5 = Occasional accidents or needs help with enema or suppository ..... |
| BLLADER<br>10 = No accidents. Able to care for collecting device if used.<br>5 = Occasional accidents or needs help with device. ..... |
| TOILET TRANSFERS<br>10 = Independent with toilet or bedpan, handles clothes, wipes<br>5 = Needs help for balance, handling clothes or toilet paper. ..... |
| TRANSFERS- CHAIR AND BED<br>15 = Independent, including looking of wheel chair, Lifting footrests<br>10 = Minimum assistance or supervision<br>5 = Able to sit but needs maximum assistance to transfer ..... |
| ANBULATION<br>15 = Independent for 50 yards. May use assistive device, except for Rolling walker.<br>10 = With help, 50 yards.<br>5 = Independent with wheel chair for 50 yards if unable to walk. ..... |
| STAIR CLIMBING<br>10 = Independent. May use assistive device.<br>5 = Needs help or supervision. ..... |
| Total: ..... |

A score of zero (0) is given in any category in which the patient does not achieve the stated criterion.

**Annex II: *SARC-F* Questionnaire (Spanish version) for the assessment of sarcopenia.**

## SARC-F Questionnaire

Date :

Name :

Test administered by :

| Component | Question | Scoring | Score |
|---|---|---|---|
| **Strength** | How much difficulty do you have in lifting and carrying 10 pounds? | None = 0<br>Some = 1<br>A lot or unable = 2 | |
| **Assistance in walking** | How much difficulty do you have walking across a room? | None = 0<br>Some = 1<br>A lot, use aids, or unable = 2 | |
| **Rise from a chair** | How much difficulty do you have transferring from a chair or bed? | None =0<br>Some =1<br>A lot or unable without help = 2 | |
| **Climb stairs** | How much difficulty do you have climbing a flight of 10 stairs? | None = 0<br>Some =1<br>A lot or unable = 2 | |
| **Falls** | How many times have you fallen in the past year? | None =0<br>Some = 1<br>A lot or unable= 2 | |
| | | **TOTAL SCORE** | |

A score equal to or greater than 4 is predictive of sarcopenia and poor outcomes.

## Annex III. Oxford Hip Score for functional capacity and hip pain.

**OXFORD HIP SCORE QUESTIONNAIRE**

Please answer the following 12 questions. Choose only one answer per question. The value for each answer is indicated to the right of the answer. Total up all of your answers to obtain a total score out of 48 points. Please only consider how you have been getting on during the past four weeks

| | |
|---|---|
| **Name:** | |
| **Date:** | |
| **Left or right Hip?** | |

**1. How would you describe the pain you usually have in your hip?** Score

None – 4
Very mild – 3
Mild – 2
Mild moderate – 1
Severe – 0

**2. Have you been troubled by pain from your hip in bed at night?**

No nights – 4
Only 1 or 2 nights – 3
Some nights – 2
Most nights – 1
Every night – 0

**3. Have you had any sudden, severe pain- 'shooting', 'stabbing', or 'spasms' from your affected hip?**

Rarely/never – 4
Sometimes or just at first – 3
Often, not just at first – 2
Most of the time – 1
All of the time – 0

**4. Have you been limping when walking because of your hip?**

Rarely/never – 4
Sometimes or just at first – 3
Often, not just at first – 2
Most of the time – 1
All of the time – 0

**5. For how long have you been able to walk before the pain in your hip becomes severe (with or without a walking aid)?**

No pain for 30 minutes or more – 4
16 to 30 minutes – 3
5 to 15 minutes – 2
Around the house only – 1
Not at all – 0

**6. Have you been able to climb a flight of stairs?**

Yes, easily – 4
With little difficulty – 3
With moderate difficulty – 2
With extreme difficulty – 1
No, impossible – 0

**7. Have you been able to put on a pair of socks, stockings or tights?** Score

Yes, easily – 4
With little difficulty – 3
With moderate difficulty – 2
With extreme difficulty – 1
No, impossible – 0

**8. After a meal (sat at a table), how painful has it been for you to stand up from a chair because of your hip?**

Not at all painful – 4
Slightly painful – 3
Moderately painful – 2
Very painful – 1
Unbearable – 0

**9. Have you had any trouble getting in and out of a car or using public transportation because of your hip?**

No trouble at all – 4
Very little trouble – 3
Moderate trouble – 2
Extreme difficulty – 1
Impossible to do – 0

**10. Have you had any trouble with washing and drying yourself (all over) because of your hip?**

No trouble at all – 4
Very little trouble – 3
Moderate trouble – 2
Extreme difficulty – 1
Impossible to do – 0

**11. Could you do the household shopping on your own?**

Yes, easily – 4
With little difficulty – 3
With moderate difficulty – 2
With extreme difficulty – 1
No, impossible – 0

**12. How much has pain from your hip interfered with your usual work, including housework?**

Not at all – 4
A little bit – 3
Moderately – 2
Greatly – 1
Totally – 0

**Total Score:** /48

**Annex IV. Questionnaire EQ-5D-5L for quality of life**

**Mobility**

I have no problems in walking about ❑
I have some problems in walking about ❑
I am confined to bed ❑

**Self-Care**

I have no problems with self-care ❑
I have some problems washing or dressing myself ❑
I am unable to wash or dress myself ❑

**Usual Activities** (*e.g. work, study, housework, family or leisure activities)*

I have no problems with performing my usual activities ❑
I have some problems with performing my usual activities ❑
I am unable to perform my usual activities ❑

**Pain/Discomfort**

I have no pain or discomfort ❑
I have moderate pain or discomfort ❑
I have extreme pain or discomfort ❑

**Anxiety/Depression**

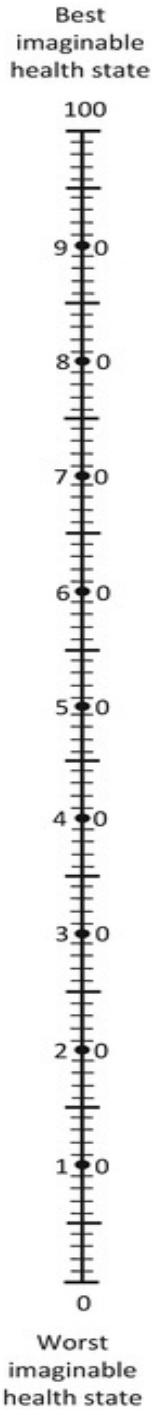
I am not anxious or depressed ❑
I am moderately anxious or depressed ❑
I am extremely anxious or depressed ❑

**Annex IV. EQ-5D-5L Quality of Life Questionnaire (continued)**

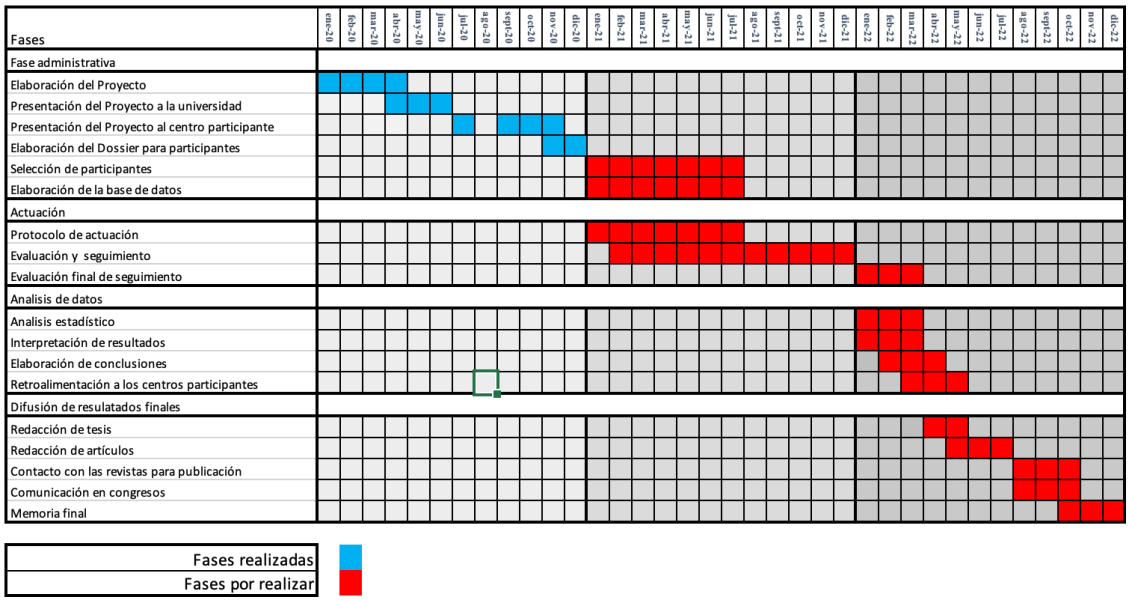
To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

**Your own health state**



## Annex V: Work Plan



**Annex VI: Participant Information Sheet**

# PATIENT/PARTICIPANT INFORMATION SHEET

**PROTOCOL NO:**
**TITLE OF THE STUDY:** Effects of a Multimodal Program of Therapeutic Exercise and Functional Recovery With Follow-up in the Elderly After Hip Fracture Surgery Using a Digital Application. Observational Study.

**RESEARCH GROUP:**
**PRINCIPAL INVESTIGATOR:**

Surname, first name: Zambrano Martín, Joaquín
Professional category: Physiotherapist
Email: jzambrano@nebrija.es

**CENTRE:** Centro Universitario San Rafael Nebrija
**DATE OF SUBMISSION TO THE RESEARCH COMMISSION:** 5 January 2021

## INTRODUCTION

We are writing to you to provide you with correct and sufficient information on the development of the study in which you are proposed to participate, so that you can evaluate and judge whether or not you wish to take part in it. The study has been approved by the Ethics Committee of the Research Commission of the Fundación San Juan de Dios and the Clinical Research Ethics Committee (CEIC) of the Hospital de la Princesa de Madrid, in accordance with current legislation.

Our intention is only that you receive sufficient and correct information so that you can evaluate and judge whether or not you want to participate in this study. To this end, please read this information sheet carefully and we will answer any questions you may have after the explanation. In addition, you are welcome to consult with any other person you consider appropriate.

## VOLUNTARY PARTICIPATION

You should know that your participation in this study is voluntary and that you can decide not to participate or change your decision and withdraw your consent at any time (communicating the decision in writing to the principal investigator, according to RD 1090/2015 of 4 December), without altering the relationship with the healthcare staff or causing any harm to your treatment.

## GENERAL DESCRIPTION OF THE STUDY* :

The aim is to explore the care process in elderly patients hospitalised for hip fracture, identifying aspects for improvement at each point, with the aim of obtaining the highest quality of care, the shortest hospital stay with the highest level of independence and avoiding a second fracture.

This programme will be carried out during their hospital stay and for one year after they have been discharged from hospital.
The recovery plan has been reviewed and approved in advance by the relevant ethics committees in order to ensure that it is not harmful.

For the statistical study, a group of people will be selected according to established inclusion and exclusion criteria, who will undergo the treatment and recovery recommendations established in the hospital protocols.

The programme consists of specific hip fracture recoveryplanre-establishing the mobility, strength and balance of the operated patient, and whose objective is to facilitate the return to a functional state as close as possible to the state prior to surgery.

This programme is divided into five phases coinciding with the different levels of the gait assessment scale and will be prescribed by your doctor depending on your physical condition after surgery. Each level of exercise is designed to achieve certain goals within your recovery and the complete programme will last for a total of 16 weeks. The estimated daily exercise time is 40 minutes, spread over different times of the day for the lower levels (levels 1, 2 and 3) and continuously for levels 4 and 5.

The exercises have been designed so that you can do them comfortably at home without the need to purchase any extra materialand they are explained in a simple way in videos that you can watch on your mobile phone. They are simple exercises adapted to your state of health that will not require any extra effort and will help you to recover.

A member of the research team,during your hospital visits or viathe mobile app, will give you precise instructions on how to perform the exercises at home (frequency and number of repetitions). In addition, you will also be told what data you have to record related to the performance of the exercises.

His progress will be monitored by the research team through the different control visits he has to make tothe Traumatology Unit of the Hospital de San Juan de Dios de León (at 6 weeks, 4 months and a year) and through the application installed on his mobile phone (1st, 3rd, 6th and 12 months). In each case, a series of tests and questionnaires will be carried out, through which different parameters related to their health will be evaluated and data on quality of life and functionality inactivities of daily living will be recorded.

Apart from having the location (telephone andemail) of the principal investigator indicated above,you will have the possibility of making any queries related to the exercise protocol and the studythe mobile application and periodic video control calls

It will be of great importance that they maintain all their usual treatments, informing the principal

investigator of any new developments (drugs, physiotherapy, etc.) that they incorporate while they are part of the study, as well as if any adverse effects appear.

**Sample selection process**

The sample will be obtained from patients admitted to the Hospital Functional Recovery Unit integrated in the Geriatrics Service of the Hospital San Juan de Dios de León and who meet the established inclusion and exclusion criteria.

## BENEFITS AND RISKS OF PARTICIPATING IN THE STUDY

It is considered that the performance of this treatment will improve his functionality after surgery and return him to a situation as similar as possible to the one he had prior to the hip fracture. It is also considered the possibility that the results of the study will allow the establishment of a scientific basis for the use of a functional recovery programme that will enable a better recovery and avoid or reduce the possibility of a second fracture.
Even if you follow the prescribed protocol, you may not gain any health benefit from participating in this study.
None of the previous studies in which exercises similar to yours have been performed have described any adverse effects derived from them. Nor is there any added risk from the diagnostic tests to be performed.

## ALTERNATIVE TREATMENTS

Your participation in this study will not change your current treatment regimens or prevent you from taking a new drug or other treatment that is considered beneficial to the progression of your disease.

The principal investigator of this study will provide more information on request.

## CONFIDENTIALITY

The processing, communication and transfer of personal data of all participating subjects will comply with the provisions of the Organic Law 03/2018, of 05 December, on the Protection of Personal Data and Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on Data Protection (RGPD). In accordance with the provisions of the aforementioned legislation, you can exercise your rights of access, modification, opposition and cancellation of data, for which you should contact the head of the study Mr. Joaquín Zambrano Martín via email jzambrano@nebrija.es or telephone 615378439.

The data collected for the study will be identified by a code and only the person responsible for the study and members of the participating research team will be able to relate this data to you and your medical history. Therefore, your identity will not be disclosed to any person except in case of medical emergency or legal requirement, but always maintaining the confidentiality of these in accordance with current legislation.

Only the data collected for the study will be transferred to third parties and to other countries, with prior notification to the Spanish Data Protection Agency, and under no circumstances will it contain information that can directly identify you, such as name and surname, initials, address, social security number, etc. In the event of this transfer, it will be for the same purposes of the study described and guaranteeing confidentiality with at least the level of protection of the legislation in force in our country.

Access to your personal information will be restricted to the study leader and members of the participating research team, health authorities, the Clinical Research Ethics Committee and personnel authorised by the sponsor, when required to check the data and procedures of the study, but always maintaining the confidentiality of these in accordance with current legislation.

**FINANCIAL COMPENSATION**

Your participation in the study will not entail any costs for you, nor will it be derived in any way from

**OTHER RELEVANT INFORMATION**

Any new information concerning the technique used in the study that may affect your willingness to participate in the study that is discovered during your participation will be communicated to you by your physician as soon as possible.

If you decide to withdraw consent to participate in this study, no new data will be added to the database, and you may request the destruction of all identifiable samples previously retained to prevent further analysis.

You should also be aware that you may be excluded from the study if the study sponsor or investigators deem it appropriate, either for safety reasons, because of any adverse events that occur, or because they feel that you are not complying with the established procedures. In either case, you will receive an adequate explanation of the reason for your withdrawal from the study.

By signing the attached consent form, you agree to comply with the study procedures outlined to you.

At the end of your participation you will receive the best available treatment that your doctor

considers most appropriate for your disease, but you may not be able to continue the study treatment. Therefore, neither the investigator nor the sponsor makes any commitment to continue such treatment outside of this study.

Date

Signature of the patient/participant.

Signature of the investigator.

**Annex VII: Informed consent.**

## INFORMED CONSENT

**PROTOCOL NO:**
**TITLE OF THE STUDY:** Effects of a Multimodal Program of Therapeutic Exercise and Functional Recovery With Follow-up in the Elderly After Hip Fracture Surgery Using a Digital Application. Observational Study.

**RESEARCH GROUP:**
**PRINCIPAL INVESTIGATOR:**
Surname, first name: Zambrano Martín, Joaquín
Professional category: Physiotherapist
Email: jzambrano@nebrija.es
**CENTRE:** Centro Universitario San Rafael Nebrija
**DEADLINE FOR SUBMISSION TO THE RESEARCH COMMISSION:** 5 January 2021

Yo,_____

(name and surname of the study participant)

- I have read the information sheet provided to me.
- I was able to ask as many questions about the study as I could think of.
- I have received satisfactory answers to my questions.
- I have received sufficient information about the study.
- I have spoken to: _____

(name of researcher)

- I understand that my participation is voluntary.
- I understand that I can withdraw from the study:
  - Whenever you want.
  - Without having to explain.
  - Without affecting my health care.

I freely agree to participate in the study.

Date

*Pursuant to Organic Law 03/2018, of 05 December, on the Protection of Personal Data and Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 onDataProtection(RGPD), you are hereby informed that your personal data will be stored in the files owned by Fundación San Juan de Dios in order to provide you with the services you require, as well as to keep you informed about these and other services that may be of interest to you. You may exercise your rights of access, rectification, cancellation and opposition by writing to the Director, C/ Herreros de Tejada, 3 - 28016 Madrid. If you do not wish to receive information, please tick the following box☐*

Signature of participantSignature of researcher

*Pursuant to Organic Law 03/2018, of 05 December, on the Protection of Personal Data and Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 onDataProtection(RGPD), you are hereby informed that your personal data will be stored in the files owned by Fundación San Juan de Dios in order to provide you with the services you require, as well as to keep you informed about these and other services that may be of interest to you. You may exercise your rights of access, rectification, cancellation and opposition by writing to the Director, C/ Herreros de Tejada, 3 - 28016 Madrid. If you do not wish to receive information, please tick the following box☐*

## CONSENT OF THE LEGAL REPRESENTATIVE

**PROTOCOL NO:**
**TITLE OF THE STUDY:** Effects of a Multimodal Program of Therapeutic Exercise and Functional Recovery With Follow-up in the Elderly After Hip Fracture Surgery Using a Digital Application. Observational Study.

**RESEARCH GROUP:**
**PRINCIPAL INVESTIGATOR:**
Surname, first name: Zambrano Martín, Joaquín
Professional category: Physiotherapist
Email: jzambrano@nebrija.es
**CENTRE:** Centro Universitario San Rafael Nebrija
**DEADLINE FOR SUBMISSION TO THE RESEARCH COMMISSION:** 5 January 2021

Yo,_____

(name and surname of the REPRESENTATIVE)

en calidad de_____

(relationship with the participant)

De_____

(participant's name)

- I have read the information sheet provided to me.
- I was able to ask as many questions about the study as I could think of.
- I have received satisfactory answers to my questions.
- I have received sufficient information about the study.
- I have spoken to: _____

  (name of researcher)
- I understand that YOUR participation is voluntary.
- I understand that I can withdraw you from the study:
  - Whenever you want.
  - Without having to explain.
  - Without affecting my health care.

In my presence it was given to _____

(name and age of participant)

all relevant information, adapted to their level of understanding.

*Pursuant to Organic Law 03/2018, of 05 December, on the Protection of Personal Data and Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 onDataProtection(RGPD), you are informed that your personal data will be stored in the files owned by Fundación San Juan de Dios in order to provide you with the services you require, as well as to keep you informed about these and other services that may be of interest to you. You may exercise your rights of access, rectification, cancellation and opposition by writing to the Director, C/ Herreros de Tejada, 3 - 28016 Madrid. If you do not wish to receive information, please tick the following box* ☐

And I freely consent to that_____

(participant's name)

participate in this study, and I consent to the access and use of the data under the conditions detailed in the participant information sheet provided.

Date

Signature of the representativeSignature of the investigated

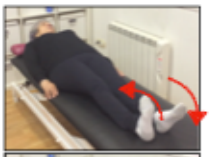
*Pursuant to Organic Law 03/2018, of 05 December, on the Protection of Personal Data and Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 onDataProtection(RGPD), you are informed that your personal data will be stored in the files owned by Fundación San Juan de Dios in order to provide you with the services you require, as well as to keep you informed about these and other services that may be of interest to you. You may exercise your rights of access, rectification, cancellation and opposition by writing to the Director, C/ Herreros de Tejada, 3 - 28016 Madrid. If you do not wish to receive information, please tick the following box* ☐

## Annex VIII: Functional recovery programme.

**LEVEL 1: EXERCISES FOR BED PATIENTS**

**Ankle flexion-extension movement.**

Slowly push your foot up and down. Repeat this exercise several times, up to every 5 to 10 minutes.
Begin this exercise immediately after surgery and continue until you fully recover.

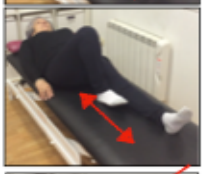


**Ankle rotations**

Move your ankle inward, toward the other foot, and then outward, away from the other foot.
Repeat 5 times in each direction.
Do this exercise 3 or 4 sessions a day.

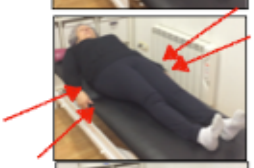
**Bed-supported knee curls**

Slide your foot toward your buttocks, bending your knee and keeping your heel on the bed. Don't let your knee roll inward. Hold your knee in the maximum flexed position for 5 to 10 seconds and then stretch it out.
Repeat 10 times.
Do 3 or 4 sessions a day.



**Gluteal contractions**

Tighten your glute muscles and keep them for a count of 5.
Repeat 10 times.
Do 3 or 4 sessions a day.

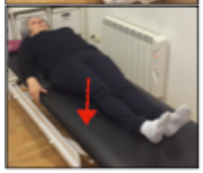


**Open legs exercise**

Slide your leg to the side as far as possible and then back.
Repeat 10 times.
Do 3 or 4 sessions a day

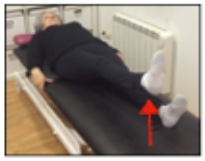
**Thigh strengthening**

Tighten the thigh muscle. Try straightening your knee. Hold for 5 to 10 seconds.
Repeat this exercise 10 times over a 10 minute period, rest for one minute, and repeat.
Continue until your thigh feels fatigued.



**Straight leg raises**

Squeeze your thigh muscle with your knee fully stretched out on the bed. Raise your leg several inches. Hold for 5 to 10 seconds. Lower slowly.
Repeat until your thigh feels fatigued.

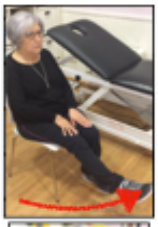


## LEVEL 2: EXERCISES TO BE PERFORMED STANDING

Shortly after surgery, you will be out of bed and able to stand. You will need help at first, but as you regain strength you will be able to support yourself independently. As you do these exercises while standing, be sure to hold on to a firm surface, such as a bar attached to your bed or a wall.

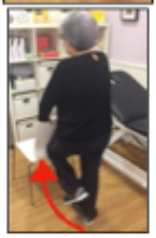
### Seated knee extension exercise

With your leg bent and your foot flat on the floor, straighten your knee and then flex your foot, bringing your toes toward you. Hold for 5 seconds and then lower your leg.
Repeat 10 times.
Do 3 or 4 sessions a day.



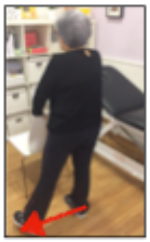
### Standing knee raise

Raise your operated leg toward your chest. Do not lift the knee above the waist. Hold for 2-3 seconds and lower your leg.
Repeat 10 times.
Do 3 or 4 sessions a day.



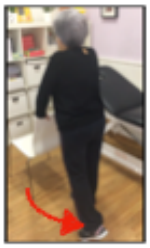
### Leg separation movements

Make sure your hip, knee, and foot point forward. Keep your body straight. With your knee straight, bring your leg to the side. Slowly lower your leg so that your foot returns to the ground.
Repeat 10 times.
Do 3 or 4 sessions a day.



### Standing hip extensions

Slowly lift your operated leg back. Try to keep your back straight. Hold for 2 or 3 counts. Return your foot to the floor.
Repeat 10 times.
Do 3 or 4 sessions a day.



### Sit-up exercise from a chair

Straighten the operated leg without bending the knee and lean on the armrest of the chair. Lean forward slightly and supporting your weight on your good leg and your hands slowly rise
Repeat several times.
Do 3 or 4 sessions a day.

## LEVEL 3: INTERMEDIATE EXERCISES GROUP

Los pacientes realizarán 5 ejercicios sentados o acostados más una pequeña cantidad de caminata utilizando ayudas para caminar durante un total de 30 minutos. Los ejercicios deben ser realizados de forma progresiva aumentando las repeticiones y la resistencia.

Patients will perform 5 exercises sitting or lying down plus a small amount of walking using walking aids for a total of 30 minutes. The exercises should be done progressively, increasing repetitions and resistance.

### To walk

Walking properly is the best way to help your hips heal. At first, you will walk with a walker or crutches. Your surgeon will tell you how much weight you can put on your leg. Walking will help you regain movement in your hips.

Stand comfortably and upright with your weight balanced evenly on your walker or crutches. Advance your walker or crutches a slight distance first; Slowly stretch the operated leg forward with your knee fully extended until the heel of the foot touches the ground. As your body moves forward, your entire foot will make contact with the ground. Then move your good leg up to the level of the foot of the operated leg.

Walk comfortably and smoothly. Do not rush. Adjust your stride length and speed so that it is comfortable for you and you can make a smooth pattern. As your muscle strength and endurance improve, you may spend more time walking. As time goes by, you will put more weight on your leg and then you can use a cane in the hand opposite the operated leg and eventually walk without assistance.

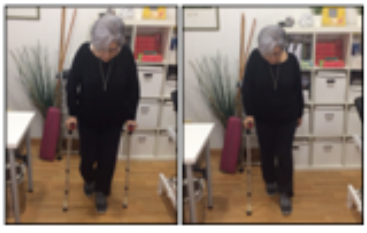
When you can walk and stand for more than 10 minutes and your leg is strong enough not to put weight on your walker or crutches, you can start using a single crutch or cane. Hold the aid in the hand opposite the side of your surgery.

### Walking with a walker

First, forward the walker, then advance with the operated leg without bearing much weight, finally, advance the good leg.


### Walking with crutches

First, forward both crutches, then advance with the operated leg without bearing much weight, finally, advance the good leg.



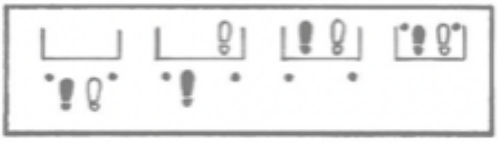
## LEVEL 4: GROUP OF INTERMEDIATE EXERCISES TO GO UP AND DOWN STAIRS

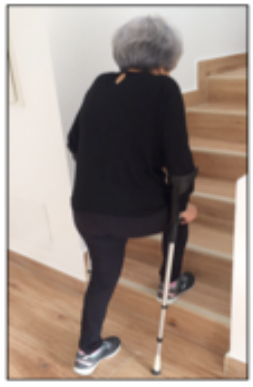
**Up and down stairs**

The ability to go up and down stairs requires strength and flexibility. At first, you will need a handrail for support and will only be able to go one step at a time. Always go up the stairs with your good leg and go down the stairs with your operated leg. You may want someone to help you until you have regained most of your strength and mobility. Climbing stairs is a great strength and endurance activity. Do not attempt to climb steps higher than the standard height (18 cm) and always use a handrail for balance. As you get stronger and more mobile, you can start climbing stairs step by step.

**Climbing stairs**

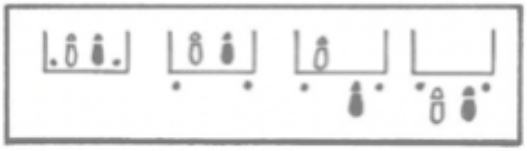
Place the good leg on the step, then raise the operated leg and finally raise the poles.

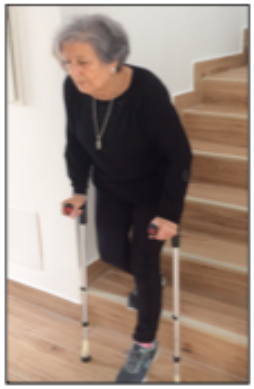




**To go down the stairs**

Place the poles on the bottom rung, lower the operated leg and finally lower the operated leg.

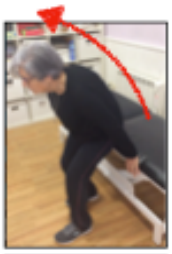




## LEVEL 5: ADVANCED EXERCISES GROUP

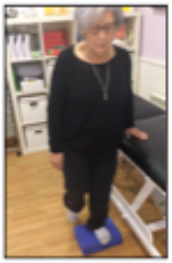
Walking and strength and balance exercises for a total of 60 minutes a day.

### Sit / stand up



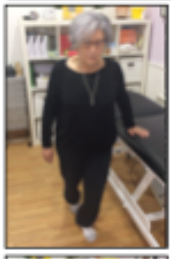
Sit on the edge of the chair with your cushion raised. Lifts from the chair and sit back several times. First begin to do it with the operated leg in front and as you are able to flex the leg more, slow down your position.
Don't bend your hips more than 90 degrees. Repeat 8 to 15 times.

### Step up / step down



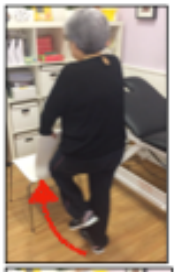
Use handrails to keep your balance. Place one foot on a step and step forward by lifting your body. Then go back to the starting position. This exercise should be done with both legs (first one 8-15 repetitions and then the other). As you find yourself with more force, you can decrease the help of the handrail.
Repeat 8 to 15 times.

### Shifting weight back and forth.



Stand next to a stable support and prop one heel in front of the other foot. Shift your weight back and forth through the balls of your feet, staying upright
Repeat 20 to 30 times.
As you feel stronger and more confident, gradually remove the support from the support.

### Standing knee raise



Raise your operated leg toward your chest. Do not lift the knee above the waist. Hold for 2-3 seconds and lower your leg.
Repeat 10 times.
Do 3 or 4 sessions a day.

### Leg separation movements

Make sure your hip, knee, and foot point forward. Keep your body straight. With your knee straight, bring your leg to the side. Slowly lower your leg so that your foot returns to the ground.
Repeat 10 times.
Do 3 or 4 sessions a day.

## Transfer exercises

### Get out of bed

If you stand on the side of your good leg: Leave your operated leg straight, being careful not to twist it. Support yourself with your elbow and forearm on the good side and move closer to the edge of the bed. Get your good leg out of bed and push yourself up with the help of your elbow and forearm. Once sitting on the edge of the bed, you can stand up, as long as you are not dizzy.

If you stand up on the side of the operated leg: Bend your good leg over the bed, leave your operated leg straight with the toe facing up. Get on your elbows and take the operated leg out of the bed, get up with the help of your arms until you get to the sitting position.

### Get out of bed

You must do the reverse process: bend your good leg supporting the operated leg on the bed. Once the good leg is supported, be careful not to twist it, the foot must always face upwards. Drop onto the bed leaning on your elbow and forearm.

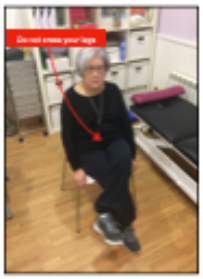
### Go to the bathroom.

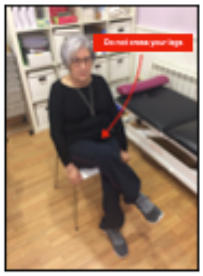
You must go through the same process as getting up from a chair. Remember that there are some adapters that can facilitate the process

## RECOMMENDATIONS

### Do not cross your legs

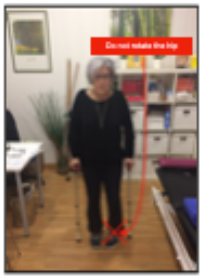
You should not sit in low chairs for a long time, or stay cross-legged.




### Do not rotate the hips when loaded

The hips should not remain rotated. Remember that your toes and knee should point forward.





### How should you sleep

During the early stages, you should not lie flat on either of your hips for a long time. The best way is to sleep on your back and with a pillow separating the two legs.