



An m-Health telerehabilitation and health education program on physical performance in patients with hip fracture and their family caregivers: Study protocol for the ActiveHip+ randomized controlled trial

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Abstract

Telerehabilitation interventions administered via a smartphone may provide new feasible and effective rehabilitation options at home for patients with hip fracture. However, to date, no such interventions have been shown to be effective in the recovery key health outcomes of these patients. The present multicentre randomized controlled trial (RCT) aims to test the effect of the ActiveHip+ m-Health system in the recovery of physical performance, functional level, quality of life, and other health-related outcomes in both patients with hip fracture and their family caregivers. A total of 104 patients older than 65 years, with hip fracture, and their family caregivers will be randomized into the ActiveHip+ rehabilitation ($N = 52$) or the control group ($N = 52$). ActiveHip+ is a 12-week smartphone-based rehabilitation program conducted in Granada and Cádiz (Spain) that includes: (1) 24 sessions of

physical exercise and 12 sessions of occupational therapy; (2) seven educational modules for patients and for caregivers; and (3) general recommendations in activities of daily living. The control group will receive the usual rehabilitation protocol offered by the Andalusian Public Healthcare System. The primary outcome is the patient's physical performance, while the secondary outcomes are the patient's functional level, quality of life, pain, fear of falling, fitness perception, pre-fracture functional level, emotional status, and caregiver burden. The present project will substantially contribute to the existing knowledge by testing for the first time the efficacy and feasibility of a multidisciplinary m-Health system in the rehabilitation of patients with hip fracture.

KEYWORDS

aging, exercise, musculoskeletal system, orthopedics, rehabilitation

1 | INTRODUCTION

Hip fracture is currently a major public health problem worldwide due to its high incidence, mortality rates, and associated economic burden (Bartra et al., 2019; Morri et al., 2019; Sterling, 2011). The number of hip fracture incidents in the world population is expected to increase from 1.7 million in 1990 to 2.6 million in 2025 and further to 6.3 million in 2050 (Dhanwal et al., 2011; Friedman & Mendelson, 2014). The reduction in physical performance, the loss of functional independence, and the detriment of the quality of life are some of the main consequences derived from hip fracture (Ortiz-Piña et al., 2019). Only between 40% and 60% of patients recover pre-fracture functional level and level of physical performance one year after the fracture, whereas between 20% and 60% of them require assistance to perform activities of daily living (Dyer et al., 2016).

Structured interventions combining physical exercise, physical therapy, and occupational therapy are effective in recovering previous mobility and functionality levels and, therefore, in improving the quality of life of these patients (McDonough et al., 2021). However, the main limitation of current rehabilitation interventions is the lack of continuity after hospital discharge derived from health professional shortage (Perracini et al., 2018). The COVID-19 pandemic has further undermined the medical staff assigned to orthopedic trauma and has also compromised the hospital length of stay to reduce infection risk (Wang et al., 2020). Furthermore, in-person rehabilitation is difficult for people living in rural areas, who have problems commuting to hospital services and have no close access to the healthcare professionals in charge of their rehabilitation (Elliott et al., 2014).

The rise of Information Communication Technology Services brings the opportunity to improve the rehabilitation process during hospitalization and, especially, after hospital discharge. This new field of medicine called telerehabilitation is defined as a set of tools, procedures, and protocols to deliver the rehabilitation process remotely (Pastora-Bernal et al., 2017). Telerehabilitation overcomes some of the limitations of more traditional home-based rehabilitation

since it does not require health professionals to commute to the patient's home while allowing an efficient monitoring of the rehabilitation (Pastora-Bernal et al., 2017). Previous telerehabilitation interventions have been demonstrated to be feasible and effective in several health conditions (Pastora-Bernal et al., 2017; Peretti et al., 2017). However, to the best of our knowledge, there are only three previous studies testing the effects of telerehabilitation interventions in patients with hip fracture (Eichler et al., 2017; Gilboa et al., 2019; Ortiz-Piña et al., 2019); one of these is the predecessor project of the current ActiveHip+.

Mobile health (m-Health) interventions are gaining relevance in the last years due to smartphone omnipresence in today's society. Smartphone use makes this technology ideal for feasibly and effectively implementing and monitoring telerehabilitation (Marcolino et al., 2018). However, only one of the available telerehabilitations incorporated the intervention via smartphone app (Doiron-Cadrin et al., 2016), while the remainder used more traditional procedures such as phone call, email, video-conference systems, or websites to conduct the rehabilitation process (Eichler et al., 2017; Gilboa et al., 2019; Ortiz-Piña et al., 2019). The lack of skills with smartphones is one of the most common barriers in using m-Health tools for older adults (Kampmeijer et al., 2016), who are the target population in telerehabilitation of hip fracture. Family caregivers (i.e., relatives or friends) represent an ideal facilitating factor to help with the usability of these technologies and engagement with the rehabilitation process, especially younger caregivers who tend to have adequate smartphone skills (Kampmeijer et al., 2016). Furthermore, these family caregivers are often forgotten in the rehabilitation process; however, they have a fundamental role in supporting older adults to recover their ability to complete activities of daily living and providing social, emotional, and economic support (Ariza-Vega et al., 2021). To date, there are no telerehabilitation interventions via m-Health tools for patients with hip fracture that actively involve family caregivers, and future studies that test its feasibility and effectiveness are needed.

The ActiveHip+ project arises as a step forward in the telerehabilitation of patients with hip fractures by offering an integral

m-Health system that assists both the patient and the caregiver through the rehabilitation process. This study project has two main objectives: (1) to test the effectiveness in patients with hip fracture of a 12-week smartphone-based rehabilitation and health education program on key clinical outcomes (e.g., physical performance, functional independence, or quality of life) based on an m-Health system; and (2) to assess the feasibility of implementing a home-based ActiveHip+ intervention. Our hypotheses are: (1) ActiveHip+ will be superior or equally effective to the current rehabilitation protocol in Andalusia (Spain) on the recovery of the above-mentioned clinical outcomes, and (2) feasibility indicators (e.g., adoption, fidelity, and users' experience with the app) will be acceptable enough to consider the implementation of ActiveHip+ in the Andalusian health system. Equal effects would be also relevant since ActiveHip+ provides several advantages (e.g., reducing healthcare costs and the possibility of rehabilitating from home) that position it as a complementary rehabilitation to be considered.

2 | METHODS

2.1 | Design

The ActiveHip+ is a multicenter randomized controlled trial (RCT) that follows a parallel-group design (1:1). Three Spanish hospitals participate in this study: Virgen de las Nieves University Hospital (Granada), Puerto Real University Hospital (Cádiz), and Jerez de la Frontera University Hospital (Cádiz). The project has been registered in [ClinicalTrials.gov](https://clinicaltrials.gov) (blinded) and will be carried out according to the guidelines established by the Helsinki Declaration and Law 14/2007 on Biomedical Research. ActiveHip+ has been approved by the Ethics Committee of... (blinded).

2.2 | Study population

A total of 104 patients with hip fracture and their family caregivers will be assigned to the intervention ($n = 52$) or to the control group ($n = 52$).

The inclusion criteria are: (1) diagnosed with a hip fracture, (2) 65 years or older, (3) allowed weight-bearing at 48 h after the surgery, (4) high pre-fracture functional level the week before the fracture (Functional Independence Measure [FIM] index scored more than 90 points), (5) live at their own home or the home of relatives after hospital discharge, and (6) have an informal or family caregiver who has the ability to access Internet to use the app ActiveHip+ and to manage the basic settings of the mobile phone.

The exclusion criteria are: (1) the presence of severe cognitive impairment (Pfeiffer test score higher than 4 errors), (2) institutionalized, (3) post-surgery complications that make impossible to start rehabilitation within the first-week post-surgery (i.e., re-surgery, breathing or heart problems) and (4) the presence of terminal diseases.

2.3 | Recruitment, allocation, and blinding

The recruitment is taking place at three large hospitals in cities located in Andalusia, Spain. Hospitalized patients and their caregivers are invited to participate during their hospital stay after hip fracture surgery. Following the inclusion criteria mentioned above, the investigator explains to patients and caregivers the main characteristics of the program. After consent is obtained, participants are assigned to the intervention or control group using sealed numbered envelopes. Due to the characteristics of the intervention, blinding of participants is not possible since they are aware that they are performing the m-Health rehabilitation program. Regarding the blinding of the research team, investigators who perform testing to assess participant outcomes and analyze study data will be blinded to group. Furthermore, the investigators assessing the outcomes will not be the same pre- and post-rehabilitation to ensure an optimal blinding strategy and, therefore, avoid possible risk of bias during the assessment process.

2.4 | Sample size and power

The G*Power V.3.1.7 software (Franz Faul, Christian-Albrechts-Universität zu Kiel) (version 3.0.1) was used to calculate the sample size required. Power calculation was based on the pilot study preceding the ActiveHip+ project (Ortiz-Piña et al., 2019). We extracted the effect sizes derived from a telerehabilitation intervention on the main outcomes, physical performance, and functional status. Considering an 80% power, an alpha error of 5%, and a dropout rate of 15%, the ActiveHip+ project needs 104 participants (52 for the ActiveHip+ group and 52 for the control group) to obtain a reliable statistical power in the main outcomes.

2.5 | Intervention

2.5.1 | ActiveHip+ intervention

Patients and their family caregivers allocated to the intervention group receive access to the ActiveHip+ mobile app loaded in their personal smartphones for a period of 12 weeks. The family caregiver will have a key role in ensuring the continuity of the monitoring of the patient's rehabilitation program, since in most cases the caregiver will be the person who will access the smartphone app and then show and deliver the sessions to the patient.

The content included in the ActiveHip+ project was co-created by several focus groups comprised of patients with experience in hip fracture recovery, family caregivers, and health professionals. Specifically, development of the m-Health system followed a rigorous 7-month process that actively involved: (1) the ActiveHip+ research team, (2) experts in the field of hip fracture and rehabilitation (i.e., endocrinologists, nurses, nursing assistants, occupational therapists, orthopedic surgeons, physiatrists, physical therapists, and physical

education specialists), (3) stakeholders who participated in the previous @ctivehip project and those who were involved in the focus groups conducted during the co-creation process, and (4) partners specialized in creating educational content and Information Technology (IT) resources. The design of the ActiveHip+ system included the following stages: (1) focus groups with patients and family caregivers with experience in the recovery process of hip fracture; (2) a review of other home-based exercise programs and telerehabilitation programs; (3) multidisciplinary team meetings to decide the type and intensity of the exercises and activities to include in each video for each session after the focus groups; (4) trial test sessions with health professionals, patients, informal caregivers and engineers to assess the functioning of the online platform; and (5) multidisciplinary team meetings considering health professionals and engineers' feedback to review and amend (if needed) the content of the videos and the online platform. The team's main concern was the creation of a program that would be safe for the patient and easily supervised by the caregivers. In Supporting Information, we provide a detailed description of final intervention content.

The ActiveHip+ m-Health system includes two virtual environments for intervention delivery: (1) the health professionals' environment to prescribe and guide the intervention and (2) the patients and caregivers' environment to carry out the intervention. Figure 1 summarizes the main features offered in each environment. Moreover, Figure 2 shows a graphical representation of examples of the content provided in the patients and caregivers' environment. The patients and caregivers have two main resources: a health educational program and a home-based multidisciplinary telerehabilitation program consisting of physical exercise and occupational therapy. The content of the telerehabilitation program is summarized in Figure 3 (physical exercise) and Figure 4 (occupational

therapy), whereas Supporting Information provides a more detailed description.

The patients have the opportunity to perform three smartphone-based sessions per week (two sessions of physical exercise and one of occupational therapy), preferably performed on nonconsecutive days with each session lasting 30–60 min. A fourth session called “bonus session” is available for those patients who complete the three sessions of the week and feel motivated to perform an extra session. Each session is performed at home with the help of prerecorded videos which include spoken instructions that describe the prescribed activities. Both the physical exercise and occupational therapy programs include four levels of difficulty, which can be prescribed by health professionals according to the patient's physical and functional level evaluated through the Short Physical Performance Battery (SPPB) and FIM questionnaires.

The educational program has a total of seven modules. Five modules are for patients and family caregivers, and two modules are specifically for family caregivers. Each module is comprised of videos with varying content related to hip fracture recovery and prevention of a second fracture (e.g., recovery process during hospital stay or keys to the physical and mental well-being of caregivers).

Finally, the mobile application includes a section of general recommendations for patients and caregivers as well as a section of Activities of Daily Living, which aims to facilitate day-to-day life through videos.

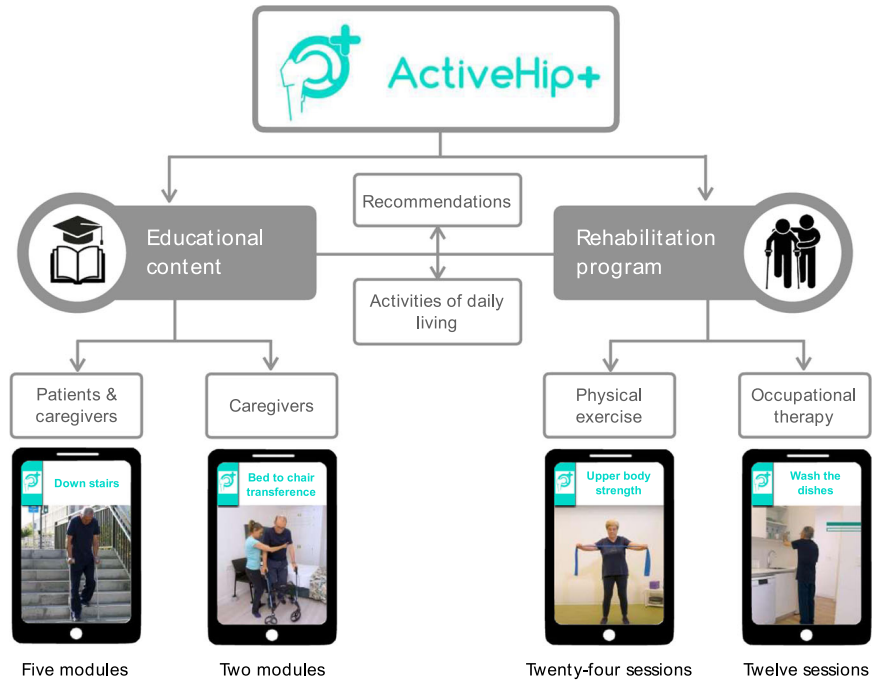
2.5.2 | Adherence strategies and facilitators

The patients and their family caregivers will be verbally encouraged via videoconference to participate in the program, perform in-home



FIGURE 1 Main features offered in both the health professionals' environment, and the patients' and caregivers' environment [Color figure can be viewed at wileyonlinelibrary.com]

FIGURE 2 ActiveHip+ content provided to patients and caregiver [Color figure can be viewed at wileyonlinelibrary.com]



sessions, and attend follow-up physical assessments with clinicians in hospital settings. Patients will have the opportunity to check the progression of the telerehabilitation program by milestone indicators within the app represented by flags to motivate them during the recovery process. During the intervention period, an investigator will record how often patients and family caregivers access the app and the number of sessions performed. Furthermore, the educational program includes two questions at the end of each module to verify the learning of the content. The health professionals will call participants once per week during the first 2 weeks, and once every 2 weeks during the following 10 weeks to encourage them to continue performing the exercises and to answer any questions. The tools that will be used to keep in contact are messages through the health professional's website and the mobile application and video conferences based on the participants' or health professionals' requirements.

2.5.3 | Control group

Patients assigned to the control group will receive the usual outpatient rehabilitation protocol offered by the Andalusian Public Healthcare System. It consists of 5–10 face-to-face rehabilitation sessions focused on general recommendations for improving balance and functional capacity (Aguar García et al., 2014). Sessions are delivered by physiotherapists and occupational therapists after hospital discharge at patients' homes. Therapists have certain autonomy in the rehabilitation process within the above-mentioned recommendations. Additionally, the control group will receive an informative booklet with recommendations on physical exercise and activities of daily living. The total number of rehabilitation sessions

performed by each patient (including those provided by the workers from the public health system and any private rehabilitation sessions paid for by the patient) will be recorded so that portion of rehabilitation received by each patient can be controlled for in the statistical analyses.

2.5.4 | Common intervention in both groups

Both groups receive the same rehabilitation process during the postoperative hospital stay, which usually lasts 1 week. This inpatient rehabilitation consists of 3–5 face-to-face rehabilitation sessions of physiotherapy and occupational therapy conducted at the hospital facilities. Thereafter, the intervention group receives the ActiveHip+ rehabilitation in the home whereas the control group receives the above-mentioned protocol.

2.6 | Clinical outcomes

The primary outcome (physical performance) and secondary outcomes for both groups will be assessed at hospital discharge and 3 months later (timepoint coincides with their first postoperative visit). An overview of the included outcomes and the study design is presented in Figure 5.

2.6.1 | Physical performance

The SPPB assessment has previously been used to evaluate older people and patients with hip fracture (Guralnik et al., 1994;










 Phases	 Exercise modality	 Time; Exercises; Rest	 Equipment	 Intensity	 Weeks
 WARM UP					
	Flexibility and joint mobility, and exercises to raise body temperature	2.5 min; 6 exercises; 60 sec at the end	Chair without armrests	Low Rated Perceived Effort (RPE): 3-4 / 10	1 - 16
 MAIN TRAINING					
Level I Initiation	Flexibility, upper-body and lower-body resistance training, and static balance	18 - 25 min; 8 exercises; 60 sec between exercises	Squeeze ball, dumbbells, walker and elastic bands	Moderate RPE: 5 / 10	1 2 3 4
Level II Moderate	Flexibility, upper-body and lower-body resistance training, dynamic balance, and step exercises	25 - 38 min; 10 exercises; 60 sec between exercises	Squeeze ball, dumbbells, walker, elastic bands and step	Moderate RPE: 6 / 10 Increase volume (sets and reps)	5 6 7 8
Level III Advanced I	Upper-body and lower-body resistance training, dynamic balance, step exercises, and gait pattern	30 - 38 min; 10 exercises; 60 sec between exercises	Dumbbells, walker, elastic bands and step	Vigorous RPE: 7 / 10 Increase volume (sets and reps) and resistance	9 10 11 12
Level IV Advanced II	Upper-body and lower-body resistance training, dynamic balance, step exercises, and gait pattern	33 - 55 min; 10 exercises; 60 sec between exercises	Dumbbells, elastic bands and step	Vigorous RPE: 8 / 10 Increase volume (sets and reps) and resistance	13 14 15 16
 COOL DOWN					
	Flexibility, joint mobility, breath and relaxation exercises	2.5 min; 4 exercises	Chair without armrests and tennis balls	Low RPE: 3-4 / 10 Weight-bearing exercises	1 - 16

FIGURE 3 Description of the ActiveHip+ physical exercise program

Latham et al., 2014; Salpakoski et al., 2014). This tool consists of three tasks: balance, walking, and chair stands (Guralnik et al., 1994). The SPPB evaluates the ability to maintain balance for 10 s in certain positions, time to walk 4 m, and time required to sit and stand up from a chair five times. We will consider the individual scores to enhance understanding of patient physical performance. The total score ranges from 0 to 12 points, where higher scores indicate better mobility. The SPPB has been demonstrated to be valid and reliable (i.e., Intraclass Correlation Coefficient [ICC] > 0.83) in older adult populations (Freire et al., 2012). Furthermore, internal consistency is high with a Cronbach's $\alpha = 0.87$ (Gómez Montes et al., 2013).

Additionally, the handgrip strength test will be used as an objective indicator of muscular strength. Handgrip strength is a valid indicator of vitality and physical function in older adults (Labott et al., 2019) and has demonstrated a high test-retest reliability in clinical settings (Ferreira et al., 2021). Participants will perform the test standing and will be asked to squeeze as strong as they can twice

per hand. The final output will be the average strength in kilograms of each hand, which will be divided by the participant's body weight to avoid the biasing effects of body size in muscular strength.

2.6.2 | Quality of life

The EuroQol (EQ-5D) is a patient-reported outcome measure used to evaluate the overall quality of life of the patients (Balestroni & Bertolotti, 2012). The questionnaire consists of five dimensions (mobility, self-care, usual activities, pain, and depression) and is used to evaluate perceived health status on a range from 0 (the worst health status) to 100 (the best health status; Balestroni & Bertolotti, 2012). This outcome measure has previously been used to evaluate patients with a hip fracture (Tidermark et al., 2003). The EQ-5D is valid, shows a good test-retest reliability (i.e., ICC = 0.74) and presents good internal consistency (Cronbach's $\alpha = 0.83$; Marti et al., 2016; Xu et al., 2021).

Phases	Task-oriented Training	Time; Activities; Rest	Equipment	Functional Status	Weeks
MAIN SECTION					
Level I Initiation	Mobility in bed	15 - 20 min; 5 - 6 activities; 60 seconds between each activity	Bed, chair, walker, ball, small boxes and bottles	Functional Independence Measure (FIM) score < 60 points	1 - 4
	Transfer from chair to stand (walker)				
	Trunk mobility in sitting position				
Level II Moderate	Walking with walker	23 - 33 min; 6 activities; 60 seconds between each activity	Chair, walker, cane, table, small balls, small boxes, bottles kitchen furnitures	FIM score between 60 and 90 points	5 - 8
	Transfer form chair to walk (walker)				
	Body turning activities				
	Save obstacles with walker				
Level III Advanced I	ADL involving objects manipulation	30 - 35 min; 6 activities; 60 seconds between each activity	Chairs, table, medium balls, cups, medium-size boxes, kitchen furnitures	FIM score between 90 and 104 points	9 - 12
	Walking without support				
	Transfer activities without walker				
Level IV Advanced II	Balance training (e.g., ball)	28 - 45 min; 7 activities; 60 seconds between each activity	Chair, cups, medium-size balls, medium-size boxes, shower tray and kitchen furniture	FIM score > 104 points	13 - 16
	Walking without support				
	ADL involving objects manipulation				
DANCING ACTIVITIES					
Levels I, II, III and IV	Dancing with support devices, multi-direction movements and playful component	5 min; 16 different choreographies	Chair and walker	The choreography is in agreement with the functional status	1 - 16

FIGURE 4 Description of the ActiveHip+ occupational therapy program

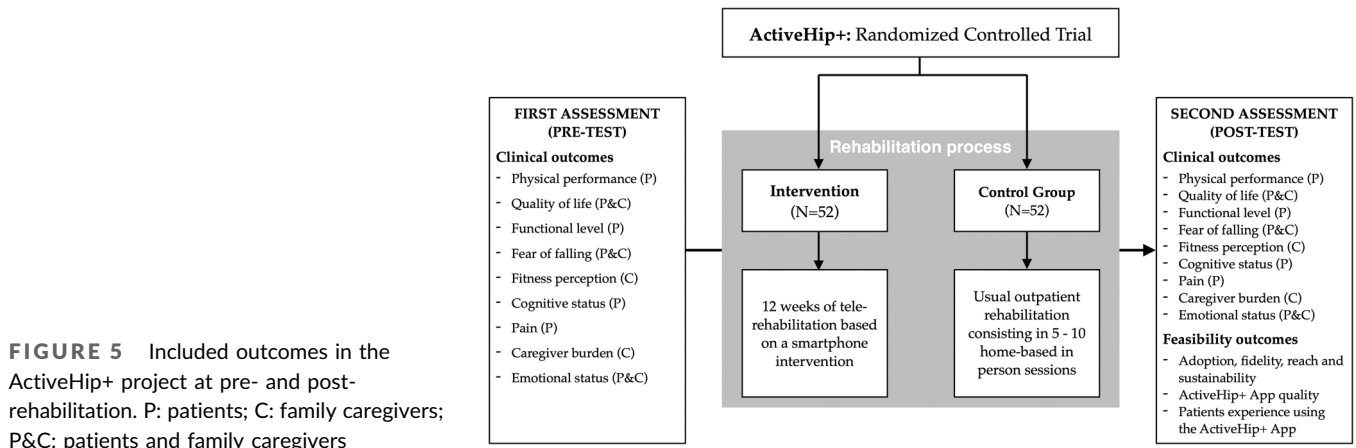


FIGURE 5 Included outcomes in the ActiveHip+ project at pre- and post-rehabilitation. P: patients; C: family caregivers; P&C: patients and family caregivers

2.6.3 | Functional level

The functional level will be assessed using two scales: The FIM and the New Mobility Score (NMS). The FIM consists of 18 items, of which 13 concern physical activities divided into four categories: self-care, sphincter control, transfers, and locomotion (Granger et al., 1986). The remaining five items relate to aspects of cognitive and social functioning divided into two categories: communication and social cognition. The total FIM score range is between 18 and 126 points. Higher scores indicate a higher level of independence. The internal consistency of the score has been reported as very good, with a Cronbach's $\alpha = 0.95$ (Hobart et al., 2001). The NMS consists of three questions to measure walking mobility across activities of daily living such as indoor walking, outdoor walking, and walking during shopping (Kristensen et al., 2008). This questionnaire evaluates the pre-fracture functional level with a score from 0 (not able to walk) to 9 (fully independent). The test-retest reliability of the NMS is very high and has been recommended to evaluate the pre-fracture functional level in patients with acute hip fracture (Kristensen et al., 2008). The internal consistency of the NMS is good with a Cronbach's α close to 1 (Prieto-Moreno et al., 2021).

2.6.4 | Fear of falling

The Short Falls Efficacy Scale-International (SFES-I) consists of seven items with four possible answers corresponding to the level of concern (Delbaere et al., 2010). The total score range is from 7 to 28 points, where higher scores indicate a higher level of fear of falling (Delbaere et al., 2010). The SFES-I has demonstrated to be valid when compared with the history of falls, muscular strength, and functional status, and has high internal consistency with a Cronbach's $\alpha = 0.92$ (Kamide et al., 2018).

2.6.5 | Fitness self-perception

The International Fitness Scale (IFIS) consists of five questions concerning the patient's perception of his/her general physical fitness (cardiorespiratory, muscular, agility, and flexibility; Ortega et al., 2011). Each question has five possible answers (very poor, poor, average, good, and very good) scored from 1 to 5 points, where the highest score corresponds to the best perception of physical fitness (Ortega et al., 2011). The IFIS is valid against objectively measured physical fitness in older adults (Merellano-Navarro et al., 2017). Furthermore, a recent systematic review with meta-analysis found a moderate-to-substantial test-retest reliability of the IFIS, where the pooled Kappa coefficient of agreement was higher than 0.60 in most of the dimensions Pereira et al. (2020).

2.6.6 | Cognitive status

The Short Portable Mental State Questionnaire (SPMSQ) has 10 items that assess various functions: orientation, recall memory,

concentration, and calculation (Pfeiffer, 1975). For clinical use, a cutoff of 3 errors appears to be most useful to detect cognitive deterioration (Pfeiffer, 1975). The internal consistency of the SPMSQ is good with a Cronbach's $\alpha = 0.82$ (Martínez De La Iglesia et al., 2001).

2.6.7 | Pain

The Visual Analog Scale for Pain (VAS) test is a rapid and convenient way to evaluate the intensity of pain perceived by the patient (Boonstra et al., 2008). The patient indicates the perceived pain by pointing out on a physical scale a value from 0 (without pain) to 10 (maximum pain; Boonstra et al., 2008). The test-retest reliability is good with the $r = 0.94$ (Hawker et al., 2011).

2.6.8 | Low back pain

Health caregivers are at risk of developing low back pain due to activities such as back bending, lifting, and carrying patients (Al Amer, 2020). Therefore, we will use the self-administered Oswestry Disability Index questionnaire to explore how a possible low back pain affects the caregivers' ability to manage in everyday life (Fairbank & Pynsent, 2000). This tool consists of 10 questions scored from 0 to 5, and the final score is calculated by summing the score of each section. The percentage of the total score over the maximum possible score (i.e., 50 points) is calculated and interpreted as follows: 0%–20%: minimal disability; 21%–40% moderate disability; 41%–60% severe disability; 61%–80% crippled; and 81%–100% bed-bound or exaggerating symptoms (Fairbank & Pynsent, 2000). The internal consistency of the Oswestry questionnaire is good with Cronbach's $\alpha = 0.82$ (Yu et al., 2016).

2.6.9 | Caregiver burden

The Caregiver Strain Index consists of 13 items with a dichotomous answer (i.e., Yes or No; Ugur & Fadioloğlu, 2010). "Yes" responses are summed. Higher numbers indicate a greater level of stress. The internal consistency of this test is acceptable with a Cronbach's $\alpha = 0.73$ (Ugur & Fadioloğlu, 2010).

2.6.10 | Emotional status

The Hospital Anxiety and Depression Scale (HADS) consists of 14 items, each with four possible answers (0–3 points), divided into two subscales: seven items for status of depression and the remaining items for presence of anxiety (Herrero et al., 2003). The maximum score of each subscale is 21 points; scores below 11 indicate the presence of depression or anxiety (Herrero et al., 2003). The internal consistency of the HADS is good with a Cronbach's $\alpha = 0.80$ (Bjelland et al., 2002).

2.7 | Feasibility outcomes

According to the recently published guidelines for conducting feasibility studies, the ActiveHip+ project evaluates the effects and determinants of the implementation strategies used in the ActiveHip+ m-Health system (Pearson et al., 2020).

2.7.1 | Adoption, fidelity, reach, and sustainability

The adoption is the proportion of patients that agree to use the ActiveHip+ out of the total number of patients invited to participate in the project. This information will be extracted from the flowchart of the invited and included participants. The fidelity or adherence will be presented as the rate of patients who complete a minimum of rehabilitation sessions and complete the educational content. The participants need to complete at least three rehabilitation sessions per week and complete all the available modules in the educational program to consider it an ideal fidelity rate. The reach or penetration is presented as the number of patients following the ActiveHip+ program with optimal fidelity divided by the total patients offered the rehabilitation. Lastly, sustainability is measured as the continuation or maintenance of the ActiveHip+ adherence throughout the 12 weeks of the program. Fidelity, reach, and sustainability information will be obtained from the ActiveHip+ professional environment (website), which automatically provides all this information about the users.

2.7.2 | ActiveHip+ app quality

To assess the quality of the ActiveHip+ app, both patients and caregivers will complete the Mobile App Rating Scale (MARS) tool (Stoyanov et al., 2015). MARS is composed of 23 items that evaluate engagement, functionality, esthetics, and information quality. The tool also has two optional sections: subjective quality (with four items) and app-specific quality (with six items). Each MARS item is scored with a 5-point scale with the following interpretation: 1 = inadequate, 2 = poor, 3 = acceptable, 4 = good, and 5 = excellent. MARS also provides the option of a mean score for each dimension (engagement, functionality, esthetic, and information quality) as well as an overall mean score. This tool has demonstrated excellent internal consistency (Cronbach's $\alpha = 0.90$) and interrater reliability (ICC = 0.79; Stoyanov et al., 2015).

2.7.3 | Patients' experience using the ActiveHip+ app

To evaluate the satisfaction level of the patients and caregivers with the ActiveHip+ app, we will use the Net Promoter Score (NPS), which is based on responding to the following question (Krol et al., 2015): How likely are you to recommend the ActiveHip+ to other patients recovering from a hip fracture? Following Sizmur et al. (2015), the response will be coded as +100 if the respondent was a promoter,

0 if passive, and -100 if a detractor. NPS provides a reasonable test-retest reliability and a strong correlation with a second survey related to the customers' satisfaction (Wilberforce et al., 2019).

2.8 | Data analyses and management

Normal distribution of variables will be checked by the Kolmogorov-Smirnov or Shapiro-Wilk tests. The differences at baseline between groups will be checked with the Chi-square test or the Student *t*-test, as appropriate. Data will be summarized using descriptive statistics. The main statistical test will be an analysis of covariance (ANCOVA) using the post-rehabilitation outcomes as dependent variables, the group (i.e., ActiveHip+ vs. control) as a fixed factor and the baseline outcomes as a covariate. Additionally, a sensitivity analysis will be performed to test the influence of potential confounders in the results, such as basic demographic data from both patients and caregivers, health status, duration of the hospital stay, falls in the last year, type of fracture, rehabilitation sessions received, or the setting where they receive the treatment. The *z*-scores and between-subject Cohen's *d* will be calculated as effect size indicators according to previously published intervention studies (Ortiz-Piña et al., 2021). All analyses will be performed using the SPSS software (version 25.0, IBM Corporation,), and the level of significance will be set at $p < 0.05$. We will adjust for multiple comparisons by using the Benjamini-Hochberg approach (Benjamini & Hochberg, 1995).

All data will be archived with restricted access in the hospital's research section by the principal investigator. A researcher from the ActiveHip+ team (other than the evaluators) will code the questionnaires for analyses. The adherence of the intervention group will be recorded automatically on the website at the end of each session. The patients in the control group and their caregivers will be asked at each interview the number of rehabilitation sessions performed.

3 | DISCUSSION

The ActiveHip+ program is a 12-week multidisciplinary rehabilitation intervention focused on hip fracture recovery and based on physical exercise and occupational therapy together with a health educational program for both the patient and the family caregiver. The ActiveHip+ program arose from the need to improve the current rehabilitation process in patients with hip fracture, a health problem that has gained relevance in the last years. Partially due to the scarcity of human resources and facilities invested in rehabilitating these patients, older adults who suffer a hip fracture may not adequately recover their previous physical performance and functional level. These issues predispose the patient and their caregiver to a deterioration in quality of life. The present study protocol aims to test how effective the ActiveHip+ program is in recovering critical clinical outcomes such as physical performance, functional level, or quality of life in patients with hip fracture when delivered using m-Health methods.

A recent systematic review about telerehabilitation in orthopedics identified two studies testing its effectiveness after hip arthroplasty (Petersen et al., 2021). Both the telerehabilitation and the face-to-face interventions induced improvement in the patients' physical performance and functional level, but neither treatment proved superior to the other (Petersen et al., 2021). The fact of obtaining results similar to a face-to-face intervention can be interpreted as a success for telerehabilitation since the in-person supervision by healthcare professionals is considered the ideal condition in which to be rehabilitated (McDonough et al., 2021). However, these interventions were focused on patients who underwent a total hip replacement instead of surgery for hip fracture. The latter is the target population in the present protocol study and presents substantial differences in clinical outcomes compared to hip replacement, resulting in different rehabilitation approaches (Manach et al., 2015). In patients with hip fracture, we are only aware of three studies that test the effects of telerehabilitation interventions (Kalron et al., 2018; Li et al., 2020; Ortiz-Piña et al., 2021); one of them belongs to the predecessor project of the current ActiveHip+ (Ortiz-Piña et al., 2021). Overall, telerehabilitations demonstrated better results in physical performance (Kalron et al., 2018; Ortiz-Piña et al., 2021), functional measures (Ortiz-Piña et al., 2021), activities of daily living, and fall prevention (Li et al., 2020) in comparison with usual treatments after hospital discharge or exercise booklet performed at home. Although results seem promising, the evidence is preliminary as it comes from pilot studies or non-randomized samples. In addition, only one study so far incorporates telerehabilitation via smartphones. Therefore, this is a knowledge gap in the literature, and there is much to be done in the creation and implementation of m-Health systems in this area of rehabilitation.

ActiveHip+ is expected to be the biggest RCT to date, in terms of sample size, that tests the effects of a telerehabilitation intervention in patients with hip fracture. Furthermore, ActiveHip+ would be the most comprehensive m-Health system by incorporating a 12-week multidisciplinary rehabilitation program (based on physical exercise and occupational therapy) together with a health education program and integrating both the patient and the family caregiver in the rehabilitation process. For developing the m-Health system, the research team of this project collaborated with patients with hip fractures, their family caregivers, and health professionals involved in the rehabilitation process to gain their perspectives on the content and delivery of the mobile application. Our conduct of a previous telerehabilitation project (@ctivehip) gave us an authentic interaction with these stakeholders (Ortiz-Piña et al., 2019), which has allowed us to create an improved telerehabilitation adapted to their requirements.

If ActiveHip+ proves to be more effective in recovering physical performance, functional level, and the other outcomes than usual rehabilitation, this m-Health system would be considered a valuable treatment option for some patients with hip fracture. Even if ActiveHip+ demonstrated similar effects to the current rehabilitation provided by the hospital, advantages inherent to the telerehabilitation (e.g., saving healthcare costs and the possibility of rehabilitating

from home) make it a complementary treatment to consider. There are m-Health tools for preventing cardiovascular diseases or obesity in older adults (Kampmeijer et al., 2016). Furthermore, a recent review demonstrated that these types of interventions are effective in treating chronic pulmonary diseases, heart failure symptoms or diabetes, and hypertensive patients in the general population (Marcolino et al., 2018). However, we are not aware of any m-Health system implemented to date in rehabilitating patients with hip fracture (Petersen et al., 2021). Therefore, ActiveHip+ has the potential to be the pioneer in treating this serious musculoskeletal condition. In addition, the fact that this telerehabilitation program is delivered through a mobile phone application increases its applicability due to the growing trend of mobile phone users worldwide.

The present protocol might show potential limitations that should be addressed. First, the recruitment process will be conducted in two Andalusian provinces, Granada and Cadiz, and the study sample cannot be generalized to the entire older adult Andalusian nor Spanish population. Second, we exclude patients with low pre-fracture functional level (i.e., FIM score < 90 points) and those with cognitive impairments. Thus, our findings on the effectiveness and feasibility of the telerehabilitation program should be interpreted in a population of older adults with a minimum functional level and without cognitive impairments. Third, due to a lack of resources, we do not include a longer follow-up assessment (e.g., 1 year after the surgery) and, therefore, our effectiveness results on the main clinical outcomes cannot be interpreted as long-term changes. Fourth, the control group received no standardized protocols apart from general recommendations by the Andalusian Public Healthcare System. This leads to considerable variability in the rehabilitation protocols that will be adjusted for several confounders (e.g., number of sessions or the setting where they receive the treatment) to limit its influence on the results. Considering all these limitations, future trials in a wider Spanish population including also patients with low functional levels and a longer follow-up assessment are needed.

4 | PROGRESS TO DATE

To date, we developed the content included in the ActiveHip+ app, which is composed of: (1) the health educational program, and (2) the home-based telerehabilitation program consisting of physical exercise and occupational therapy. The recruitment process started on June 2021 and so far 71 participants (31 belonging to the ActiveHip+ intervention and 30 to the control group) have completed the first assessment (i.e., pre-test), and 52 participants have completed the second assessment (i.e., post-test). Given the current situation with the COVID-19 pandemic, the recruitment process is slower than we predicted. Hospitals have invested more effort and resources in COVID-19 pandemic and traumatology services have suffered important delays in surgeries, hip fractures among them. In some phases of the pandemic, family caregivers were not allowed to visit patients during their hospital stay to avoid contagion and, therefore, we could not offer them the ActiveHip+ intervention. However, we expect to

reach 104 participants at the end of April 2022. The ActiveHip+ intervention is being carried out satisfactorily despite the COVID-19 pandemic since it is conducted from home through the mobile *app*.

5 | CONCLUSION

Current hip-fracture rehabilitations do not offer satisfactory results in recovering an optimal physical performance and functional level in older adults, mainly due to a lack of continuity in the rehabilitation process after hospital discharge. Smartphone-based interventions are valuable solutions to improve the rehabilitation process. However, to date, there is no m-Health system that has proved to be equally or more effective than the currently prescribed rehabilitation in recovering key health outcomes. The ActiveHip+ project will test how effective the ActiveHip+ m-Health system is in the recovery of physical performance, functional level, quality of life, and other health-related outcomes in patients with hip fracture and in their family caregivers.



AUTHORS CONTRIBUTIONS

Marta Mora-Traverso, Pablo Molina-Garcia, Rafael Prieto Moreno, and Patrocinio Ariza-Vega coordinate the project. Marta Mora-Traverso, Víctor Cruz Guisado, Rogelio del Pino Algarrada, Margarita Hidalgo Isla, Patricia Jimenez Andrés, and Marta Linares Gago recruit participants in the hospitals of Cádiz (Spain). Rafael Prieto Moreno, Paz Moreno-Ramírez, Gema Gomez-Jurado, Consuelo Gomez Tarrías, Ana Lirola-Liebanas, Antonio Mesa-Ruiz, Araceli Muñoz-Garach, and Susana Salazar-Graván recruit participants in the hospitals of Granada (Spain). Fernando Estevez-Lopez and Miguel Martín-Matillas perform supervision tasks, provide scientific advice, and critically reviewed the manuscript. Pablo Molina-Garcia conducts the statistical analyses and creates the figures. Marta Mora-Traverso and Pablo Molina-Garcia wrote the first draft of the manuscript. Patrocinio Ariza-Vega conceptualized the research idea and is the principal investigator of the project. All authors read and approved the final manuscript.

DATA AVAILABILITY STATEMENT

Data available on request due to privacy/ethical restrictions: The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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