Tesis Doctoral Internacional / International Doctoral Thesis

Tele-rehabilitación y educación sanitaria para personas mayores con fractura de cadera y sus cuidadores informales; factibilidad y efectividad del programa ActiveHip+

Tele-rehabilitation and health education for older adults with hip fracture and their family caregivers; feasibility and effectiveness of the ActiveHip+ program

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"Ever tried. Ever failed. No matter. Try again. Fail again. Fail better"

Samuel Beckett

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Title

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Abstract

Hip fracture is a traumatic and life-disrupting event for the patient and their family caregivers. Both of them feel a sudden loss of control in their lives. The patient become dependent and their family caregiver often assumes an important responsibility. Despite the benefits of multidisciplinary approach and early in-person rehabilitation are well known in older adults with hip fracture, healthcare resources are not enough to offer such a care. In this context, digital health is a promising alternative to provide rehabilitation and health education both for older adults with hip fracture and their family caregivers.

This Doctoral Thesis aimed to improve the quality of care in older adults with hip fracture and their caregivers through digital health tools. To do so, we conducted 2 qualitative studies to understand: (i) the needs of the key stakeholders in the recovery process (i.e., older adults with hip fracture, family caregivers and healthcare providers) during the development phase of the ActiveHip+ mHealth system (study IV) and (ii) the experience of caregivers after using the @ctivehip tele-rehabilitation program (study III). Additionally, we conducted 4 quantitative studies that aimed: to facilitate health providers' follow-up of older adults with hip fracture through easy-to-use validated scales (study I) and to test the feasibility (study V) and effectiveness (studies II and VI) of @ctivehip tele-rehabilitation program and ActiveHip+ mHealth system in the recovery of older adults with hip fracture and their family caregivers.

Study I showed that the New Mobility Score Spanish version is a valid, reliable and easy-to-use scale to measure the functional status of older people with hip fracture. Furthermore, it can be integrated into the daily clinical practice of the health providers. Studies III and IV identified aspects that the stakeholders considered necessary to include in digital health tool for the recovery of older adults with hip fracture. Digital health tools have to be user-friendly, simple, contain information that is permanently accessible and address not only the recovery process but also the prevention of future fractures. In addition, they should provide information to both patients and caregivers because the latter' supportive role is important in the patients' recovery process. Moreover, these digital tools have to be a channel to facilitate the communication of patients and caregivers with health providers. Studies II, V and VI demonstrated the feasibility and effectiveness of @ctivehip and ActiveHip+ to increase the functional status and to reduce the pain in older adults with hip fracture.

Collectively, the knowledge gained from the present doctoral thesis improve the understanding about the potential that digital health has for the recovery of older adults with fracture and their family caregivers. This thesis provides scientific evidence on the feasibility and effectiveness of digital health in hip fracture recovery. This thesis also outlines some aspects for further implementation in this field, identifying barriers and facilitators to achieve satisfactory results in terms of recovery.

Resumen

La fractura de cadera es un acontecimiento traumático y que altera la vida del paciente y de sus familiares (conocidos como cuidadores informales). De forma repentina, tanto el paciente como el cuidador pierden el control de sus vidas. El paciente se vuelve dependiente y el cuidador con frecuencia se ve obligado a asumir una gran responsabilidad. Aunque los beneficios de una rehabilitación tanto multidisciplinaria como precoz en personas mayores con una fractura de cadera son bien conocidos, los recursos sanitarios no son suficientes para llevarla a cabo. En este contexto, la salud digital es una alternativa prometedora para proporcionar rehabilitación y educación sanitaria tanto a las personas mayores con fractura de cadera como a los familiares.

El objetivo de esta Tesis Doctoral ha sido mejorar la calidad de la atención sanitaria a personas mayores con fractura de cadera como a sus cuidadores a través de herramientas de salud digital. Para ello, hemos llevado a cabo 2 estudios cualitativos con el objetivo de comprender las necesidades de los principales implicados en la recuperación (personas mayores con fractura de cadera, cuidadores informales y profesionales sanitarios) durante la fase de desarrollo del sistema de salud móvil ActiveHip+ (estudio IV) y, por otro lado, conocer la experiencia de los cuidadores después de utilizar el programa de tele-rehabilitación @ctivehip (estudio III). Además, hemos realizado 4 estudios cuantitativos con el objetivo de: facilitar a los profesionales sanitarios el seguimiento de pacientes con fractura de cadera a través de escalas validadas y fáciles de usar (estudio I) así como para determinar la factibilidad (estudio V) y efectividad (estudios II y VI) del programa de tele-rehabilitación @ctivehip y el sistema de salud móvil ActiveHip+ en la recuperación de personas mayores con fractura de cadera y sus cuidadores informales.

El estudio I demostró que la versión española del New Mobility Score es una escala válida, fiable y fácil de usar para medir el estado funcional de las personas mayores con fractura de cadera que ser integrada en la práctica clínica diaria. En los estudios III y IV se identificaron aspectos necesarios para una herramienta de salud digital para la recuperación de personas mayores con fractura de cadera. Han de ser fáciles de usar, abordar tanto la recuperación como la prevención de fracturas secundarias y contener información permanentemente accesible tanto para el paciente como para el cuidador, ya que el apoyo de estos últimos es importante en el proceso de recuperación. Además, las herramientas de salud digital deben ser un medio facilitador de la comunicación del pacientes y cuidador con el profesional sanitario. Los estudios II, V y VI demostraron la factibilidad y la eficacia del programa de tele-rehabilitación @ctivehip y el sistema de salud móvil ActiveHip+ para aumentar la funcionalidad y reducir el dolor en personas mayores con fractura de cadera.

En conjunto, el conocimiento adquiridos en esta Tesis Doctoral mejora la comprensión del potencial de la salud digital en la recuperación de personas mayores con fractura de cadera y sus cuidadores. Esta tesis aporta evidencia científicas sobre la factibilidad y la eficacia de la salud digital en la recuperación de una fractura de cadera. Esta tesis también describe algunos aspectos de cara a futuras implementaciones en este campo, identificando barreras y facilitadores para lograr resultados satisfactorios en términos de recuperación.

General introduction

Hip fracture

Osteoporotic hip fracture is an injury which occur in the proximal part of the femur, between the femoral head and 5 cm to the lesser trochanter [1]. Figure 1 illustrates the anatomical location of the hip [2]. Although there are several classifications for the type of fracture, the most common classification used by health providers is based on the anatomical position in relation to the joint capsule [3]. Accordingly, there are two main categories: intracapsular fracture (inside the joint capsule) and extracapsular fracture (outside the joint capsule) [4].

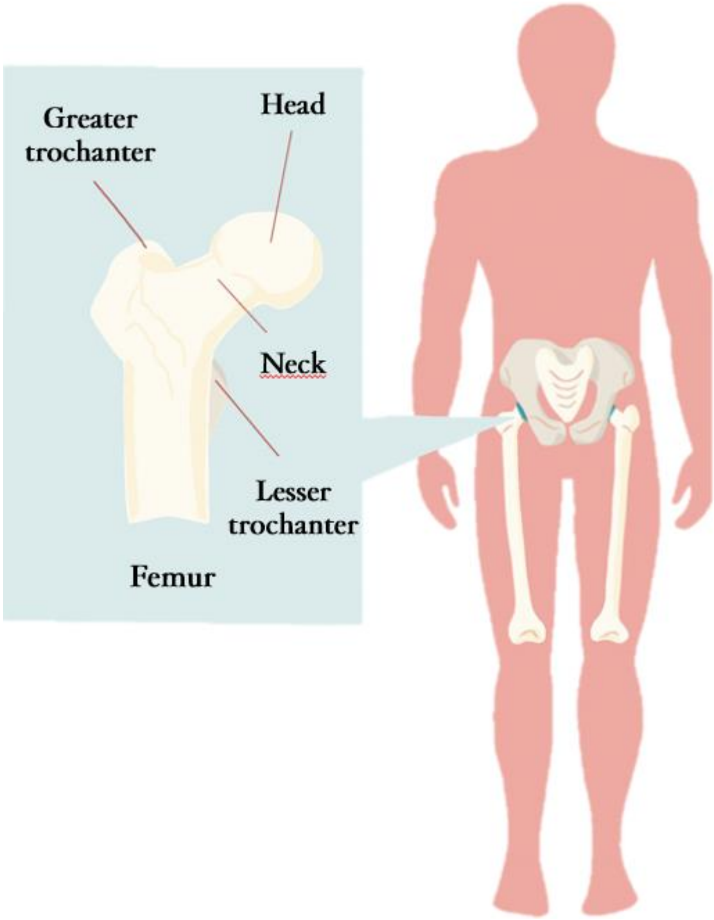

Figure 1. Anatomical hip description (Figure adapted from *Guía práctica para pacientes con fractura de cadera* [2]).

Figure 2 illustrates the two main categories of hip fractures: intracapsular and extracapsular fractures [2]. Intracapsular fractures are those that occur at the neck of the femur and can be referred to as subcapital (at the head-neck junction of the femur), transcervical (at the middle of the femoral neck) and basicervical (at the base of the femoral neck) [3]. Extracapsular fractures occur between the femoral neck and 5 centimetres distal to the lesser trochanter [3]. They are divided into intertrochanteric (between the greater and lesser trochanter) and subtrochanteric (between the lesser trochanter and 5 cm distal to the lesser trochanter) [5].

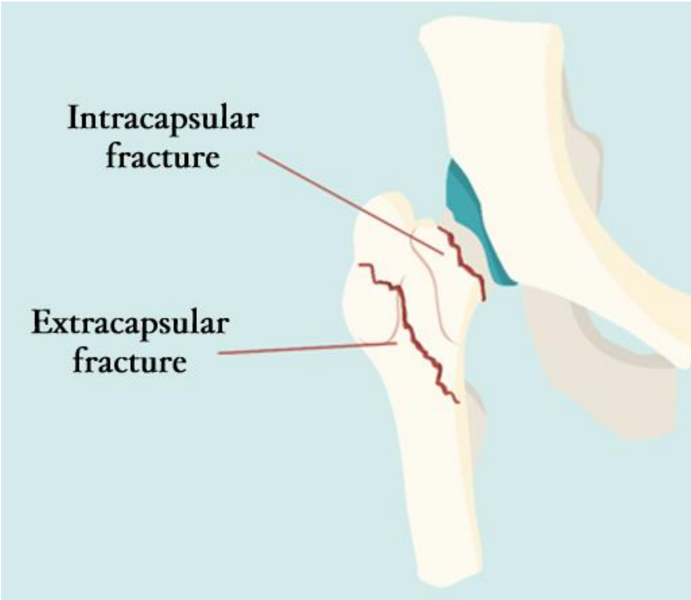

Figure 2. Classification of hip fractures according to its anatomical location (Figure adapted from *Guía práctica para pacientes con fractura de cadera* [2]).

Worldwide impact of hip fracture

Osteoporosis is a disease characterised by reduced bone mineral density and increased bone fragility [6]. Hip fracture is one of the most serious consequences of osteoporosis, representing a disruption in the life of the patient and their environment (e.g., family caregivers) [7–9]. Falls are the most common cause a of hip fracture [10]. Hip fracture represents a public health concern. The incidence of hip fracture is high: 250,000 cases/100,000 in Europe. Moreover, it is estimated that, between 1990 and 2050, the number of cases of hip fractures will increase from 1.6 million to 6.2 million [11]. This increase is related to the increase in life expectancy and the consequent ageing of the population [12]. In 2050, 1 in 6 people is expected to be older than 65 years of age [13]. The incidence varies between countries, with northern Europe and North America currently having the highest number of cases [14]. In Spain, the risk of hip fracture is considered moderated;, particularly 40,000 hip fractures per year [15,16] of which 90% affects older adults (those over 65 years of age) [17]. Spain is one of the countries with the longest life expectancy [18]. In 2037, 26% of the total Spanish population will be older adults [19]. It should be noted that the incidence of hip fracture increases progressively with age [20]. Therefore, hip fracture is a health condition that needs to be adequately addressed.

A hip fracture results in a considerable hospital stay (e.g., in average, 9 days in Spain) [21] and in a long rehabilitation period [22]. These results in a high socio-economic burden, especially because 35 to 80% of patients experience disability [23]. The cost of a hip fracture depends of several factors (e.g., its location and the delay on the surgery). The average cost is estimated to be €10,000 for the initial hospitalisation and €43,700 for the rehabilitation during the year after the surgery [24,25]. This cost grows exponentially with the surgical procedure. There is a wide variation in costs between countries, as each country sets its own health policies [26]. In Europe, for instance, the associated cost to each hip fracture ranges from €5,306 in Slovenia [27] to €30,906 in Finland [28]. In Spain, the cost of each hip fracture is €9,421 [16]. The total cost of each hip fractures in Spain is €9,690 [17]. This cost also ranges from the different Autonomous Communities since there are significant differences in key management aspects of hip fracture as surgical delay or early start of the rehabilitation [15,29]. The estimated cost per person in Madrid (€12,000) or Catalonia (€10,000) are higher than the cost in Andalusia (€6,500) [17]. However, in these estimations the cost assumed by the sufferer and their relatives are not taken into account, which are especially high during the first months of the recovery.

Consequences of a hip fracture

For the older adult

One of the main reasons why hip fracture is such a serious problem is the severe, sudden and unforeseen impact on the older adult life. Because it occurs mostly in older people who suffer from fragility [12], hip fracture has a high mortality rate that is close to 24% one year after the fracture for those older adults who undergo surgery [30], compared to 11% mortality rate for healthy people with similar characteristics [31]. Mortality rate after hip fracture doubles in older adults who do not undergo surgery [32,33]. Although a large proportion of hip fractures occurring in women [34], mortality is higher in men, ranging from 30 to 60% one year after fracture, while in women this range from 15 to 30% [35,36].

Older adults with hip fracture often do not regain pre-fracture mobility, with 50% of them having problems walking independently one year after fracture [37]. This lack of mobility remains for a long period of time, which also affects their recovery, as they become discouraged by how long the recovery takes [22]. Despite the benefits attributed to perform at least 150 mins of moderate physical activity per week [38], the majority of older adults with hip fracture are inactive [39]. Moreover, there is a severe functional limitation, with 60 to 80% of older adults needing assistance to perform essential activities of daily living (ADLs) such as toileting and dressing [40]. It is a breaking moment for older adults and their surroundings when, after a hip fracture, they suddenly become highly dependent [22]. Moreover, to recover their previous functional status is considered by older adults with hip fracture one of the main goals for the recovery process [22]. Unfortunately, this process takes much longer than desired [41], which affects their mood [22]. The impairment of the older adults' functionality leads to an increase in their fear of falling, a cognition that affects 60% of older people [42]. This fear is often the cause of an avoidance of ADLs [43], which often results in a poor recovery of functionality and mobility and a decrease in self-efficacy [44,45]. This dependence causes that 20% of the older adults with hip fracture have to move to long term caring setting [46]. Collectively, the consequences of hip fracture have an impact on quality of life in the older adults [47,48]. This causes a disruption in the older adults' routine and a loss of contact with their social environment [9]. For this reason, older adults with hip fracture tends to decrease their social participation [37], which is considered as a key component for healthy ageing, as it represents the highest degree of functionality according to the International Classification of Functioning and Disability [49].

For the family caregivers

Because of the unexpectedness and suddenness of hip fracture, family caregivers (hereafter referred to as caregivers) play an essential role in recovery. The importance of the caregivers is of the utmost importance immediately after hospital discharge, when older adults are highly dependent functionally to be in their own home [22]. Thus, caregivers are key in offering physical, psychological and social support [50] for older adults with hip fracture and are also key in encouraging older adults with hip fracture to participate in their rehabilitation [51]. Caregivers usually are relatives of the older adults with hip fracture [52] who carry out this task on an unpaid basis [53]. Although caregivers perceive this time as an opportunity to spend more time with their relatives [54], recovery is a process characterised by a high burden for them [55]. One of the causes of this burden is the fact that this new role implies an adjustment in the caregivers' routine, as they have to combine caregiving with their daily life [56]. In fact, more than 50% caregivers perform this work more than 8 hours daily [57]. Playing the role of caregiver and trying to maintain their previous life causes a sense of stress [58] especially high during the transition after hospital discharge [54]. Moreover, caregivers usually experience both physical and mental problems [59], as well as a decrease in their quality of life [54]. This decrease is observed as early as one month after the fracture, but is even worse one year after the fracture [50]. Given that caregivers health status impact directly in the older adults' recovery [53,60], considering them during the recovery process is important. Furthermore, caregivers' ability to manage such a sudden situation and its disruptive consequences is also related to whether older adults with hip fracture are sent to a nursing home [55].

Despite the essential role played by caregivers due to older adults with hip fracture lack of independence after the surgery[53], caregivers are not recognised and supported during the recovery process [57]. Caregivers often face the recovery process without the knowledge or skills needed to face this abrupt situation [57]. There is existing evidence of caregivers demanding more information during the recovery process [61]. Despite some existing interventions for caregivers provision of information [56,62], it is needed to provide them more comprehensive tools to support them through the different phases of the recovery [59].

Hip fracture recovery

Currently, the mainstay option to care a hip fracture is the surgical repair [63], which is expected to present a high success rate (near to 85%) and positive clinical outcomes, including a reduction of mortality or morbidity [32,63–65]. The surgical option chosen by surgeons depends on the patient´s physiological condition, the fracture location and displacement [66]. Non-surgical treatment is a less used alternative due to loss of hip function, increased pain and increased length of hospital stay [65]. Despite of the high success rate of the hip surgery, it is not exempt of complication, as periprosthetic hip fractures [67] or reoperation rate, ranging from 1040%, make needed further research in the surgery procedure [66,68]. There is evidence supporting that a prompt action in the hip fracture treatment is crucial [69,70]. Thus, guidelines suggest surgery within 48 hours of fracture to reduce some of the complications associated to the hip fracture, as bleeding [71], immobility [71] and mortality [72]. This recommendation is also supported by studies showing that longer hospital stays increase the risk of mortality [73,74]. The most frequent reasons for delaying surgery are modifiable factor as operating room availability or pre-operative medical approval [71]. Because hip fracture is associated to osteoporosis, food intake and supplementation (calcium, vitamin D) are recommended to increase bone health and prevent future fractures [75,76]. In fact, the most frail older adults who suffer a hip fracture are malnourished [77] and their food intake is inadequate [78]. Given that these facts are related to poorer recovery outcomes, they must be addressed [75].

It is recommended that surgical repair and food intake be accompanied by early rehabilitation [79], both during hospital stay and after hospital discharge aiming to recover the previous functional status [66]. Thus, it is recommended to weight bear in the same day of the surgery or in the following 24 hours [80]. Rehabilitation interventions are usually focused on physical aspects. However, there is a need for comprehensive and multidisciplinary interventions, combining physical activity and occupational therapy, where work is based on training in activities of daily living [45]. This approach, based on meaningful activities training can lead to an increase in self-efficacy, which can have a beneficial effect on the patient's health [81] and in turn increase rehabilitation compliance [82]. Clinical guidelines establish the relationship between a proper rehabilitation, early and continued after hospital discharge, and better recovery outcomes [83]. However, the lack of resources means that, in many cases, patients do not have rehabilitation or only have sessions during their hospital stay [84]. This is still worse for older people who do not have easy access to the care settings, as during COVID-19 waves [85] or those living in rural areas [86].

Other critical aspect during the recovery is the of follow-up for older adults with hip fracture, which is important to get better outcomes. First, there is no consensus in the optimal period of time to do this follow up [87]. Moreover, patients' age, functional status and, for some of them, living in nursing homes make it difficult for them to attend post-operative medical appointments [88]. In fact, follow-up losses are estimated to be in the range of 20 to 70% [89]. The follow-up also represents a high burden for both patients and health providers [90], so ease their clinical practice is needed [91]. Thus, providing health providers with reliable, easy and quick-to-use measurements tools as the New Mobility Score Spanish Version (NMS-ES) may improve follow-up and recovery outcomes [92,93]. The NMS-ES let health providers to measure comprehensively the functional status of older adults with hip fracture for both, inside their home and outside, which let health providers to monitor the evolution of the recovery process [91].

As mentioned above and due to the problematic of rehabilitation, the inclusion of the caregiver as an active element of the recovery process is necessary [53]. Previous interventions have aimed to support caregivers with information and some techniques for the older adult with a hip fracture management during the first phase of the recovery [94]. However, these approaches are scarce and time-limited, as they focus on the early days and are not adapted to the evolution of the older adult.

Considering the described above context, further alternatives are needed to face hip fracture and its consequences. Therefore, home-based rehabilitation is a promising alternative, as this option is less resource-intensive, allows patients to continue rehabilitation in an environment perceived as safer by them [95] and promote active participation in the treatment [96].

Digital health

Digital health, the use of information and communication technologies (ICT) to support health provision [97], is ideally placed to address the need to develop alternatives for hip fracture rehabilitation, particularly now with the increasing widespread use of the ICT. Tele-rehabilitation, the provision of rehabilitation services at a distance [98] and mobile health (mHealth), the use of mobile and wireless technologies to support the achievement of health objectives [99] are two of the types of digital health that are considered easier to implement. These option makes use of the most widespread devices (e.g., tablets or mobile phones) [100]. Digital health offers different advantages as it can reach a bigger amount of people [101]. Moreover, through it, health providers can conduct an easier follow-up [102], which is critical as just 30% of older people with a fracture receive a proper follow-up [103]. In addition, digital health has the advantage of improving the communication between users and health providers, which is widely demanded by patients and caregivers [61,104]. Additionally, digital health can be used to provide useful and on-demand information for the transition from the different settings [102], as often requested by patients and caregivers [104,105]. The inclusion of digital health in orthopaedic settings is also supported by systematic reviews, where digital health has demonstrated similar efficacy to in-person rehabilitation (e.g., functionality, quality of life and mental health) [106–108].

Scarce research has been conducted using digital health on hip fractures [109–111]. Some barriers are considered for the implementation of digital health in the recovery after a hip fracture (i.e., the lack of skills using mobile systems due to the high average age [112,113] or high attrition rate [101]. These barriers can be addressed through a number of techniques. One of them is to include their family caregivers in the recovery process, as they are younger and have better smartphone skills [112]. It is also stated the need of include stakeholders during the development phase of digital health interventions to ensure a better uptake and adherence to the treatment [114,115].

Summary of gaps knowledge and contribution of this thesis

In summary, a number of gaps in the evidence on digital health in older adults with hip fracture are:

- There are scarce valid, reliable and brief assessments tool to be used by health providers.
- There is a paucity in knowledge about the effects of digital health interventions for the recovery of older adults with hip fracture, including the study of its feasibility and effectiveness.
- Family caregivers are not usually involved in the design of interventions for the recovery of older adults with hip fracture.

Based on these gaps in the literature, this doctoral thesis seeks to contribute to current state-of-the-art by gaining knowledge about:

- The validity and reliability of a brief scale to measure the functional status of older adults with hip fracture (Study I).
- The effects of a tele-rehabilitation intervention on reducing fear of falling experienced by both older people with a hip fracture and their family caregivers (Study II).
- The experiences of family caregivers using a tele-rehabilitation program for older people with a hip fracture (Study III).
- The perspectives of older adults with hip fracture, family caregivers and health providers (key stakeholders) to co-create a mHealth system (Study IV).
- The feasibility of a mHealth system for older people with a hip fracture and their family caregivers (Study V).
- The effectiveness of a mHealth system in increasing functional status and lowering fear of falling and pain in older adults with hip fracture (Study VI).

Aims

Overall aim

The overall aim of the present Doctoral Thesis was to improve the quality of healthcare in the recovery process of older adults with hip fractures and their family caregivers through the development and implementation of digital health tools.

Specific objectives

Section 1: Validation of the New Mobility Score Spanish version.

* Study I:
  - To translate and cross-culturally adapt the New Mobility Score (NMS) into Spanish.
  - To measure the validity and reliability of the NMS Spanish version (NMS-ES).

Section 2: The @ctivehip tele-rehabilitation program for older adults with hip fracture.

* Study II:
  - To establish the effectiveness of the @ctivehip tele-rehabilitation program on the fear of falling perceived by both older adults with hip fracture and their family caregivers.
* Study III:
  - To describe the experience of family caregivers with the @ctivehip tele-rehabilitation program.

Section 3: The ActiveHip+ mHealth system for older adults with hip fracture and their family caregivers.

* Study IV:
  - To establish the needs of older adults with hip fracture, their family caregivers and health providers for the development of a mHealth system to improve physical function after hip fracture and reduce caregiver's burden.
  - To use their perspectives to co-create the ActiveHip+ mHealth system.
* Study V:
  - To establish the feasibility of the ActiveHip+ mHealth system in older adults with hip fracture in two different health systems.
* Study VI
  - To test the effectiveness of the ActiveHip+ mHealth system in the functional status, fear of falling and pain in older adults with hip fracture.

Methods and Results

Table 1. Overview of the methodological approaches of the studies included in the thesis.

Section	Study	Design	Sample	Inclusion and exclusion criteria	Variables or data collected
Section 1	Study I	Reliability and validity study	(*n*= 60) *60 older adults with hip fracture*	Inclusion criteria: - To have undergone hip surgery - To be 65 years or older - To sign consent form	Main variables - Inter-rater reliability: Cronbach´s Alpha and Bland-Altman analysis. - Validity: Correlations of NMS-ES with age, cognitive status, functional status prior fracture
Section 2	Study II	Non-randomised controlled trial	@ctivehip study (*n*= 71) 35 allocated to tele-rehabilitation group 36 allocated to control group	Inclusion criteria: - To have undergone hip surgery - To be 65 years or older - To have high functional level before fracture - To be authorised weight-bearing on the operated limb 48 hours after the surgery - To be discharged home - Self or family caregiver with internet access - To sign consent form Exclusion criteria: - To have severe cognitive impairment - To be diagnosed with a terminal disease - To have postoperative complications	Main variables - Older adults with hip fracture´s fear of falling (SFES-I) - Family caregivers´ fear of falling (SFES-I) Secondary variables - Influence of physical performance (SPPB and TUG) in the fear of falling - Influence of functional status (FIM) in the fear of falling
	Study III	Qualitative study; Interviews	@ctivehip study (*n*= 21) 21 family caregivers	Family caregiver of an older adult of the study II	Family caregivers´ perceptions about: - Their experience with tele-rehabilitation. - Gaps for improving tele- rehabilitation.
		Qualitative study; Focus groups	ActiveHip+ study (*n*= 45) 14 older adults with hip fracture 21 family caregivers 10 health providers	Inclusion criteria: - Older adults older than 65 years who suffered a hip fracture in the previous 3 months;	Key stakeholders (Older adults with hip fracture, family caregivers and health providers) perceptions about: - mHealth design

Section 3	Study IV			- Family caregivers of an older adult with hip fracture; - Health providers with 2+ years of clinical experience treating older adults with hip fracture. Exclusion criteria: - Older adults with severe cognitive impairment	- Contents needed in a mHealth system for older adults with hip fracture - Barriers and facilitators for the implementation.
	Study V	Longitudinal feasibility study	ActiveHip+ study (*n*= 69) 36 Spanish participants 33 Belgian participants	Inclusion criteria: - To have undergone hip surgery - To be, at least, 60 years of age -To be authorised weight-bearing on the operated limb 48 hours after the surgery - To have high functional level a week before surgery - To be discharged to their own home or to a relative's home - Self or caregiver's internet access and the ability of using mobile phone Exclusion criteria: - To have severe cognitive impairment - To be discharged to an institution or nursery home - To have postoperative complications - To be diagnosed with a terminal disease	Main variables - Adoption - Dropout - Usage - Satisfaction with the app (MARS) - Perceived quality of the app (NPS) Secondary variables - Functional status (FIM) - Physical performance (SPPB) - Pain (NRS)
	Study VI	Randomised controlled trial	ActiveHip+ study (*n*= 99) 46 intervention group 53 control group	Inclusion criteria: - To have a hip fracture - To be, at least, 65 years of age -To be authorised weight-bearing on the operated limb 48 hours after the surgery	Main variables - Functional status (FIM and NMS-ES) - Fear of falling (SFES-I) - Pain (NRS) Secondary variables - Adoption

	- To have high functional level a week before surgery - To be discharged to their own home or to a relative's home - Self or caregiver's internet access and the ability of using mobile phone Exclusion criteria: - To have severe cognitive impairment - To be discharged to an institution or nursery home - To have postoperative complications - To be diagnosed with a terminal disease	- Dropout - Usage - Satisfaction with the app (MARS) - Perceived quality of the app (NPS)

SFES-I, Short Falls Efficacy Scale International; SPPB, Short Physical Performance Battery; TUG, Timed Up and Go; FIM, Functional Independence Measure; MARS, Mobile App Rating Scale; NPS, Net Promoter Score; NRS, Numerical Rating Scale

Section 1

Validation of the New Mobility Score

Spanish version

Study I

Translation, reliability and validity of the Spanish version of the modified New Mobility Score (NMS-ES)

INTRODUCTION

One of the most significant consequences of hip fracture for many older adults' is the persistent loss of function [37]. The aetiology of functional loss post-hip fracture is multifactorial, and well documented in the literature, including factors such as: age, cognitive impairment [116], comorbidities [117], low prefracture functional level [116,118], delay of hip fracture surgery [119], and late mobilization and rehabilitation after surgery [120]. The Barthel Index [121], Functional Independence Measure (FIM) [122], Katz Index of Independence Measure [123], and the New Mobility Score (NMS) [124], are frequently used scales in clinical practice globally to assess and monitor function. Of these, the Barthel, FIM, and Katz Index have been translated and validated into several languages, including Spanish [125–127]. Even though Spanish is the second most spoken language in the world, the NMS has to our knowledge not been translated into Spanish yet, which would be beneficial for clinical care and in the research setting [117,128], due to the fast use of the NMS-ES when compared with others assessment instruments and the limited time available to health care providers so as to care patients with hip fracture in acute care settings.

The NMS was initially developed by Parker and Palmer [124] and later modified by Kristensen and Kehlet [129]. It is a valid predictor of long-term mortality [124,130], short-term mobility outcomes [129,131], and hospital discharge destination [118,129]. The NMS has three self-reported questions related to pre-fracture walking ability that can be obtained within a few minutes. It is reliable [132], and can easily measure pre-fracture function that is understandable for patients and for caregivers of patients with cognitive impairment. Thus, the NMS can be used to measure pre-fracture function for all patients with hip fracture. This is a crucial factor, as up to one-third of all those patients with hip fracture have moderate or severe cognitive impairment [133].

The NMS has potential to support research, registries and hip fracture clinical care, which nowadays is focused on the development of new ways of treatment, apart from the traditional rehabilitation protocol in the balance and walking ability during the hospital stay [96,134]. It provides a self-reported pre-fracture functional baseline for clinicians to monitor the recovery process [124]. Furthermore, the NMS is gaining popularity as an instrument in clinical research conducted across different countries such as the United States [135], Denmark [130], and Ireland where it is included in the Irish Hip Fracture Database [131,136]. Despite its many benefits, NMS has not been adapted for Spain, a country with significant adjusted rates of hip fracture: 722/100,000 for women and 284/100,000 for men [137].

Therefore, the aim of this study is to translate the modified English version of the NMS into Spanish (NMS-ES), and to measure its reliability and validity for health professionals in an acute orthopaedic unit. Adapting and evaluating the NMS-ES would provide clinicians and patients of different Spanish speaking countries, an easy to use, reliable and valid clinical instrument to support the recovery process, advance research and clinical practice.

METHODS

New Mobility Score

The NMS consists of three questions to measure walking mobility across daily life activities. If possible, the NMS is completed by the person being evaluated, or by a caregiver for people with cognitive impairment [132]. The NMS asks for a self-report (on a four point ordinal scale) of their ability to complete: (i) indoor walking (e.g., in a house); (ii) outdoor walking and; (iii) walking during shopping [132]. Each question is scored from 0 to 3 points based on the person's self-reported ability [129]: zero points indicates the person is not able to complete the task; for 1 point the person requires help from another person; 2 point means the person completed the task with a walking aid; and 3 points means the person completed the task independently without a walking aid [129,132]. Total scores range from 0-9 points; 6 points or less indicate functional impairment; and above 6 points signify a high level of prefracture function in patients with hip fracture [118]. In addition, some research has shown that a score ≥7 indicate patient may be able to return home from acute unit care directly and not need inpatient rehabilitation [118].

Translation of the NMS-ES

We translated the English version of the modified NMS manual following the recommendations of Ramada-Rodilla and colleagues [138]. Two occupational therapists (OT), unfamiliar with the NMS, independently translated the modified English version [129], including frequently asked questions (FAQ) into Spanish, after approval for translation was given by one of the authors of the modified NMS, (Morten T. Kristensen). Modifications were made in order to be consistent with Spanish culture and language while preserving the original meaning. A physiotherapist (PT), also unfamiliar with the NMS, created a third version by merging the two previous versions. Following this, a committee of two OTs, a PT and a physician reviewed the merged version, and finalized a fourth version. The committee's aim was to correct possible Spanish culture and language errors or misunderstandings in the translated version. The final version was back translated into English by a native English speaker (unfamiliar with the NMS). The back translated English version was reviewed and approved by an author of the modified NMS, (Morten T. Kristensen). We made minor changes to the NMS-ES based on this feedback. Please see the final version of the NMS-ES in Appendix A. All people involved in the translation process approved the final version.

Reliability

We included 60 patients 65 years and older with hip fracture admitted consecutively to the acute trauma service of the Health Campus Hospital of Granada between January 2017 and March 2017. The study was approved by the ethics committee of the Research Center of Granada (cBI-cni.Nana 2017/02/28) and was carried out according to the guidelines established by the Helsinki Declaration and Law 14/2007 on Biomedical Research. All patients or their caregivers (for patients with cognitive impairment), signed an informed consent form before participating in the study.

In the present study, patients and their caregivers were interviewed by an OT and PT during the first week after surgery. Each patient or his/her caregiver (in case of patients with severe cognitive impairment) were interviewed and asked for NMS-ES questions by one of the therapists. The therapists exchanged the role of interviewer, so each one asked the questions to 30 patients or caregivers. Both therapists completed the scale blinded to each other's rating until the end of study, using standard procedures [139]. Patients without cognitive impairment and caregivers of patients with severe cognitive impairment were requested to provide a response based on patients' ability to perform the tasks considered in the NMS during the week prior to the hip fracture. This method was used to determine the inter-rater reliability for the NMS-ES.

To determine the concurrent validity we collected the following data during the hospital interview: age, gender, highest level of education, place of residence before fracture (own home, with family, nursing home, or other), change of residence after hospital discharge (yes or no), previous falls during the last year (yes or no), support at hospital discharge (formal caregiver or informal caregiver), pre-fracture functional level (assessed by the Functional Independence Measure, [FIM, 18 (minimum level of independence) to 126 (maximum level of independence)] [122], cognitive status [(using the Short Portable Mental Status Questionnaire test (SPMSQ) (SPMSQ test 0-10 points)] coded as: <3 points=no cognitive impairment; 3-4 points=mild cognitive impairment; 5-7 points=moderate cognitive impairment; and >8 points=severe cognitive impairment] [140,141], and basic mobility [assessed by the Cumulated Ambulation Score, Spanish version (CAS-E)] [142]. We also collected the following information from patients´ medical record: weight and height (to calculate the Body Mass Index; BMI), type of hip fracture, and type of surgery.

Statistical analysis

We calculated the sample size following the suggestion to include at least five participants per questionnaire item [143], and the recommendations to include a minimum of 50 participants for reliability estimates [144]. The NMS has three items with four options for each item, therefore we included a total of 60 patients in the present study.

We calculated mean (standard deviation; SD), or median (interquartile range; IQR) depending on the distribution of data as indicated by the Kolmogorov-Smirnov Test. Cronbach´s Alpha test was used to determine internal consistency of the NMS-ES. Using this test, results range from 0 to 1, with values closer to 1 indicating greater consistency [145]. For the measurement of the inter-rater reliability of the NMS-ES, Bland-Altman analysis was carried out so as to analyse scoring differences between the two raters measurements [146,147]. We assessed systematic inter-rater bias using the McNemar-Bowker test.

For testing concurrent validity, we use Spearman´s Rho to explore association between NMS-ES and selected variables based on the literature [118,129]: age, cognition, the pre-fracture FIM, the CAS-E after surgery. Mann Whitney´s U test was used to compare the results of the NMS-ES between patients according to their prefracture residential status (own home versus nursing or relative home). For all analyses, we used IBM SPSS Statistics Version 25.0 (IBM Corp., Armonk, New York).

RESULTS

Translating the NMS-ES

We translated the NMS-ES as described in the Methods. The main differences between versions one and two (developed independently by two OTs) were grammar-related, and a change in the shopping activity: "walking when the person goes shopping" vs. "walking during shopping time"). The third version of NMS-ES, (developed by a PT) decided on the term "walking during shopping", and adopted the use of the passive voice to describe the scoring process. The fourth (and final) version of the NMS-ES developed by the committee changed the term "technical aids or aids" (used in the three previous versions) to “supportive devices”, a term more appropriate to use in Spanish culture and language. The back translated version resulted in some formatting changes, and minor changes in wording, such as “punctuation” for “scoring”, “punctuate” for “record”, and “due to the fact that” for “although”.

Reliability and validity of the NMS-ES

The flow diagram of the participants in the development of the NMS-ES is shown in Figure 3.

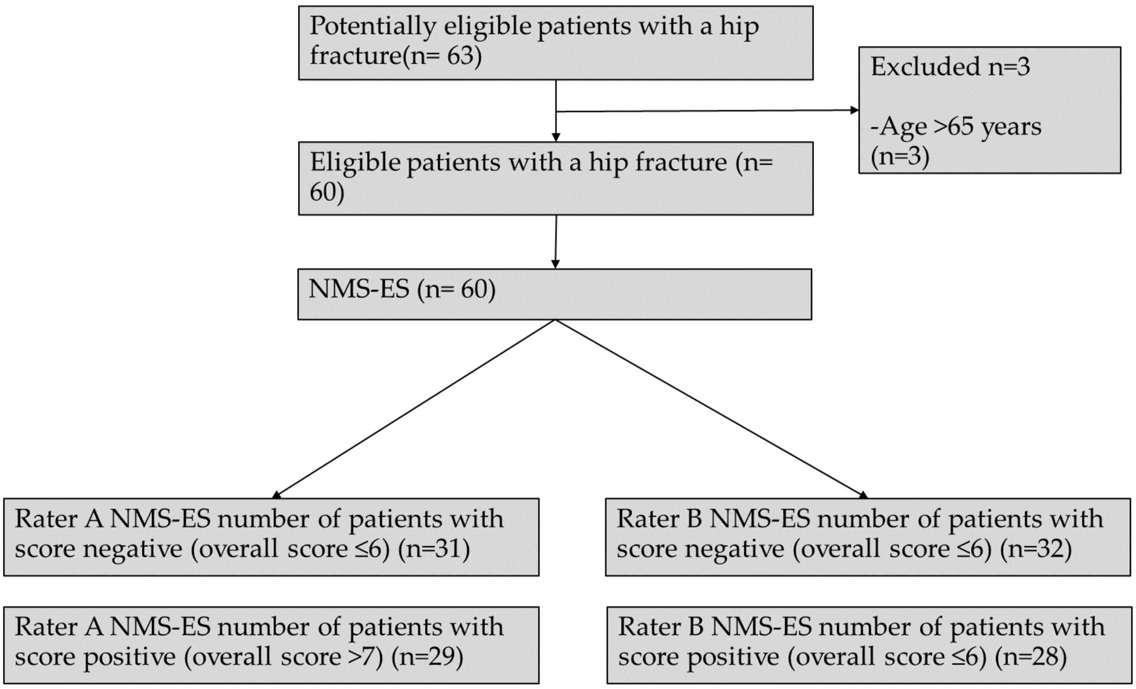

Figure 3. Flow diagram of the NMS-ES.

The sociodemographic and clinical data of the 60 patients with hip fracture are provided in Table 2. Patients or their caregivers were asked for their pre-fracture NMS-ES between the second and sixth day after surgery. It took approximately 3-5 minutes to complete the NMS-ES. Rater A classified 31 patients of 60 with 6 points or less and 29 patients with an overall bigger than 6 points meanwhile rater B assigned 6 points or less for 32 patients and over 6 points for 28 patients.

Table 2. Sociodemographic and clinical data of 60 patients with hip fracture

Variable	*n* = 60
Age, years: mean (standard deviation), minimum-maximum	81.7 (6.8), 65-96
Gender, *n* (%)	
Women	46(77)
Men	14 (23)
Body Mass Index (kg/ m2) Classification, *n* (%)	
Underweight (<18.5)	1 (2)
Normal (18.5-24.9)	18 (30)
Overweight (≥ 25)	41 (68)
Educational level, *n* (%)	

Cannot read and write	16 (27)
Can read and write	25 (42)
Primary school	13 (22)
High school	3 (5)
College (University)	3 (5)
Pre-fracture Functional Independence Measure: median (IQR)	100.5 (79-123.8)
Cognitive Status (SPMSQ test, 0-11 points), *n* (%)	
No cognitive impairment (0-3 points)	27 (45)
Mild cognitive impairment (3-4 points)	15 (25)
Moderated cognitive impairment (5-7 points)	9 (15)
Severe cognitive impairment (8-11 points)	9 (15)
Type of fracture, *n* (%)	
Cervical Femoral (Intracapsular)	40 (67)
Trochanteric (Extracapsular)	20 (33)
Type of surgery, *n* (%)	
Prosthesis	28 (47)
Intramedullary hip screw	32 (53)
Falls in the previous year, *n* (%)	
Yes	18 (30)
No	42 (70)
Pre-fracture residence, *n* (%)	
Own home	45 (75)
Nursing or relative´s home	15 (25)
Change of residence at hospital discharge, *n* (%)	
Yes	17 (28)
No	43 (72)
Support at hospital discharge, *n* (%)	
Formal caregiver	14 (23)
Informal caregiver (relative or friend)	46 (77)
Post-surgery Cumulated Ambulation Score assessed during the first week (between day 2 and 6 from surgery): median (IQR)	3 (2-5)

Values are presented as; number of patients (%), mean (standard deviation), minimum-maximum or as median (IQR) as appropriate.

Reliability

The internal consistency of the total NMS-ES presents a Cronbach's α coefficient of 0.90, and with the corresponding data of each item showed shown in Table 3. The correlations between the three items were a mean of 0.81 with a minimum of 0.77 and a maximum of 0.86. The scores by the two raters differed in one of the 60 patients but the difference was only 1 point.

Table 3. Internal consistency (Cronbach's α) of the Spanish version of the New Mobility Score.

Item	**α** coefficient if item deleted
Indoor walking	0.92
Outdoor walking	0.79
Walking during shopping	0.84
Total	0.90

The scores by two raters only differed in one point in an only patient, as illustrated in the Bland-Altman plot (Figure 4). The mean of differences between these two measurements was 0.02 (95% confidence interval (CI): (-0,23 - 0,27). There was not systematic inter-rater bias for the overall NMS-ES.

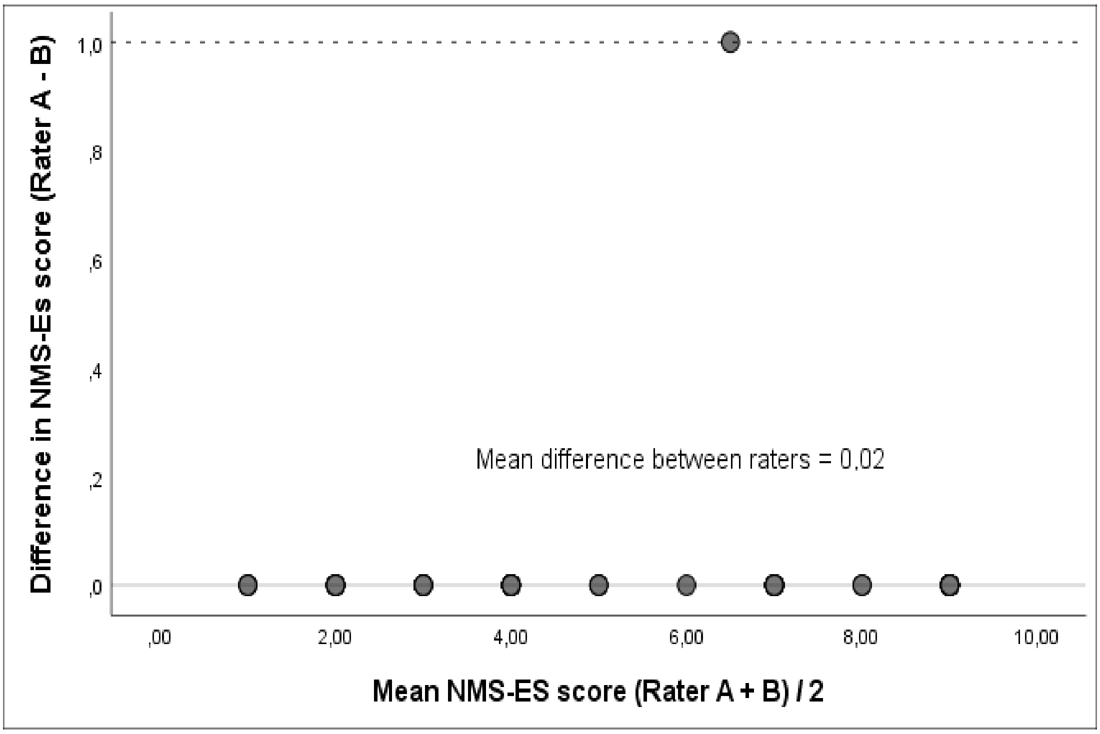

Figure 4. Bland-Altman plot of an occupational therapist (rater A) and a physiotherapist (rater B) scores for the Spanish version of the New Mobility Score (NMS-ES).

Validity

Correlations of NMS-ES with: age was r=-0.42 (p=0.001); cognitive status (SPMSQ Test) was r= -0.71 (p>0.001); pre-fracture FIM was r=0.64 (p<0.001); CAS-E assessed between day 2 and 6 post-surgery was r=0.70 (p<0.001). The mean (SD) of the NMS-ES was 3.33 (1.80) for patients from nursing homes or relative's home vs. 6.48 (2.60) for patients living at home (p<0.001).

DISCUSSION

The modified English version of the NMS was successfully translated into Spanish, and was a reliable and valid instrument to evaluate the prefracture functional status of patients who sustained a hip fracture. In addition, excellent internal consistency, almost perfect agreement, moderate correlation with age, and strong correlation with cognitive status and functional level was observed.

The NMS-ES demonstrated excellent internal consistency (Cronbach's α=0.90), even though the scale is only composed of three items; short scales usually decrease the value of α coefficient [145]. This Cronbach´s α result is considered as the minimum value for clinical application by Bland et Altman [148]. According to Tavakol and Dennick, who consider a Cronbach´s α =0.7 as acceptable

[146], the NMS-ES has a better than acceptable internal consistency. The good agreement between raters showed in the Bland-Altman plot [33,34], with only one difference is a result consistent with that previously established for the NMS [intraclass correlation coefficient (ICC) = 98% (95 CI 0.96-0.99)] [132]. Raters of the present study were a PT and OT, providing support for the use of the instrument by different health care providers. The use of scales that can be administered by different health care providers facilitate the interdisciplinary work in clinical practice. According to its excellent internal consistency and inter-rater reliability, NMS-ES could be considered as a useful instrument in acute care settings where the large number of patients and limited staff resources usually results in low priority for assessing patients´ function.

Age and cognitive impairment were moderately and strongly negatively correlated with the NMS-ES, respectively [149], which confirms previous findings [129]. The results are particularly relevant if we consider possible difficulties assessing patients with cognitive impairment. One of the advantages of the NMS is the ability for caregivers to provide relevant information in those cases when the patient is not able to do it due to its cognitive impairment. This feature extends the instrument to include all patients with hip fracture, including patients with cognitive impairment, a group frequently excluded in research for this clinical area [150]. Thus, beyond the clinical utility of the NMS-ES, it can provide valuable insights for research. These results provide further support for the NMS, in general, as an important instrument to measure patients' pre-fracture functional level. We need to rely on patients' and caregivers' perception of pre-fracture function to provide context for goal setting and overall management.

The association of the NMS-ES with the FIM was considered, according to previous studies, as strong [149]. Both scales have shown excellent reliability and almost perfect agreement and good validity [122,132]. However, the NMS was specifically designed for older people with hip fracture and it requires much less time to complete compared with the FIM; although it also provides less information. Nevertheless, because of limited time, the clinicians who work in acute care settings request short scales that can be easily incorporated into practice to develop appropriate rehabilitation strategies. Further, short hospital stays also supports the use of quick and easy to use instruments to ascertain important information such as pre-fracture function.

The NMS-ES was also strongly correlated with the CAS-E [147]. These findings are consistent with the study by Kristensen et al. [118], that reported patients with a low prefracture NMS would be 18 times more likely not to regain independence in basic mobility, assessed by the CAS, when discharged from an acute orthopaedic ward. Corresponding findings were reported by Hulsbæk et al. [151], and Fitzgerald et al. [131]. The relation of the NMS as predictor of the basic mobility of patients after surgery support the recommendation to include the NMS-ES in the assessment protocol for patients admitted to hospital with hip fracture. Further, the association between the NMS-ES and the place of residence showed that people who lived in their own home before the fracture, as expected, presented higher NMS-ES scores than those not living in their own home, due to these patients usually are less involved in carrying out their activities of daily living by having professionals or relatives at their disposal.

These results proved the concurrent validity of the NMS-ES as an assessment tool to measure the pre-injury functional level in patients with a hip fracture.

Study strengths and limitations

This study has many strengths to support clinical practice and research. First, we provided a comprehensive approach to the translation of the NMS into Spanish according to international recommendations [136]. Second, to test some psychometric properties of the NMS-ES, we enrolled a representative sample of patients with hip fracture, across different levels of cognitive status, types of fracture and places of residence [152]. Third, we confirmed the results of the NMS-ES with previously validated scales such as the FIM [122], and the CAS-E [140]. However, we also acknowledge some limitations regarding the interrater estimates. Despite of the fact that the two raters were blinded to each other's NMS scoring, they were both present when the instrument explanation were provided to patients and their caregivers. This may explain the almost 100% interrater agreement. Nevertheless, our results are consistent with the only previous inter-rater reliability study of the NMS [132]. Finally, the NMS-ES has been translated into the European Spanish language and validated in a European Spanish population. A cross-cultural adaption of the NMS-ES is required for its use in other Spanish speaking countries.

CONCLUSIONS

The NMS-ES is a reliable and valid outcome measure to assess the pre-fracture functional status of older patients with hip fracture in Spain. We confirm the NMS-ES as an easy to use and quick to complete score that can be used for all patients with hip fracture, with information provided by the caregivers for those patients with cognitive impairment. Furthermore, it is reliable when used by OTs and PTs, important for consistency within team-based assessment of patients with hip fracture. Overall, the NMS-ES has strong potential as an important instrument for clinical assessment and monitoring pre-fracture function of patients with hip fracture in Spain, but also for follow-up assessments to monitor the level of recovery after fracture.

Supplementary Material

Appendix A. Spanish version of the modified New Mobility Score (NMS-ES).

Nuevo Test de Movilidad (NMS-ES, 0-9 puntos)				
Movilidad	Sin dificultad Y sin ningún dispositivo de apoyo	Con un dispositivo de apoyo para caminar	Con ayuda de otra persona	De ningún modo
Capaz de moverse por la casa (Caminar dentro)	3	2	1	0
Capaz de salir de la casa (Caminar fuera)	3	2	1	0
Capaz de ir de compras (Caminar cuando va de compras)	3	2	1	0

Spanish version by Prieto-Moreno R et al. 2019, after modified English version by Kristensen MT January 2010, from Parker and Palmer [10]. J Bone Joint Surg 1993; 75: 797-9 approved by Dr. Parker, and published in Kristensen and Kehlet. Danish Medical Journal 2012; 59: A4447 [129].

El Nuevo Test de Movilidad (NMS-S) fue diseñado en su origen para pacientes con fractura de cadera [124], pero puede usarse para otros grupos diagnósticos con problemas de movilidad [153]. El NMS valora la marcha; dentro de la casa, fuera de la casa y al ir de compras. Se asignan de 0 a 3 puntos para cada función, resultando una puntuación total de 0 a 9 puntos. Aunque no ha sido evaluado formalmente, una mejora de un punto en el NMS indica un cambio clínicamente relevante. La excelente fiabilidad Inter evaluador del NMS en pacientes con fracturas de cadera [18], ha sido probada, así como su elevada utilidad predictiva sobre la mortalidad y otras consecuencias de la fractura de cadera [118,124,129-131,151]. El NMS puede utilizarse para la evaluación del cambio y evolución de la movilidad tras una fractura de cadera [117,154,155].

Manual para la puntuación del Nuevo Test de Movilidad (NMS-ES): Si el paciente utiliza ocasionalmente algún dispositivo de apoyo o una silla de ruedas para las actividades descritas, se puntúa con el nivel más bajo de función.

Al evaluar, por ejemplo, el nivel funcional previo, se le pide al paciente que recuerde su funcionalidad en la semana previa a la fractura de cadera. Muchos pacientes tienden a describir su nivel funcional previo refiriéndose a meses o años atrás, por lo que hay que confirmar su respuesta, por ejemplo, el caminar fuera de casa, se les pregunta cuándo fue la última vez que estuvieron fuera de casa o que bajaron las escaleras.

A una persona que usa el coche como medio de transporte para ir a comprar y utiliza un bastón mientras compra, se le asignan 2 puntos en ir de compras.

En personas con deterioro cognitivo, con el fin de garantizar la exactitud, la información sobre la movilidad del paciente será obtenida a través de los cuidadores del paciente en casa o en la residencia.

A una persona, que por ejemplo usa silla de ruedas fuera de la casa o para ir de compras se le asignan 0 puntos tanto para caminar fuera como para ir de compras.

A una persona que no usa dispositivos de apoyo para moverse dentro de la casa, pero que se apoya en muebles, marcos de las puertas o similares, se le asignan 2 puntos en la actividad de caminar dentro.

Dispositivo de apoyo terapéutico para caminar:

Dentro de casa ___________ Fuera de casa________ Al ir de compras_____

Resultados:

Dentro de casa (0-3) ___ Fuera de casa (0-3) ____ Al ir de Compras (0-3) ____ Total (0-9)__

El NMS es también conocido como el" Test de Movilidad de Parker" aunque fue desarrollado conjuntamente con el Dr Palmer. La presente versión del NMS debería ser citada como:" La versión modificada y fiable del Nuevo test de Movilidad" [10,15,18].

Section 2

The @ctivehip tele-rehabilitation program for older adults with hip fracture

Study II

Effects of the @ctivehip tele-rehabilitation program on the fear of falling of older adults with hip fracture

INTRODUCTION

Osteoporotic hip fractures are a major health problem by several reasons. First, they are common. In Europe, 830.000 hip fractures occur annually [6], a figure that is increasing due to the ageing of society [156]. Second, the cost of osteoporotic hip fractures is estimated in €57,000 million per year [6]. Third, the health consequences of this type of fractures are serious including a mortality rate that is close to 25% during the first year [17]. Lastly, hip fractures negatively impact caregivers´ health [50], they supposes a considerable overload [157] and stress [58].

Falls are the main cause of osteoporotic fractures [10]. Falls are a recurrent episode as 1 in 3 older adults fall at least once a year [158]. Therefore, one of the worst psychological symptom in older adults recovering from hip fracture is the fear of falling, which is experienced by 50 to 65% of older adults [42]. Fear of falling represents an important barrier during the recovery with patients avoiding activities of daily living (ADLs) [43], which in turn results in lowering mobility, functionality [44,159] and self-efficacy [45]. Avoidance of ADLs is further exacerbated by family caregivers, who are often concerned about potential new falls leading to increased dependency [160]. During the recovery, family caregivers also have to change their routine, which affects their own health [161]. Family caregivers play an essential role during the recovery because they may promote that older adults get involved in recovery programmes for fall prevention [51].

Widely accepted rehabilitation guidelines for older adults with hip fracture highlight the need of targeting fear of falling to ensure an integral recovery, which includes doing ADLs [83]. There is available literature testing the effects of in-person interventions on reducing fear of falling in older adults with a hip fracture [162–164]. However, the number of studies is scarce and they did not include the effects on fear of falling experienced by caregivers, yet they play a key role [160].

Despite the benefits attributed to early rehabilitation and continuity of care after hospital discharge [83,165], the provision of optimal rehabilitation is constrained by the limited resources of the healthcare systems [84], which in some ends up not providing continuity of rehabilitation after hospital discharge. This is still worse for older adults who do not have easy access to rehabilitation (e.g., those living in rural areas) [61]. Additionally, due to COVID-19, care in acute trauma centres for hip fractures has been reduced [85]. Tele-rehabilitation, the remote provision of rehabilitation services [98], may contribute to enrich the offered rehabilitation adding the advantages of Information and Communications Technologies (ICTs). ICTs may facilitate monitoring by health providers´ [102] and reduce the patients´ visits to the hospital for rehabilitation, allowing them to rehabilitate at home, where they feel safer [95]. Although the evidence shows that tele-rehabilitation is effective in many diseases [102,166,167], limited information is available in hip fracture [110,113,168–170]. These studies are focused on aspects as the functional status or quality of life [113,171]. However, to the best of our knowledge there are not studies testing the effects of tele-rehabilitation in fear of falling of older adults with a hip fracture, even though falls are considered as one of the main reasons for increasing care to older adults [172].

Thus, the aim of this study was to test the effectiveness of the @ctivehip tele- rehabilitation programme on the fear of falling perceived by both older adults with hip fracture and their family caregivers.

METHODS

Study design

The present study was a non-randomized controlled trial, conducted following the established guidelines by the Helsinki Declaration and Law 14/2007 on Biomedical Research.

The Ethics Committee of the Research Centre of Granada (CEI-GRANADA) approved the present study. It was also registered at ClinicalTrials.gov (NCT02968589).

Participants

Older adults with hip fracture included in this study had to meet the following inclusion criteria: i) to have undergone a hip fracture surgery; ii) to be 65 years or older; iii) to have a high pre-fracture functional status one week before the injury. It was measured through the Functional Independence Measure (FIM) and was necessary at least 90 points to be included; iv) to be allowed to full weight-bearing 48 hours after the surgery; v) to be discharged to their own home or to a relative's home and vi) to have a caregiver with internet access and the ability of using internet to use the @ctivehip programme.

On the other hand, the exclusion criteria of the present study were: i) to suffer severe cognitive impairment (established as a score <24 in the Mini-Mental State Examination); ii) to have a terminal disease and iii) to suffer post-surgical complications that prevent the start of rehabilitation in the first week after the surgery.

Recruitment, allocation and blinding

Recruitment was carried out in the University Hospital of Granada, from January 2017 to July 2018. During this time, two health providers of the orthopaedic service, an occupational therapist (OT) and a physical therapist (PT), invited all the older adults who met the inclusion criteria to be included in this study. Those older adults and their family caregivers who agreed to be included could choose to be placed in the tele-rehabilitation group, which consisted of usual care during the hospital stay, an educational workshop and the @ctivehip tele-rehabilitation intervention, or to be placed in the control group, which consisted of usual care during hospital stay, an educational workshop, and OT and PT home rehabilitation. The assessments of the older adults with a hip fracture and family caregivers were carried out by an occupational therapist, a physical therapist and a sports scientist blinded to the allocation of the older adults and family caregivers.

Intervention

Common intervention for both groups

There were some parts of the intervention in this study that are common to the enrolled older adults with a hip fracture, regardless of which group they belonged to, the tele-rehabilitation group or the control group. During their hospital stay, all the older adults received the standard care established by the Andalusian Public Healthcare System for a hip fracture, which is composed of a few rehabilitation sessions during weekdays (no weekends). In addition, older adults and family caregivers could assist to a Workshop in the hospital carried out by the @ctivehip researchers. This Workshop was designed to provide family caregivers some tools and information about the management of the patient after the surgery. Moreover, all the participants received a leaflet during the hospital stay with recommendations and some exercises to perform during the first days.

Tele-rehabilitation group

The intervention for the older adults with a hip fracture allocated in the tele-rehabilitation group was, apart from the common part described above, a multidisciplinary tele-rehabilitation programme of 12 weeks. This tele-rehabilitation programme was delivered through a webpage and consisted of two video-recorded rehabilitation programmes, one on physical exercise and one on occupational therapy, as well as a number of videos with general recommendations on the recovery process. Each week, older adults with a hip fracture, with the help of their family caregivers, could do up to 5 rehabilitation sessions of about 40 to 60 minutes, 3 physical exercise sessions and 2 occupational therapy sessions. The rehabilitation sessions are grouped into 4 levels of difficulty. Each patient was assigned a level based on the results of their assessment. A more detailed description of the @ctivehip programme is provided elsewhere [173].

Control group

In addition to the common intervention described above for all the older adults with a hip fracture, the older adults allocated in the control group received the usual care established by the Andalusian Public Healthcare System after the surgery. It consisted of between 5 and 15 home sessions delivered by an occupational therapist or a physical therapist.

Variables and instruments

The older adults with a hip fracture included in this study were assessed in three different moments: a) during their hospital stay (first week after the surgery); b) in the surgeon´s appointment one month after the hospital discharge; c) three months after hospital discharge, at the end of the intervention planned for this study.

Fear of falling

The Short Falls Efficacy Scale-International (SFES-I) is a reliable (Cronbach's α = 0.92) and feasible [174] tool to measure the fear of falling in older adults. This is a scale which can be assessed in a fast way, something considered essential to be used in the health providers´ daily practice. The SFES-I is composed by 7 items relating to some ADLs inside and outside the home and each item has a score between 1 (not worried about the possibility of fall) and 4 (extremely worried about the possibility of fall). The overall score of this scale ranges from 7 (not worried at all about falling) to 28 (extremely worried about falling). The SFES-I was also used in this study to assess the fear of falling of older adults and their family caregivers as it was used in a previous study [160].

Functional status

The functional status of the older adults with a hip fracture of this study was measured through the Functional Independence Measure (FIM). The FIM is a scale widely used to measure not just the need of assistance in ADLs but also the social and cognitive function in older adults with a hip fracture [175,176]. This scale is comprised by 18 items with a score from 1 (totally dependent) to 7 (totally independent). The overall score ranges from 18 to 126 points. Lower scores are associated with a lower level of independence. The psychometric properties of the FIM have been reported as adequate [177].

Physical performance

The physical performance of older adults with a hip fracture was measured through two scales, the Short Physical Performance Battery (SPPB) and the test Timed Up and Go (TUG). On one hand, the SPPB is a battery used previously to measure healthy older adults and also specifically older adults with a hip fracture [178,179]. This battery is comprised by 3 tests, measuring balance, walking and chair stands [178]. The score ranges from 0 (worst physical performance) to 12 (best physical performance). The psychometric properties of the SPPB have been reported as adequate [180]. On the other hand, the TUG is a test that measures the time it takes a patient to get up from a chair, walk 3 metres, turn around and sit back down in the chair. The psychometric properties of the TUG have been reported as adequate [181].

Sociodemographic variables

The sociodemographic data (for example, age, gender, BMI, place of residence) of older adults with a hip fracture and their family caregivers were collected during the first assessment through an interview. In addition, other data as the surgical risk, the type of fracture, the number of falls during the previous year of the fracture, the number of falls at 3-months after surgery were collected through the clinical record of the hospital.

Sample size

We estimated the sample size using the primary outcome, the Functional Status, based on the tele-rehabilitation intervention conducted by Tappen et al. [168]. To anticipate possible losses, an extra 35% was added, resulting in a total of 70 participants, (35 in the tele-rehabilitation group and 35 in the control group) to obtain an 80% statistical power and an α error of 5% using a two-sample t-test. Sample size was estimated using the software Epidat 3.1 (Xunta de Galicia).

Statistical analysis

Firstly, main outcomes were checked for normal distribution through visual inspection of histograms together with the Kolmogorov-Smirnov test. Fear of falling in both patients and caregivers demonstrated a normal distribution. The characteristics of the sample divided into the tele-rehabilitation and control groups are presented as mean values and SDs or percentages.

The main effects of the tele-rehabilitation programme were tested with analysis of covariance (ANCOVA), using post-rehabilitation values outcomes as dependent variables, group (i.e., tele-rehab vs. control) as a fixed factor and baseline outcomes as covariate. A priori sensitivity analysis was performed to test the influence of potential confounders in the results (i.e., age, sex, educational level, health status before the hip fracture, falls in the last year and type of fracture), but none were included after verify that they did not influence the model. Apart from the raw values, the z-scores for the fear of falling at post-rehabilitation were also formed by dividing the difference of the post-rehabilitation raw score of each participant from the baseline mean by the baseline standard deviation (i.e., [post-rehabilitation individual raw value – baseline mean] / baseline SD). Additionally, within subjects Cohen's d was calculated as effect size indicator using the following formula: Cohen's d = Mean difference / pooled SD. As effect size indicators they can be interpreted according to the standard benchmarks, i.e. a value around 0.2 is considered a small effect size, 0.5 is considered a medium effect size and 0.8 is considered a large effect size [182]. We also explored the role of potential mediators, such as physical performance and functional independence, on the effects of the tele-rehabilitation programme. The mediation analyses are in line with the AGReMA (A Guideline for Reporting Mediation Analyses): https://agrema-statement.org/. We present the intention-to-treat analyses as supplementary files. The same procedures were followed as the explained above for the per-protocol analyses. For the intention-to-treat approach, all participants (N = 71) were included and those without valid data were imputed through multiple imputations.

All analyses were performed using the SPSS software (version 24.0, IBM Corporation), and the level of significance was set at $p < 0.05$.

RESULTS

The characteristics of the participants dividing the sample into both tele-rehabilitation and control groups are showed in Table 4. The exclusion and dropouts of older adults with a hip fracture are detailed in the CONSORT 2021 flowchart in Figure 5.

Table 4. Participants' characteristics divided into the tele-rehabilitation and control groups.

Variables included	Tele-rehabilitation (*n* = 31)	Control (*n* = 33)
Older adults, age (years)	76.59 ± 6.08	80.48 ± 5.65
Family Caregivers' age (years)	47.74 ± 8.00	54.79 ± 14.47
Body mass index (kg/m^2)	26.56 ± 3.83	27.64 ± 3.74
Older adults´ Sex, *n* (%)		
Men	9 (29%)	7 (21%)
Women	22 (71%)	26 (79%)
Family Caregivers' Sex, *n* (%)		
Men	10 (32%)	13 (39%)
Women	21 (68%)	20 (61%)
Type of fracture, *n*		
Intra. subcapital	14	7
Intra. transcervical	1	2
Intra. basicervical	1	1
Extra. pertrochanteric	13	22
Extra. subtrochanteric	2	1
Fear of falling		
Older adults at baseline	16.86 ± 6.17	15.76 ± 6.64
Caregivers at baseline	14.80 ± 5.72	14.06 ± 6.01
Older adults at 3 months	12.69 ± 6.52	15.12 ± 7.07

Caregivers at 3 months	11.2 ± 5.48	13.12 ± 5.38
Additional variables		
FMI at baseline	77.46 ± 5.48	78.12 ± 6.62
FMI at 3 months	119.12 ± 8.24	108.23 ± 14.89
SPPB basal	3.03 ± 1.32	2.62 ± 1.47
SPPB at 3 months	7.82 ± 3.03	5.81 ± 3.05
TUG basal	81.02 ± 71.04	102.17 ± 70.67
TUG at 3 months	14.78 ± 9.12	24.94 ± 13.78
Surgical risk	2.26 ± 0.86	2.64 ± 0.86
N° falls basal	0.43 ± 0.66	0.76 ± 1.35
N° falls at 3 months	1.97 ± 0.17	1.82 ± 0.39

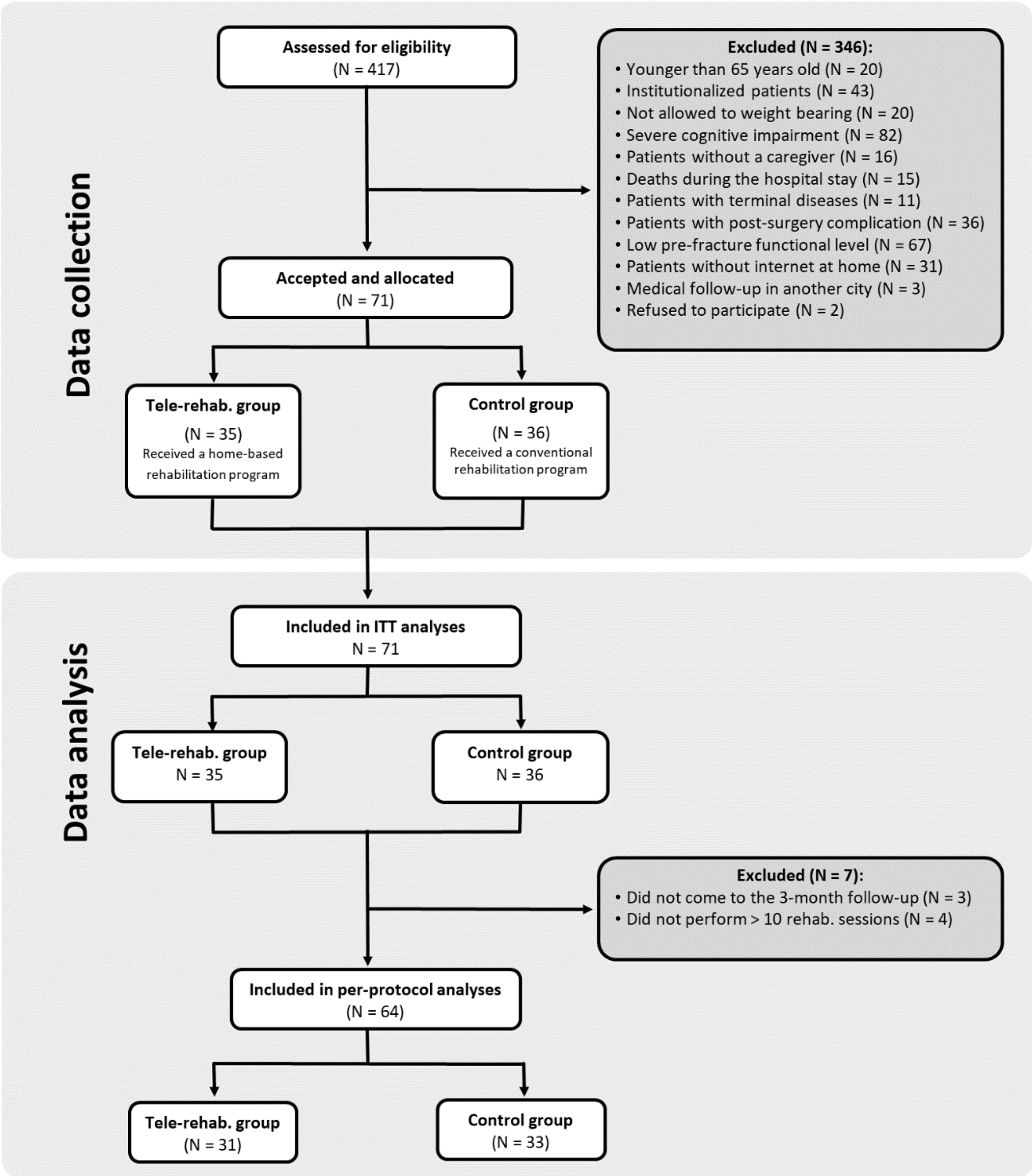

Figure 5. Flowchart describing the included participants for both analyses.

Table 5 presents the differences between the tele-rehabilitation and control groups in the fear of falling of both the older adults with a hip fracture and their family caregivers 3 months after the hip fracture occurred. Fear of falling of the participants decreased more in the tele-rehabilitation group than in the control group (medium effect size: 0.5 Cohen's d; p = 0.042), while there were not statistical differences in the fear of falling of their caregivers between both groups (Figure 6). The positive impact of tele-rehabilitation on older adults' fear of falling was mediated 79.2% by the improvements in functional independence (Figure 7). Physical performance, evaluated through SPPB and TGU, did not mediate the effects on the fear of falling. The intention-to-treat analysis shows that the effect size in the fear of falling of patients was slightly attenuated (-0.48 SDs; p = 0.047), although it maintained statistically significant. Results in the fear of falling perceived by the caregiver remained non-significant (p = 0.098).

Table 5. Effects of the @ctiveHip intervention in fear of falling (*n* = 64).

Adjusted post-intervention means and group differences (95% confidence interval)				
	Tele-rehabilitation group (*n* = 31)	Control group (*n* = 33)	Groups difference#	*P*
Patients	11.80 (9.65 to 13.95)	15.43 (13.34 to 17.52)	3.63 (0.63 to 6.64)	0.02
Caregivers	11.00 (9.09 to 12.91)	13.18 (11.33 to 15.03)	2.18 (-0.48 to 4.84)	0.11

#Group differences are presented as: post-intervention means minus pre-intervention mean. A one-way analysis of covariance (ANCOVA) was used to test differences between the tele-rehabilitation and control group at the post-intervention. adjusting for baseline values. Adjusted means and confidence intervals of the mean are represented. Significant differences (p < 0.05) are highlighted in bold.

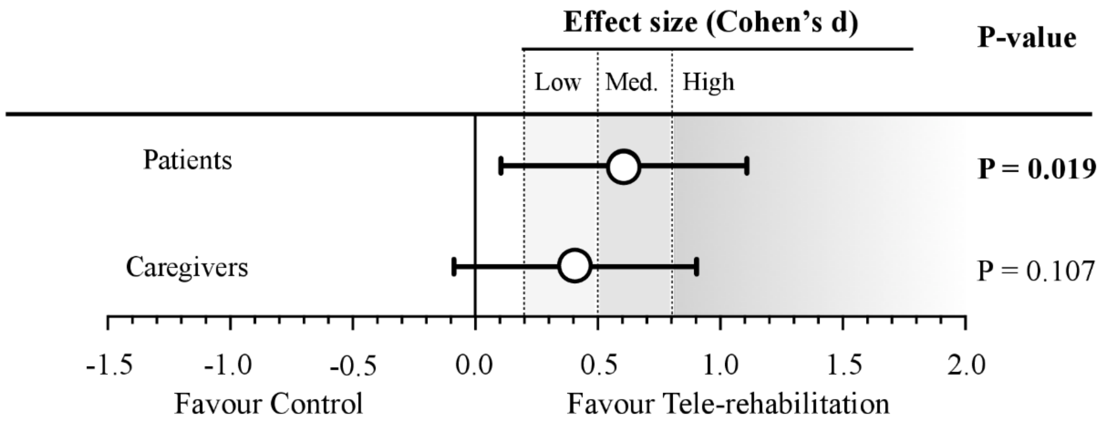

Figure 6. Effect sizes of the @ctiveHip intervention on the fear of falling of older adults with hip fracture and caregivers.

One-way analysis of covariance (ANCOVA) was used to test z-score differences between the tele-rehabilitation and control group at 3-month assessment, adjusting by baseline values. Bars represent 95% confidence intervals.

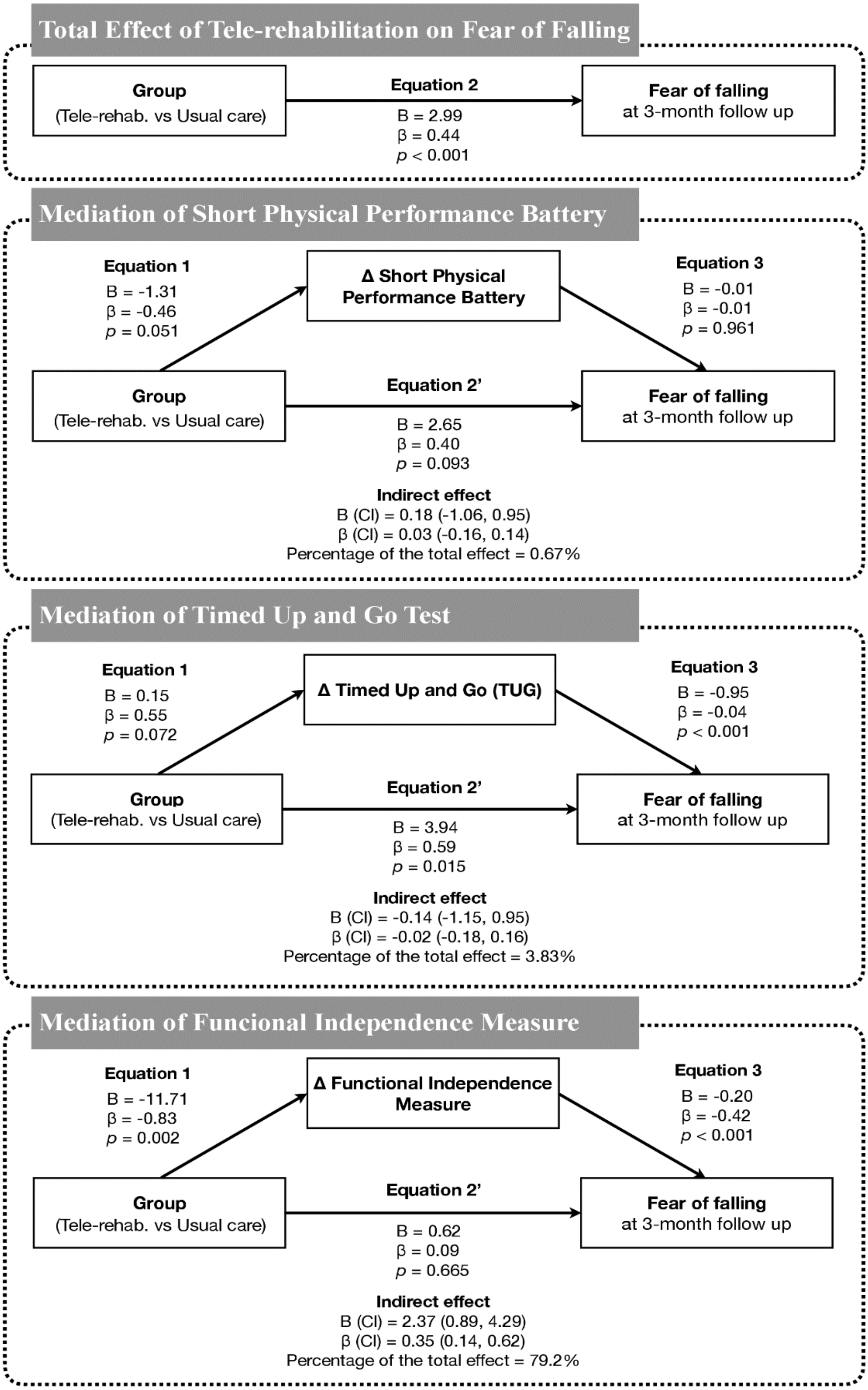

Figure 7. Mediation models (physical performance and functional independence) of the tele-rehabilitation effects on the fear of falling of older adults with a hip fracture.

B: unstandardized regression coefficient; β: standardized regression coefficient; CI: confidence interval.

DISCUSSION

The @ctivehip tele-rehabilitation programme was effective in decreasing fear of falling in older adults with a hip fracture but had no effects in their family caregivers. This decrease in fear of falling was completely mediated by the improvement in functional status experienced during the 3-month tele-rehabilitation intervention. The findings of this study must be cautiously interpreted because of its quasi-experimental design. Further research following the strictest standards for experimental research is warranted. Particularly, it is of interest to conduct an appropriately designed RCT, including strict randomisation when allocating participants to the groups.

Previous studies focused on studying the effect of tele-rehabilitation on the functional status or quality of life of older adults after hip fracture [113,171]. To the best of our knowledge, the effects of tele-rehabilitation on fear of falling was not studied [183]. In the present study, the tele-rehabilitation programme reduced the levels of fear of falling experienced by older adults with a hip fracture. Despite of the fact that @ctivehip was a tele-rehabilitation intervention, our results are in line with the systematic review published demonstrating that in-person rehabilitation interventions are effective in reducing fear of falling [184]. Thus, tele-rehabilitation may be effective for reducing fear of falling of older adults with a hip fracture. Further research comparing the effects of in-person vs tele-rehabilitation on patients' fear of falling seems of interest.

Findings from our mediation analysis suggested that the effects of the @ctivehip tele-rehabilitation intervention in patients' fear of falling was completely mediated by recovery of their functional status. These results are in line with the studies of Kempen et al. [185] and Lawson et al. [186], where people with worse functional status showed more fear of falling. Moreover, the studies of Jellesmark et al. [44] or Achterberg et al. [187] reported that the association of fear of falling and functional status is higher than the association of fear of falling and physical activity. However, previous studies have shown than physical activity interventions based on task-oriented ADLs training have positive results in increasing functional status in older adults [188-190]. The recovery of the functional status of the older adults with a hip fracture through practice and repetition of activities of daily living is essential to develop self-efficacy [45] (people's belief about their capacity) [191], which is strongly related with a better results of recovery [192,193]. According to these results, future interventions reducing fear of falling should include physical activity but focused on task-oriented ADLs training to improve the self-efficacy of older adults with a hip fracture and decrease the fear of falling.

Our results also support the recommendation of comprehensively measure physical function by the combination of both performance-based measurements (such as the SPPB and the TUG) and assessments based on Patients Reported Outcomes Measures (PROMs, such as the FIM) in both research and clinical settings [194,195], which may help to develop a patient-centred care [196]. On one hand, this complementary approach may let to improve the communication between health providers and patients and even the way patients understand their condition [197]. On the another hand, it places patients as the centre of the decision-making process [196]. In this line, tele-rehabilitation seems to be a promising option for the functional status recovery reported by older adults [109,110,113].

In the present study, the @ctivehip tele-rehabilitation intervention had no effects on fear of falling experienced by family caregivers. We speculate that our intervention did not pay enough attention to the needs of family caregivers. This speculation is in line with previous study highlighting the need of including family caregivers in the rehabilitation and provide them with detailed information about this process [198,199]. This is even more essential when considering the role that family caregivers play in overcoming the age barrier for older adults using ICTs [200,201]. Therefore, future tele-rehabilitation programs should make a strong emphasis on family caregivers [202] as their fear can be a barrier in the recovery of older adults with a hip fracture [160].

Visschedijk et al. reported that fear of falling is strongly related with psychological factors [42]. The results about the decrease in the psychological impact after the @ctivehip tele-rehabilitation programme are published elsewhere [171] as well as the decrease in the fear of falling presented in this study support the evidence of this relationship. This information should be used in future studies to develop integral tele-rehabilitation programmes, as reported in previous studies where integral geriatric care showed better results than care focusing only physical aspects [203,204].

The present study has limitations. Firstly, the allocation of the participants was not randomized. The allocation was based on the older adults with a hip fracture´ choice, which could have made older adults in the tele-rehabilitation group more predisposed, with more time and resources available for rehabilitation. To alleviate this limitation, all the analyses were performed adjusting for baseline values and despite of the fact that any variable resulted as a confounder, a sensitivity analysis was carried out. Secondly, we did not measure the involvement of each family caregiver in the recovery neither in the tele-rehabilitation group nor in the control group. More information on this regard would help us to understand whether more implied caregivers have less fear of falling during the recovery process. This needs to be taken into account in future studies, given the important role of the caregiver in the recovery process. This role is essential in the use of ICTs considering the average age of older adults with a hip fracture and the existing relationship between the old age and the lack of skills using ICTs [200]. The main strength of this study is the provision of rehabilitation through the @ctivehip tele-rehabilitation programme for those older adults with a hip fracture who do not have access to in-person option with health providers. This is particularly important for older adults who do not have easy access to rehabilitation (e.g., those living in rural areas) and for older adults during the COVID-19 pandemic, who are more likely to suffer severe conditions if infected [205]. The longitudinal design of the present study is also a strength.

CONCLUSIONS

In comparison to the standard in-person care provided by the Andalusian Public Healthcare system, the @ctivehip tele-rehabilitation programme is effective in reducing the fear of falling in older adults with a hip fracture. This reduction is supported by the recovery of functional status, as patients gain confidence in their own abilities as they perceive that they are able to perform activities independently. However, the @ctivehip tele-rehabilitation programme had no effects on fear of falling in family caregivers. These results support the inclusion of tele-rehabilitation programmes for older adults with a hip fracture and family caregivers in the daily clinical practice as a useful alternative when in-person rehabilitation is not feasible.

Study III

Family Caregivers Experiences' with

Tele-rehabilitation for of older adults with hip fracture

INTRODUCTION

Loss of functional independence [37], decreased social participation [37], and reduced quality of life [206] are some of the main consequences of hip fractures. Early hospital rehabilitation with follow-up post-discharge can support older adults' recovery of function [84]. Family caregivers play an essential role in helping older patients to complete activities of daily living (ADL) in the home setting [52,207]. The sudden and unexpected nature of hip fractures can impact both older adults and family caregivers, who as a result can experience increased stress and burden [94]. As a result, hip fracture is associated with worse overall health status in family caregivers [58]. These factors indicate a need for new post-discharge management strategies [83,208] to improve older adults' function post-hip fracture and reduce caregiver stress [209].

There are barriers to delivering rehabilitation after hip fracture, such as limited access to health professionals after discharge to home. Telerehabilitation (telerehab) is a promising management strategy to support recovery after discharge, and may be especially important in rural and remote areas with limited access to in-person rehabilitation [167]. Of note, there has been an increase in remote delivery of health care because of the SARS-CoV-2 (COVID-19) pandemic [85]. Based on previous studies, telerehab for musculoskeletal injuries or conditions were effective for improving physical function, quality of life, and psychological factors [102,107,108,210]. However, there is limited evidence for: (i) the effect of telerehab for older adults after hip fracture [211], and (ii) the inclusion of family caregivers in telerehab for hip fracture [212]. We focus on family caregivers to support older people using information and communication technologies (ICT), and to provide support for the telerehab program. Involving family caregivers in telerehab also addresses their request for more information on the recovery process [198]. Thus, we aimed to address these knowledge gaps [211] by designing and testing a telerehab program called @ctivehip for older adults with hip fracture and their family caregivers.

We previously published results from the main trial [113]—a choice-based multiple methods clinical trial comparing @ctivehip telerehab with home-based in-person rehabilitation for functional recovery of older adults with hip fracture [173]. The @ctivehip intervention consisted of: (i) web-based information to increase family caregivers' knowledge and skill development; (ii) a supported exercise and ADL program for older adults (delivered by the family caregiver); (iii) a specific section on family caregivers' health; and (iv) an option for family caregivers to video conference with health professionals.

The aim of the present exploratory study was to describe family caregivers experience with the @ctivehip telerehab program. We anticipated that family caregivers' feedback could be used to refine the intervention by identifying implementation opportunities and challenges from a person-centered approach.

METHODS

Design

This was a substudy of a multiple methods clinical trial (Clinical Registration NCT02968589). We previously published the results of the main study (quantitative findings, primary outcome functional level) [113], and patients' and family caregivers' overall experience with hip fractures (qualitative findings) [157]. In this second qualitative study, we aimed to synthesize experiences of the family caregivers of older adults with hip fracture enrolled in the @ctivehip telerehab program. We were guided by the principles of interpretive description [213] when designing the interview guide, conducting interviews, and synthesizing findings.

Participants

A description of participant recruitment is provided elsewhere [173]; please see Figure 8. At the final assessment of the main trial (conducted at three months after hip fracture surgery), family caregivers were invited to participate in semi-structured interviews. For the present study, we summarize responses only from participants who requested @ctivehip (e.g., the intervention group). There were 23 family caregivers who agreed to participate and signed the study consent form. When we telephoned family caregivers three months later, two family caregivers did not answer the telephone after several attempts. Thus, 21 family caregivers representing 21 older adults with hip fracture were interviewed for the present study.

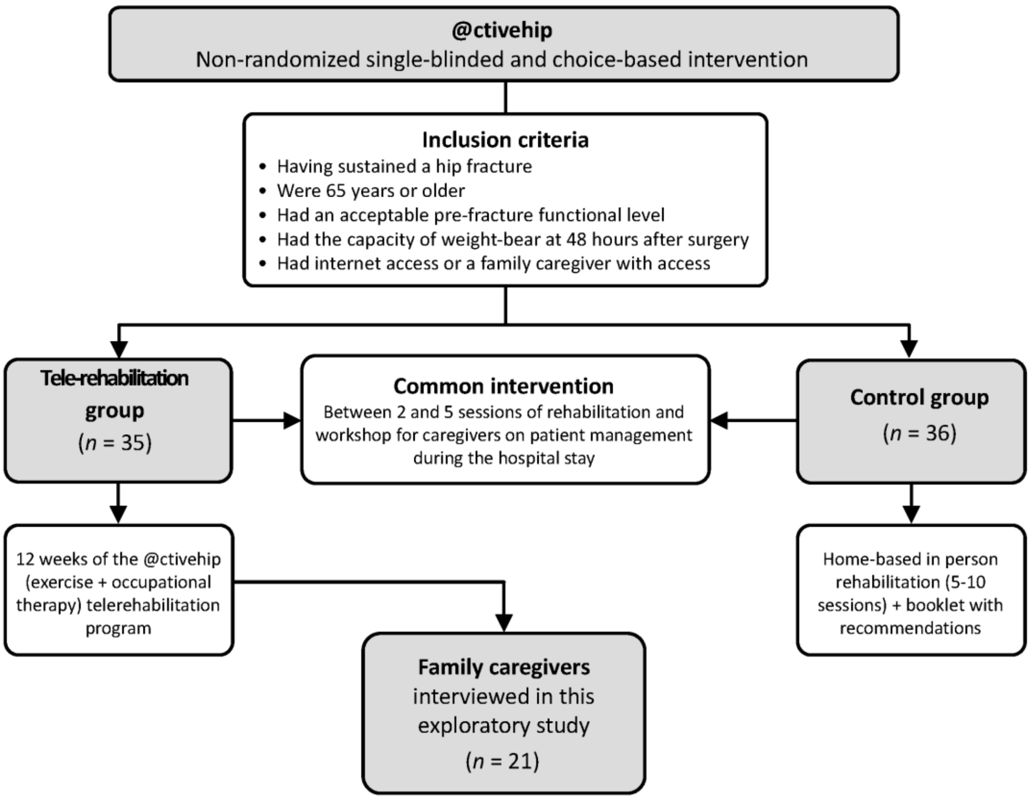

Figure 8. Flowchart for caregivers recruitment.

Semi-Structured Interviews

Between October 2017 and December 2018 an occupational therapist (OT), with related clinical experience but not involved in the main clinical trial, conducted the telephone interviews between three and six months after participants finished the main clinical trial. The virtual interviews were scheduled when family caregivers were at home, to minimalize potential distractions. The OT recorded and transcribed the interviews within two days after each interview and kept field notes for reference during the analysis process. The interview guide is provided in Appendix A. During the interviews, the OT encouraged discussion using prompts such as "please explain how you did it", “tell me more about it”, and follow-up questions to encourage participants to provide more details of their experience. To explore family caregivers' perceptions about the utility of, and satisfaction with, the telerehab program we asked participants to rate their experience using a scale of 0–10 points (0 = not useful and 10 = very useful; 0 = lowest level of satisfaction and 10 = highest level of satisfaction). On average, interviews lasted 18 (range 1–22) min.

Data Analysis

We followed the recommendations of Graneheim and Lundman [214] to conduct a multi-step content analysis. Two authors P.A.-V. and R.P.-M. first read the transcripts (in Spanish) several times. Following this they met three times to review data, create a coding framework, and synthesize findings. The process involved one coding cycle and two re-coding cycles [215] to increase confidence in the response classification. During this process, the authors identified meaning units, sorted them into subcategories, and then categories. Data (categories and quotes) were translated into English by the first and third authors (native Spanish speakers with proficiency in English) and reviewed by the last author (native English speaker). There was lengthy discussion between authors to ensure the cultural context was considered.

Trustworthiness of the Findings

We included several processes to increase trustworthiness of study findings [216]. First, the OT who conducted the interviews was experienced in the management of older adults with hip fracture, however they were not involved in the main clinical trial. Second, the interviews were recorded (with permission) and the interviewer took field notes. They also checked in with participants during the interview to clarify responses. Third, data were transcribed by the OT and one assistant within two days of the interview. Fourth, an audit trail was maintained throughout the process to summarize analysis steps and decisions. Fifth, a representative subgroup of participants checked a summary from emerging themes and quotes, and they were invited to add or change information. Finally, investigator triangulation was applied [217]. The first author (dual-trained physical therapist (PT) and OT with a doctoral degree) and third author (experienced OT with a research MSc) analyzed the data. Following this, the last author (PT and professor with a doctoral degree) reviewed the findings and discussed them multiple times with the first author.

We used NVivo 10 (QSR International, Doncaster, Australia) during data analysis to assist with data management (i.e., managing files, coding process, and analysis). We present participants age and scores for telerehab program utility and satisfaction using median (q25–q75) values.

RESULTS

Demographics Characteristics

Twenty one family caregivers (16 women and five men; median (q25–q75) age 50 (43–54) years) participated in the present study. Most family caregivers were the offspring of the patients with a hip fracture (18/21; 86%) supported by other family caregivers (15/21; 71%), who lived with the patient (14/21; 67%), and more than half were also working (14/21; 67%) part-time or full-time. The median age of older adults with hip fracture was 78 (73–82) years; most were women (76%), and their functional level at the end of the telerehab program (12 weeks) was similar to their pre-fracture functional level assessed through the Functional Independence Measure (FIM) [175]. A detailed description of family caregivers' characteristics is provided in Table 6.

Table 6. Caregivers´ characteristics.

Age	Gender	Relationship to Patient	Living With the Patient	Employment	Support of Other Caregivers (number)
44	Woman	Daughter	No	Part-time	Yes (2)
53	Woman	Wife	Yes	Unemployed	Yes (1)
64	Woman	Daughter	Yes	Unemployed	Yes (2)
56	Woman	Daughter	Yes	Part-time	No (0)
42	Woman	Daughter	Yes	Part-time	Yes (3)
41	Woman	Daughter	Yes	Full-time	Yes (1)
38	Man	Son	No	Full-time	No (0)
40	Woman	Daughter	No	Full-time	Yes (1)
50	Woman	Daughter	Yes	Unemployed	No (0)
45	Woman	Daughter	Yes	Unemployed	Yes (2)
54	Woman	Niece	Yes	Full-time	No (0)
55	Woman	Niece	No	Part-time	No (0)
53	Woman	Daughter	No	Unemployed	Yes (2)
50	Man	Son	No	Unemployed	Yes (2)
54	Woman	Daughter	Yes	Part-time	Yes (1)
52	Woman	Daughter in law	Yes	Unemployed	No (0)
43	Man	Soon	Yes	Full-time	Yes (1)
44	Woman	Daughter	Yes	Full-time	Yes (1)
53	Man	Son	Yes	Part-time	Yes (2)
51	Man	Son	No	Full-time	Yes (3)
40	Woman	Daughter	Yes	Full-time	Yes (2)

Adherence to the Telerehab Program

Ten of twenty-one caregivers completed the program as intended (high fidelity at 12 weeks), and an additional six participants completed 8 weeks or more of the program (76% in total). Half of the caregivers (10/21; 48%) stated their older family member completed the program, and then continued doing the exercises for a few more months. However, the remaining caregivers reported their family member stopped doing the exercises before the end of the 12 weeks. Most family caregivers (20/21; 95%) expressed 12 weeks was long enough to learn the program, or they believed their family member did not require rehabilitation beyond 12 weeks.

"...We spent about one month doing the exercises with her. Afterwards she continued doing the exercises alone, but I think she did not do them for twelve weeks... She stopped when she felt she did not need to do [any] more..." (Caregiver 8).

The caregivers with lower adherence to the telerehab program (5/21) were all women, older than 50 years of age (range; 52–56 years) and had no support from other caregivers (4/5; 80%) or the support of one additional caregiver to help the patient with ADLs (1; 20%). From the five caregivers with lower program adherence, two were unemployed, two worked part-time, and one worked full-time.

Categories

There were two categories generated during data analysis: (1) the telerehab program was perceived to be useful for older adults' functional recovery without being onerous for family caregivers; and (2) there was room for improvement in the telerehab program. A visual summary of the main findings is provided in Figure 9.

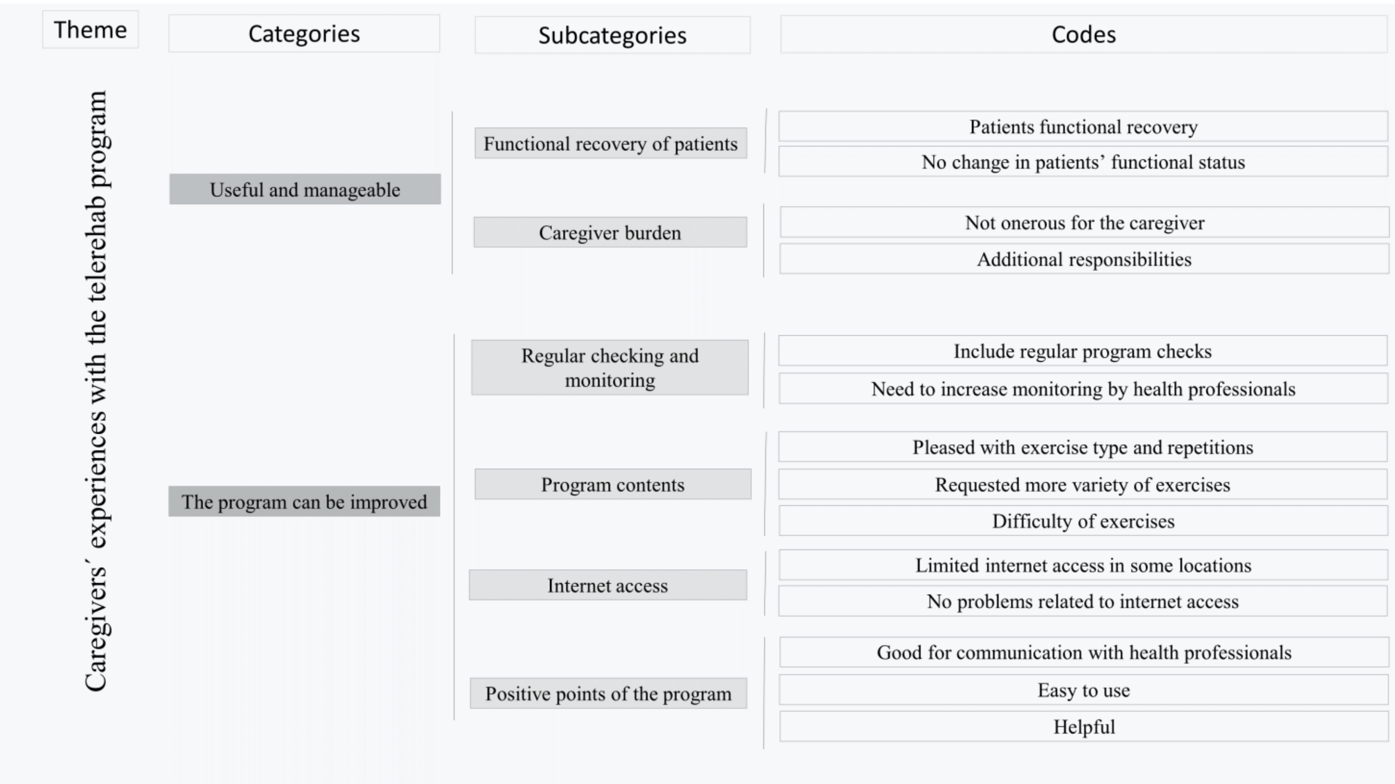

Figure 9. Caregivers experience with the telerehab program.

The telerehab clinical program: Useful and manageable

Caregiver support was essential for implementing @ctivehip. Overall, family caregivers were highly satisfied with the telerehab program and rated it useful (median (q25, q75): 8 (8–9)/10 points for utility and 9 (8–9.5)/10 points for satisfaction. Though the use of the program required more time and additional responsibilities for the caregivers, most participants stated there was no additional caregiving burden with using @ctivehip:

"...At first, it took a while but then we [created a] habit. I came home from work and connected the tablet. I helped her with the exercises that seemed more difficult." (Caregiver 12).

"...You need to [make time] to use the program... my brother and I organized [it] between us and it was not too much burden..." (Caregiver 15).

Although most caregivers noted improvement in patients´ health after using @ctivehip, a few family caregivers reported no change in their family member's function with the program:

"...She could almost not walk and now she is completely independent..." (Caregiver 15)

"...We started in the hospital, then he spent 3 months in my house doing the exercises and then he went home and continued doing them but without [the] internet... He already memorized the exercises and keeps doing them because he says they are good for him and that the doctor told him he could continue doing them every day... I would say that he is better than before the surgery..." (Caregiver 4).

"...No, she won't be the same person anymore... She is having a setback in general..." (Caregiver 3).

Room for improvement

Based on the caregivers experience, there was an identified need to develop new approaches for health professionals to support them during the recovery process. Study participants provided valuable insights for how best to implement @ctivehip in the future. Although family caregivers were aware they could request a video-conference session with a health professional, they preferred a regular check-in within the telerehab program to verify everything was proceeding as planned. Some family caregivers further suggested regular health professional monitoring to support older adults' confidence with completing exercises:

"... I [missed] that the staff would call us from time to time to ask us how we were doing and to test if we were doing the exercises properly. ...I know we could have called to ask for a video conference, but we felt in some way alone..." (Caregiver 13).

There were some differences among suggestions to improve the program content. Many family caregivers suggested the program should include more variety in the exercises to reduce the risk of boredom, and possibly increase older adults motivation. In contrast, some family caregivers were pleased with the repetition of the exercises, as it made them easier to remember:

"*...All the exercises were very similar and became very monotonous and repetitive after the first week...*" (Caregiver 18).

"*...I'm not an expert but I believe the exercises were [good] because my father memorized them every week and if he did not have internet one day, he would do it himself...*" (Caregiver 16).

Family caregivers rated the program's level of difficulty as either low or average. Nevertheless, eight family caregivers stated their family member avoided using weights to perform some exercises due to low confidence:

"*...She did not do some exercises because she did not feel safe. For example, the exercises with the weights... She did the exercises but without weights...*" (Caregiver 13).

Almost half of the caregivers stated they liked most components of the telerehab program, while seven family caregivers liked everything about the program. Constructive feedback on the program included difficulty accessing internet in some locations, and the exercises were repetitive (and possibly created boredom). Family caregivers also reported positive attributes of the program, such as usefulness for functional recovery (helpful and well-presented information, and ease of use).

DISCUSSION

Telerehab is a rapidly growing mode of health care delivery, but there are known gaps for using ICTs for older adults with hip fracture [211]. Recognizing ICT barriers in the early discharge recovery period, we engaged family caregivers to facilitate the adoption of remote delivery of health care after hip fracture. Here we provide a detailed description of family caregivers experience using a telerehab program called @ctivehip. Overall, family caregivers reported a high level of satisfaction with the program, stated it was manageable to use, and reported it was useful for functional recovery. Importantly family caregivers provided valuable insights for future program content and implementation to strengthen delivery and uptake of the intervention.

Although participants chose to receive the telerehab program, our sample was similar to other studies where the caregiving was mainly provided by women [52,207] at middle-age [60,218] who were adult children, [94] and were supported by other family caregivers. [60,207] In our study most family caregivers worked full-time or part-time, in contrast to other studies where caregivers were mostly unemployed. [52,94] These characteristics can be influenced by social and cultural norms and by the organization of the social and healthcare systems. Our work provides a novel perspective on caregiving while employed showing similar adherence to the program between caregivers who were unemployed, and those with part-or full-time work. Further, caregivers with lower adherence to the program reported lower support from other caregivers. This finding generates hypotheses on support (amount and type) needed by caregivers to deliver and manage the program. Although telerehab in general may be cost-effective [219], future research is needed to determine the acceptability, costs, feasibility, and (cost) effectiveness of telerehab considering the caregivers perspective in a program like @ctivehip.

We observed a high level of satisfaction and perceived usefulness for family caregivers with the @ctivehip program. These factors may contribute to users´ motivation to adopt and persist with the program, a key component of the technology acceptance model [220]. Our findings are similar to other ICT studies based on health communication and family caregivers' health literacy and caregiving skills [104,221]. Of note, in our study family caregivers did not perceive the program as onerous, even with the additional time commitment. Further, in our other qualitative study from @ctivehip, these same family caregivers in the intervention group reported lower levels of stress and anxiety and requested less social and health services compared with caregivers of patients who received only a few sessions of in-person rehabilitation [157]. An explanation for these findings may be related to the perceived benefits of the telerehab program: it was an opportunity for family members to receive education and skills training to prepare for the recovery process. Other studies reported family caregivers wanted role clarification and active participation in their family members recovery [10,18,22]. It is possible caregivers' observation of older adults' functional improvement with the program may have benefited both the caregiver (improved self-efficacy in caregiving) and the older adult with hip fracture (adoption and use of the program, mastery with exercises, improved self-efficacy, etc.) However, as we did not measure the effect of these factors in our study, we can only generate hypotheses on the "active ingredients" [222] or behaviour change techniques associated with the telerehab program or its delivery.

Family caregivers requested regular communication with health professionals after hospital discharge (using a person-centered approach) to update and progress rehabilitation plans. At present we do not know if the family caregiver "regular check-ins" need to be face-to-face or via ICTs. Technology may provide opportunities for more frequent communication with family caregivers and patients, especially during the transition back home [104]. An automatic system with personalized patient/caregiver feedback and monitoring to enhance motivation could be considered, similar to a system described in a pilot study of older adults with hip fracture [223]. We also recognize some patients and caregivers prefer face-to-face interactions [224]. Thus, health education should be individualized to each person, and consider internet resources available, motivation (habitual processes, emotional responses, and analytical decision-making), capability (knowledge and skills) and opportunities (context) of the patients, caregivers, and health professionals [224,225].

Family caregivers in our study requested more and varied exercise options within @ctivehip but, as some of the caregivers recognized, some patients did not use weights during the sessions for safety reasons. More frequent communication with health professionals could have addressed concerns, develop strategies, and explain why using weights (if possible) was recommended to increase strength and physical condition. It is difficult to know how the content of our telerehab program [173] compares with other published studies in this area [110,168,223] as previous work only provided a brief description of interventions.

We acknowledge that only half of participants completed the full program but overall, three-quarters completed eight weeks or more of the intervention. Reasons to explain the lack of fidelity to the program could be boredom related to the repetitive nature of the core exercises, participants higher level of function (pre-and post-intervention) reported in the main trial [113], or older adults (and family members) may have stopped the program when they felt independent in completing ADLs. The unified theory of acceptance and use of technology (UTAUT) describes factors which impact on technology adoption and use, such as social influence, effort expectancy, and performance expectancy [226]. Considering the UTAUT, possible elements to increase @ctivehip program adherence include reimagining work organization, with the inclusion of periodic health monitoring [227]; clear communication with patients and caregivers and a detailed explanation of the program [212,218]; discussing caregivers expectations [61]; and/or specific information on program progression (if/when appropriate). For example, progressing exercises with weights, if possible. Although we collected some implementation metrics, our future work needs to discern the optimal "dose" of the program, individualized for older adults following hip fracture.

Strengths and Limitations

We note some limitations within our study. First, due to the study's inclusion criteria, the older adults with hip fracture did not have cognitive impairment. Future studies should consider expanding the inclusion criteria to reflect a wider population of people who fracture their hip. Second, we conducted interviews three to six months after the telerehab program ended, and this delayed timing may have impacted family caregivers' responses. Third, we conducted short interviews although provided prompts and cues to explore caregivers' experience using the program. Fourth, group assignment was by choice, therefore participants who wanted to receive the telehealth program may have a different experience. Although many caregivers liked the program there were some perceived limitations such as the limited variety of exercises and monitoring. Fifth, we did not capture psychosocial factors such as caregivers' self-efficacy with delivering the telerehab program, but we recognize behavioural factors (for the older adult and family caregiver) are important to include in future research. Despite these limitations, our study provides valuable information to extend the limited evidence for ICTs for older community-dwelling adults with hip fracture [228,229] and their family caregivers [221].

CONCLUSIONS

To our knowledge, this is the first study to provide a detailed description of family caregivers' experience with a post-hip fracture telerehab program delivered before the SARS-CoV-2 (COVID-19) pandemic. Family caregivers who enrolled in the @ctivehip telerehab program were satisfied with the program, stated it was manageable, and reported perceived benefits for older adults' functional recovery after hip fractures. Family caregivers also provided helpful feedback to enhance program content and its delivery. Taken together, this work extends existing literature, and generates research hypotheses for future studies to test telerehab content and program implementation.

Section 3

The ActiveHip+ mHealth system for older adults with hip fracture and their family caregivers

Study IV

Co-creation of an mHealth Intervention for Older Adults with Hip Fracture and Family Caregivers: a qualitative study

INTRODUCTION

Hip fracture can result in older adults' reduced quality of life resulting from the loss of functional independence [206], decrease in social participation [47], and the all too common failure to recover previous function [37]. Dependence in activities of daily living (ADLs) post-hip fracture impacts caregivers [52] (defined here as family caregivers or caregivers) in countries around the world [60,94,207]. Following hip fracture, caregivers frequently become the main support system for older people after hospital discharge [209,212]. As a result, additional (and often sudden) responsibilities lead to an increase in caregiver burden [52], stress, and negative consequences for their overall health [50].

Rehabilitation can improve function and ability to complete ADLs after hip fracture [48,84]. However, limited resources can lead to reduced access to much needed healthcare [84]. Tele-rehabilitation and, in particular mobile Health (mHealth), defined as the use of mobile and wireless technologies in healthcare [99], is a promising alternative for care provision [167]. In fact, it has been one of the alternatives used in the orthopaedics services during the COVID-19 pandemic [230,231]. But there are few evaluation studies testing remote delivery of rehabilitation after hip fracture [168,173,223]. Despite perceived barriers for older adults to use information and communication technologies (ICTs), Crotty and colleagues reported tele-rehabilitation as a viable option for this age group [232]. Family caregivers may be another option to support older people to use ICTs, and specifically tele-rehabilitation. Family caregiver involvement in rehabilitation is complex. For example, involving the family may lead to additional burden, while in contrast it provides an opportunity to respond to caregivers' request for information during the recovery process [198]. However, less is known for the delivery of information and tele-rehabilitation through ICTs to older adults with a hip fracture and their family caregivers [173] and further studies should be conducted.

Despite the fact that during the last years, there has been some research projects about tele-rehabilitation in hip fracture [109,111,113], further research on this topic is needed. It was previously tested a tele-rehabilitation program for older adults with hip fracture and family caregivers delivered through a webpage [173]. Following the results of that study and participants' lived experience reported elsewhere [157] we attempted to upgrade this tele-rehabilitation intervention into a mobile app for easier delivery and adoption. Following a proof-of-concept study, we planned the next step as a co-creation process for the mHealth system, which is considered especially important for future uptake, adoption, usage and sustainability of the solution [114,115].

The aim of this study was to establish perspectives of older adults with hip fracture, family caregivers and health providers (stakeholders) for the development of an mHealth system designed to improve physical function after hip fracture and reduce caregiver burden. Our secondary aim was to use these perspectives to co-create the ActiveHip+ mHealth system.

METHODS

Study Design

This was a qualitative study guided by a user-centered design (UCD) framework [233]. We used focus groups to engage stakeholders (older adults, caregivers, providers) in the recovery of older adults with hip fracture. The Ethics Committee of the Research Centre of Granada (CEI-GRANADA) approved this study, and all participants signed a consent form. The study was conducted according to guidelines established by the Helsinki Declaration and Law 14/2007 on Biomedical Research.

We conducted seven focus groups on January 28-30, 2020 at the Virgen de las Nieves University Hospital. The composition of the focus groups included the following participants: (1) two groups were composed of older adults who had previously sustained a hip fracture; (2) two groups were family caregivers of older adults who had previously sustained a hip fracture; (3) one group included family caregivers; however, the family member was not able to walk independently after hip fracture (≥3 months); and (4) two groups of health providers.

Focus groups were designed and conducted in partnership between a research team with clinical experience managing recovery after hip fracture, and a team experienced with conducting focus groups. One female experienced moderator (and academic faculty member) conducted all focus groups, and one person took notes. The focus groups were recorded and transcribed [234] in Spanish. Six focus groups were 90 minutes, and one focus group was 60 minutes in duration. Following the content analysis (completed in Spanish), quotations were translated into English by the last author (Spanish native speaker) and discussed with the fifth author (English native speaker) to ensure the translation considered the cultural context of the participants.

Recruitment

We recruited three stakeholder groups: older adults with hip fracture, family caregivers of older adults with hip fracture, and health providers. Older adults were aged 65 years and older, sustained a surgically repaired hip fracture in the previous 3 months, and did not have severe cognitive impairment. Invited caregivers could be adult children, spouses, other relatives, or friends of older adults with a surgically repaired hip fracture in the previous three months. Health providers had two or more years of experience working with people after hip fracture.

Older adults with hip fracture and family caregivers were invited to participate in the study at their routine follow-up orthopaedic surgeon visit. After consenting to join the study, a research team member telephoned to organize focus group attendance. We telephoned 17 older adults with hip fracture and 23 family caregivers (all relatives of older adults). However, only 14 older adults and 21 family caregivers participated in the focus groups. Two older adults did not answer the telephone after several attempts, one older adult was unwell, and two caregivers were not able to attend the focus groups.

The hospital supervisor (from one publicly funded acute care hospital) invited health providers to enrol in the study. There were 11 health providers enrolled in the study representing: orthopaedic surgery, physical and rehabilitation medicine, endocrinology, nursing, nursing assistant, occupational therapy, physical therapy, and social work. Only one health provider (social worker) was not available to attend the focus group. Thus, 10 health providers in total attended the focus groups. The flowchart of participants is shown in Figure 10.

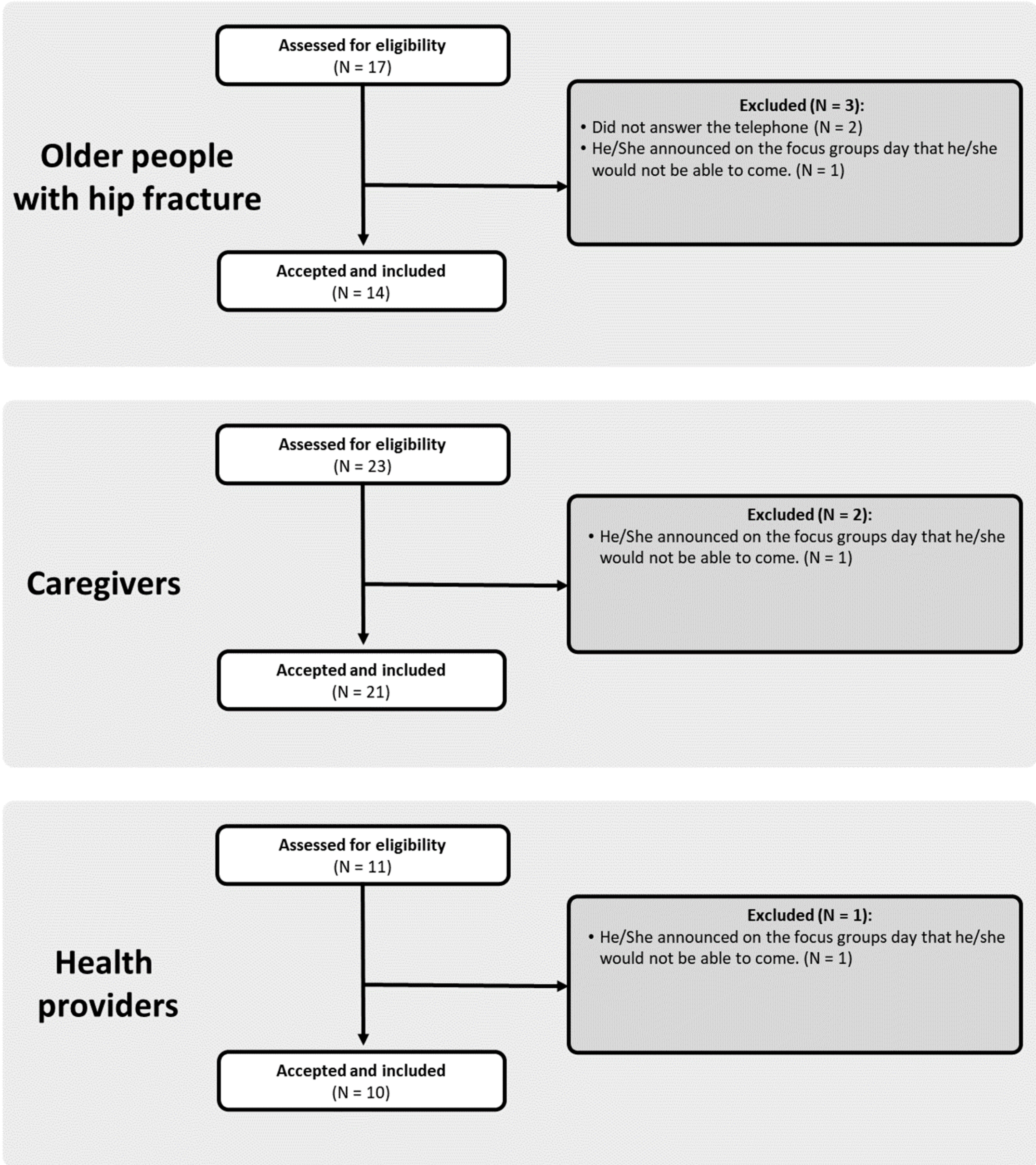

Figure 10. Flowchart description of the recruitment process of the participants of the focus groups carried out for the co-creation of the ActiveHip+ mHealth system.

Discussion Guide

The discussion guide for all focus groups had two main topics to identify potential strengths, weaknesses, a strategy followed by previous tele-rehabilitation studies with other populations [235]. During the focus groups, we asked the participants: (i) based on your experience, which factors are most relevant for recovery after hip fracture? (Topic 1) Once they discussed that first topic, we asked them: (ii) how should an mHealth system support recovery and which contents should be included? (Topic 2). In order to adapt it as well as possible to the participants´ requests, based on the design thinking process, we established an open mobile application concept, without test version or mobile app mock-up, to avoid conditioning their opinion during the first steps [236]. We intentionally started the discussion by asking participants to comment on their experience with hip fracture, followed by questions related to mHealth systems. We iteratively adjusted the interview guide in the focus groups, as needed. For example, in some focus groups we needed to redirect the questions back to the two topics when the discussion changed to personal experiences with hip fracture, rather than information for the app development. Participants (across focus groups) provided more information for topic 1 and, therefore, for the later focus groups we directed the discussion more towards content relevant to include in the mobile app.

Analysis

After each focus group, the moderator (a professor) and one team member (an occupational therapist with 3 years of research experience in tele-rehabilitation for older adults with hip fracture) independently took notes *(RP-M)* to summarize impressions of the discussion and any major themes. The audiotapes were transcribed within two weeks by one author (a pre-doctoral student) *(RP-M)*. We followed the immersion-crystallization technique: a continuous process whereby researchers are immersed in data via: reading transcripts in detail, discussing reflections on how to analyse data, and identifying patterns and themes [237]. Saturation was achieved for some topics (i.e., information on pain and mobility) in the different focus groups, while other information was exclusively stated in some groups but not in other ones (i.e., information about nutrition). The content analysis [238] was conducted by three authors (the senior author, a physical and occupational therapist with 12 years of research and clinical experience treating older adults with hip fracture, an occupational therapist with 3 years of research experience in mHealth, and a pre-doctoral student) (*PA-V, RP-M and MM-T*). Two authors *(PA-V and MM-T)* reviewed each of the transcripts independently [238]. Following this step, they both, inductively developed coding categories to examine similarities and differences between stakeholder groups [239]. Next, three authors *(PA-V, RP-M and MM-T)* met twice to discuss and confirm the findings; they also categorized them into three themes [240,241]. The interviews and analyses were conducted in Spanish. The senior author *(PA-V)* translated quotes from Spanish into English. In the final step of the analysis process, another author *(MCA) (a physiotherapist and full professor with clinical and research experience in rehabilitation for older adults)* reviewed the themes, categories, and subcategories and discussed them (via email) at length with the first author *(PA-V)*. The results were finalized by the original three authors *(PA-V, RP-M and MM-T)*. We used NVivo 10 (QSR International, Doncaster, Australia) to organize quotes, subcategories, categories, and themes.

RESULTS

Fourteen older adults with hip fracture, 21 family caregivers, and 10 health providers participated in the focus groups. We present a summary of participants' sociodemographic variables in Table 7.

Table 7. Characteristics of focus group participants.

Characteristics	*n* (%) Older adults with hip fracture (*n* = 14)	Caregivers (*n* = 21)	Health providers (*n* = 10)
Sex			
Female	10 (71)	13 (62)	8 (80)
Male	4 (29)	8 (38)	2 (20)
Age; Mean (SD) and range			
	76.36 (7.70) 66-92	59.71(14.61) 32-84	43.22 (6.65) 35-53
Education level			
Primary school	10 (72)	3 (14)	0 (0)
Secondary school	3 (21)	12 (57)	1 (10)
College or university	1 (7)	4 (19)	4 (40)
Masters or doctoral degree	0 (0)	2 (10)	5 (50)
Relationship older adult and caregiver			
Husband/Wife		6 (29)	
Son/Daughter		13 (62)	
Brother/Sister		2 (9)	
Health providers			
Endocrinologist			1 (10)
Nurse			2 (20)
Nursing assistant			1 (10)
Occupational therapist			2 (20)
Orthopaedic surgeon			1 (10)
Physiatrist			1 (10)
Physical therapist			2 (20)

Three main themes were generated from the content analysis, as shown in Table 8: (1) mHealth design and function (simple, user-friendly design and function); (2) mHealth content (content focused on recovery and prevention); and (3) Implementation factors for mHealth. Figure 11 and Figure 12 summarize how these themes have been integrated in the ActiveHip+ mHealth system which consist in a mobile app for older adults with hip fracture/caregivers (Figure 11) linked to a web page for health providers (Figure 12). A summary of the technical solutions designed for each issue is provided in the Supplementary Table 1.

Table 8. Post-Hip Fracture mHealth Themes, Categories, and Subcategories.

Themes	*Categories*	*Subcategories*	*Groups providing that information*
mHealth Design and Function	Simple and user-friendly	Clear messages	Older adults with hip fracture and caregivers
		Easy to use	All the groups
		Videos and voiceover	Older adults with hip fracture and caregivers
	Positive messaging	Attitude for the recovery process	All the groups
		Encourage older adults to complete exercise	All the groups
	Prompts and cues	Medical appointments	Caregivers and health providers
		Rehabilitation sessions	All the groups
	Lived experience with hip fracture examples	Key motivator	Older adults with hip fracture and caregivers
		Older adults attitude to the recovery process	Older adults with hip fracture and caregivers
	Communication system with health providers	Messages	Older adults with hip fracture and caregivers
		Videoconferences	Caregivers and health providers
	On-demand Information	Much information in a short time frame for older adults and caregivers	All the groups

		Frequently asked questions	All the groups
mHealth Content	Roadmap of hip fracture recovery journey	Useful information on the recovery process	All the groups
	Specific information on different topics	Information on pain and mobility ADLs and home equipment Nutrition	All the groups All the groups Health providers and caregivers
	Exercise Instructions	Personalized exercises Follow-up by health providers Supervision to optimize exercise performance	Older adults with hip fracture and caregivers All the groups All the groups
	Caregivers' health resources	Training to mobilize with older adults at home Suggestions to minimize the risk of injury and recommendations for healthy lifestyles Stretching and relaxing exercises, mindfulness sessions	Caregivers and health providers Health providers Caregivers and health providers

Implementation Factors for mHealth	Caregiver as the main users	Knowledge and skill development	All the groups
	Health providers' role	Training and policy changes	All the groups
	Personalized action plans	Consideration of each person characteristics and comorbidities	All the groups
		Individualized follow-up	All the groups
	Some people will not use the app	Increasing age and low motivation	All the groups
		Limited skills to use ICTs	All the groups

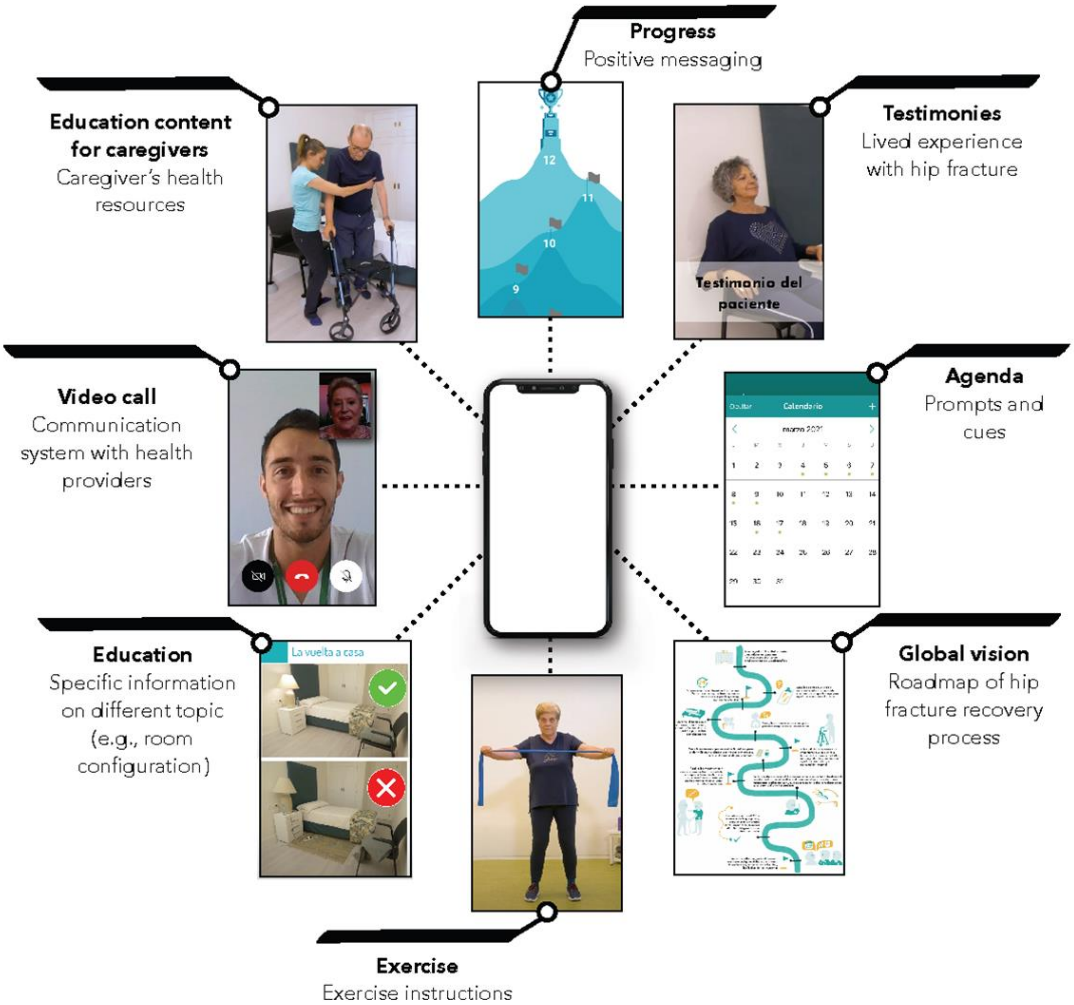

Figure 11. Examples of the ActiveHip+ content for older adults and caregivers integrated from the stakeholder perspectives.

Figure 12. Examples of the ActiveHip+ content for health providers integrated from the stakeholder perspectives.

mHealth Design and Function

There was a unanimous agreement for a simple and user-friendly app design, with clear information for older adults with hip fracture and caregivers. "*It has to be very simple and easy to use*" (Caregiver 9). There was also agreement information should be delivered using videos and voiceover for better uptake and retention of information. *"... It is easier to learn [how to use a walker] when you watch a video, instead of reading the information about how to use it]"* (health provider 5).

Positive messages were perceived by older adults as encouragement to complete exercises and support recovery. *"The app could be used to send messages of encouragement at the end of each session and also between sessions to encourage them to continue doing the exercises..." (Caregiver 4).* Older adults with hip fracture also stated a positive attitude towards the fall and recovery from the fracture was especially important and a notification system with reinforcement messages could help them to have this attitude. Caregivers suggested ICTs should have prompts and cues, such as reminders for medical appointments and rehabilitation sessions.

Older adults with hip fracture and caregivers recommended including stories of lived experiences from other older adults with hip fracture. The stories of recovery were perceived as a key motivator for older adults with hip fracture, especially during the first weeks after fracture. *"... Listening to other people who suffered the same can help you to feel a bit better... Mainly when you are at the* *hospital, and you do not know how you will when you come back home..."* (Older adult with hip fracture 3).

As suggested by participants, a communication system (e.g., text messages and videoconferences) was provided between older adults with hip fracture, caregivers, and health providers to facilitate communication, resolve any concerns, and supervise older adults with hip fracture in their home environment.

Finally, health providers acknowledged families and older adults with hip fracture are overloaded with information during the acute hospital stay. Thus, the app could provide additional on-demand information for caregivers and older adults after returning home. "*They receive so much information and dialogue that they become anxious and disorientated (at the hospital)"* (Health provider 3). A section for answering frequent queries was also suggested.

How this new information was integrated into the mHealth system

Firstly, the mHealth system was designed with as few sections as possible to make navigation easier. The font and font size were chosen to be easy to read, as well as the audio-visual content, which included a voice-over to facilitate comprehension. Secondly, to encourage older adults with hip fracture and caregivers during the recovery process, some automatic messages of encouragement were programmed after each rehabilitation session. Third, videos in which individuals gave a summary of their lived experience in the hip fracture recovery process were included to motivate older adults and caregivers that it is possible to resume their pre-fracture daily lives. Fourth, a two-way communication system was included in the mHealth system where older adults with hip fracture and caregivers can receive or send messages from/to their healthcare providers to solve possible concerns. Lastly, to allow older adults and, especially, caregivers to access information at a time that suits them best, all content in the mHealth system is available on demand.

mHealth Content

Caregivers and health providers suggested the app provide an overview of the recovery process after hip fracture. "*Having more information about the entire process helps make the experience more positive*" (Caregiver 7).

There was an agreement between all three groups for the inclusion of information on pain and mobility, ADLs and home equipment, and nutrition. Pain and mobility were the most common concern expressed by older adults with hip fractures and caregivers. Although older adults with hip fracture reported moderate-intensity pain during the first days (and sometimes weeks) following hip fracture, they refused to have more medication. They explained they were living with other chronic conditions and already had too many pills. Second, health providers suggested including information on ADL equipment and home environmental adaptations to minimize the risk of falls. Finally, for health providers, it was important to include nutrition-related information in general, and specifically for people living with chronic conditions, for example, dysphagia, osteoporosis, and diabetes. "*Several older adults are malnourished when they come to the hospital... we have to inform them how to improve their nutrition with clear information about the type of foods they should intake, and the app could be a tool used for that*" (Health Provider 1).

The app was perceived by health providers as an opportunity to provide instructions for completing exercises. Older adults with hip fractures, caregivers and health providers noted different experiences following discharge from the hospital. For some older adults and families, they received either no formal follow-up rehabilitation or some sessions of home-rehabilitation (public or private). Thus, they considered the app as an opportunity to guide older adults with hip fracture with home exercises. *"... I was sent home with a few simple instructions to walk, but they did not tell me how much..."* (Older adult with hip fracture 1). They further highlighted exercise must be personalized and monitored by health providers to maximize performance and minimize the risk for injury.

Finally, in the category of essential app content, caregivers and health providers suggested providing information specific to family caregivers. For the recovery process, there was a suggestion to provide tips and strategies for caregivers to support older adults with hip fracture' mobility at home. For caregivers' health and wellness, there were suggestions to include relevant information to minimize the risk for injury and to engage in lifestyle interventions (e.g., physical activity, mindfulness, etc.). *"...The caregivers' section could include relaxing exercises, mindfulness sessions and recommendations to find time for themselves to perform leisure activities*" (Health Provider 1).

How this new information was integrated into the mHealth system?

First, to guide older adults with hip fracture and their caregivers through the whole recovery process, we included information (through infographics, text, and videos) on how to face the first weeks up to how to prevent secondary fractures once older adults have recovered their previous life. Second, we included information not just on rehabilitation but also on pain, support devices, home adaptation, as well as nutrition. Some videos of healthcare providers explaining the management of these aspects were recorded and included in the mHealth system. Third, a rehabilitation program with physical activity and occupational therapy was included to provide older adults and caregivers with a home exercise guide for rehabilitation after the surgery, with a weekly follow-up from the healthcare providers. During the time that the older adults with hip fracture are using the ActiveHip+ mHealth system, they provide feedback about their feelings (effort after pre-recorded rehabilitation sessions, satisfaction with the program, and pain). With this information, healthcare providers adjust the rehabilitation program delivered through the app to adapt it to the older adults' status. Lastly, a specific section for caregivers was included in the mobile application to provide information on the safe management of the older adult with hip fracture during the first weeks of recovery, when the older adult is unable to perform ADLs independently, as well as information on the caregiver's well-being.

Implementation Factors for mHealth

Health providers suggested the app should contain information for older adults with hip fracture and caregivers, but the main users would be caregivers. *"...it would be difficult for the older adults [to use the app], however some caregivers could [use the app] if someone explains how it [the app] works..."* (Health Provider 2). Further, health providers were concerned about who would train and support the use of the app if it was embedded within clinical practice. There was discussion on the need for hospital strategies to implement an app (including training health providers). *"...but the majority of them look overwhelmed. We will have to teach them how to use the app, and we do not have time. Who will do that?*" (Health Provider 8)

Caregivers and health reinforced the importance of personalized care plans. For example, some caregivers suggested modifying the information for older adults living with other chronic conditions, and the importance of regular follow-up by health providers. *"...Each person is different. My mother has heart problems and high blood pressure. She would need specific follow up by the physician" (Caregiver 4).*

Finally, it was recognized the app might not appeal to everyone. All participants agreed there are barriers for older adults to use ICTs. Caregivers further highlighted the lack of internet skills for some older adults. Although some older adults with hip fracture stated low motivation to use smartphones, they also believed they could learn to use them. "*I do not use those devices* (mobiles) *because I do not need it, but I could learn how to use it...*" (Older adult with hip fracture 5).

How this new information was integrated into the mHealth system?

The main concern for the implementation of the mHealth system in the hospital environment was who would use the app and who would explain how to use it. To address this, it was established that although the main beneficiary of the app would be the older adult with hip fracture, the main user would be the caregiver. To facilitate the explanation of use, as well as to make it user-friendly, leaflets were created to explain its use in a summarised way, thus avoiding the need for healthcare providers to spend a lot of time on it.

DISCUSSION

Principal Results

We present perceptions shared by older adults with hip fracture, family caregivers, and health providers for the development of ActiveHip+, a post-hip fracture mHealth system. Older adults with hip fracture and caregivers described their experiences during the hip fracture recovery process, and the potential benefits of an app to guide them during the recovery. They also highlighted possible difficulties for older people to use ICTs, as well as some strategies to overcome these barriers, being considering essential the need to include caregivers in mHealth training and deployment. Health providers offered rich information on app content, delivery and implementation in a real acute orthopaedic setting. Overall, these results provide a blueprint for the app design and function, essential content, and implementation factors for testing it as a supplement of clinical care in our next study phase.

Sociodemographic characteristics of older adults with a hip fracture and caregivers were similar to other studies [52,60,207,218]. Majority of older adults with hip fracture [37], caregivers [52,207], and health providers [104] were women. Most caregivers were middle-aged [60,218] and children of the older adults with hip fracture included in this study [94]. These similarities may lead to an increase in the applicability of the finding in this study for further design and development of mHealth systems in the rehabilitation of a hip fracture.

mHealth Design and Function

All stakeholders in our study recommended to create the ActiveHip+ mobile application following a user-friendly mobile app design, with useful content for communication and information sharing, which has been reported in previous work analysing the implementation of mHealth systems in different health conditions [114,242]. The need to develop a user interface design with appropriate visual objects, such as large buttons that can be distinguished from other resources, or the use of font size adjusted to the needs of older adults were previously highlighted [243]. The participants in our study also made suggestions for the app to increase uptake of health technology and reduce the frustration during the use of the app [114,244], which was previously tied to the need to develop a clear navigational structure and an interface aligned with the expectations of older adults [243,245]. The specific recommendations for older adults with hip fracture were mainly focused on the contents and the delivery modes such as, short videos, infographics, positive messaging, and older adults stories to improve user experiences [246]. One of the main contributions of the participants in this study was the request to include a specific section for caregivers in the app, which was a major design feature that was added to the ActiveHip+ mHealth system. To our knowledge, there was only a previous study providing information for both older adults with hip fracture and their family caregivers, but the specific contents for family caregivers were very limited, and the information was provided through a website [157]. In this earlier study, caregivers received, during the hospital stay, some instructions on safe management during transfers and basic mobility. After hospital discharge, caregivers received a website with some videos with general recommendations for the recovery process. However, according to the results of the present study, older adults with hip fracture and caregivers are overloaded with information during the hospital stay, but need information once they are in their own home. Therefore, we deliver through our mHealth system a comprehensive educational programme with information focused on health promotion both for older adults with hip fracture and specifically for caregivers. We provide caregivers with information on how to protect them from back pain during care, strategies to prevent mental health problems and a wide range of examples on how to support the development of ADLs. This extensive information needs to be on-demand so that they can adapt it to their everyday situations, and can refer to it whenever they want [247]. mHealth solutions offer the opportunity to overcome potential communication barriers [248], and via remote information sharing between older adults with hip fracture and health providers [104]. Nevertheless, the success of the mHealth solutions to improve communication and information sharing is linked with the use of behaviour strategies [249], such as, personalization (i.e., text messages, videoconferences), tailoring (i.e., positive messages, reminders for medical appointments), health behaviour benefits (i.e., nutrition and physical activity), providing instruction (i.e., pre-recorded rehabilitation sessions), or providing materials for education. Including all above suggestions, is a way of supporting mHealth adoption and maintained use by stakeholders [199,250,251], which is one of the biggest barriers to face in this kind of intervention [252].

mHealth Content

In the current study, stakeholders suggested the creation of specific contents to guide and support older adults with hip fracture and their family caregivers through the recovery process for hip fracture [246]. They emphasized the need to personalizing the contents of the ActiveHip+ app and connecting it to resources usually delivered by health providers, such as, written information at hospital discharge (i.e. exercise and nutritional recommendations and medication) [157]. Previous literature highlights the importance of older adults' knowledge and skill development to self-manage their health and the difficulties to adequately achieve older adults' empowerment (defined as "process through which people gain greater control over decisions and actions affecting their health" by World Health Organization) [253] during the short length of acute hospitalization [254]. mHealth solutions may contribute to older adults with a hip fracture' functional recovery [157], increase health literacy, and help people gain greater control over their health-related decisions and actions [248]. Beyond older adults, caregivers request more active involvement in the hospital discharge planning process [212], and requested knowledge and skill development to manage the new situation after the hip fracture [209].

Implementation factors for mHealth

In this study, participants expressed some concerns for older adults using the app. Although there are perceived barriers using ICTs [255], there is also support for remote delivery of health care in older populations [166,232]. There was a positive research experience for a tele-rehabilitation program post hip fracture [157]. However, in this previous trial, family caregivers facilitated the online program. In this non-randomized (choice-based) intervention, family caregivers expressed a high level of satisfaction for the tele-rehabilitation program and older adults with hip fracture experienced an improvement in functional recovery [157]. Overall, the past and present findings suggest remote care delivery may not work for all older adults after hip fracture, but it may be a viable option for some people, with or without additional support from family members [157]. However, integration of, and training for, any new mHealth into clinical practice must be considered as key factors for their usability, adoption, and sustainability [246] both for older adults and health providers. In addition, the provision of personalized action plans must be considered to increase adherence and satisfaction of older adults with hip fracture and caregivers [254]. Moreover, due to the COVID-19 pandemic, the development of mHealth systems is perceived as acceptable [256], since the delivery of orthopaedic trauma face-to-face care has suffered a decrease in the resources available [85].

Strengths and Limitations

The main strength of this study is the findings from the lived experience from multiple key stakeholder perspectives: older adults, caregivers, and health providers. We captured their feedback (both positive and negative) based on real-world experience with hip fracture recovery. Although we observed similarities of responses across stakeholder groups, the nuances provided from the different groups imparted a rich understanding of experiences and perceptions. We also have some study limitations. First, despite our best efforts to recruit a representative sample of older adults with hip fracture, we were not able to capture the experiences and mHealth perceptions of older adults with impairments after hip fracture. However, we conducted a focus group with family caregivers of older adults with functional impairments. Second, as the different profiles of participants were not mixed in the focus groups, some issues that were mentioned in some groups but not in others were not discussed by all. For example, nutrition was something that was not mentioned in the older adults with hip fracture group. A final check mixing participants could have been used. However, a pilot version of the mHealth system was tested by a representative group of stakeholders who participated in the focus groups to add any suggestions before starting to test it. Third, all participants were from a region of Spain. Therefore, findings may not be generalizable to other populations.

CONCLUSIONS

Older adults with hip fracture, family caregivers, and health providers identified key elements for the design of a mHealth system, function and contents, and factors to consider for future testing in a clinical trial setting. All the above elements were included in the mHealth prototype developed considering the perspectives of the main stakeholders.

Supplementary material

Supplementary Table 1. Technical solutions included for the stakeholders' needs

Themes	*Needs to address*	*Technical solutions included*
mHealth design and function	*Simple and-user friendly design*	– *Easy navigation in the app.* – *Easy to read font.*
	Clear information	– *Videos with voice-over to ease understanding.* – *Videos permanently available on-demand.*
	Positive messages	– *Automatic encouraging message system.* – *Videos relating stories of lived experience.*
	Prompts and cues	– *An agenda to include reminders for medical appointments and rehabilitation sessions*
	Communication with health providers	– *Communication system between health providers and users.*
mHealth content	*Information about the entire recovery process*	– *Information through videos, text and infographics about:* ○ *General aspects (e.g., pain, mobility).* ○ *Use of supporting devices and environmental adaptations.* ○ *Medication.* ○ *Nutrition.* ○ *Prevention of secondary fractures.*
	Rehabilitation guide	– *Rehabilitation program adapted to the type of surgery* – *Adaptation of the level of difficulty of the rehabilitation program.* – *Alerts system for the monitorization after each rehabilitation session.*
	Specific information for caregivers	– *Information for caregivers about:* ○ *Safe management of the older adult with a hip fracture.* ○ *Promotion of their own well-being.*
Implementation factors for mHealth	*Barriers for older adults to use the app*	– *Caregivers would be main users of the app to support older adults.*
	Easy training in the use of the app	– *Simple and-user friendly design.* – *To provide users with a leaflet summarising the use of the app.*
	Personalized care plans	– *Information not only focused on hip fracture.*

Study V

ActiveHip+: a feasible mHealth system for the recovery of older adults after hip surgery during the COVID-19 pandemic

INTRODUCTION

Hip osteoarthritis and hip fractures due to osteoporosis are leading causes of disability in older adults [257]. In general, both conditions are particularly concerning because of their high prevalence, health impact and socio-economic cost [258]. The prevalence of hip osteoarthritis is 40 million people worldwide [259], a figure that is expected to rise with increasing life expectancy [260]. The consequences of osteoarthritis include loss of function [261,262] and reduced quality of life [263]. The economic cost invested in treating hip osteoarthritis is high due to the high rate of disability [264] and the expensive medical interventions such as hip replacement. The annual cost of each person with hip osteoarthritis during the year prior to the surgery is up to €810 [265]. This cost increases exponentially considering the expense associated with hip replacement surgery [266]. Similarly to osteoarthritis, people with osteoporosis face increased risk for hip fractures; 250 cases out of 100,000 Europeans [6]. The cost associated with osteoporotic hip fractures is €57,000 million in Europe [6]. Importantly, in hip fractures due to osteoporosis, mortality one year after the hip fracture episode ranges from 20% and 40% [267]. Additionally, half of those who survive that first year do not fully recover their functional status after surgery [37]. In both hip osteoarthritis and hip fractures due to osteoporosis, hip surgery is considered the most effective treatment [268,269] and post-surgery rehabilitation is crucial. Thus, it is important ensuring the continuity of care in people with hip osteoarthritis or osteoporotic hip fractures, especially from a value based health care perspective [83,165,270].

Currently, to continue the rehabilitation after hospital discharge is often limited [84]. In fact, acute trauma centres for hip fractures reduced the care of people with osteoarthritis or osteoporosis during the COVID-19 pandemic [85]. These limitations concur with the increasing trend in the use of mobile health, also known as mHealth, the use of mobile and wireless technologies to support the achievement of health objectives [99]. MHealth offers the potential of reducing the hospital visits, allowing patients to rehabilitate from home and facilitating follow-up by health professionals [102]. The evidence shows that this type of rehabilitation is effective in many diseases [102,271,272]. Despite the existence of evidence supporting the use of digital tools after hip surgery [113,169,273,274], to the best of our knowledge, there are just a few mHealth interventions for this population [109,111,275–277]. It is important to develop new mHealth interventions to provide a comprehensive tele-rehabilitation program, focusing not only on rehabilitation but also on secondary fracture prevention. Thus, we developed the ActiveHip+ mHealth system as an alternative for those older adults who cannot access to in-person rehabilitation. The ActiveHip+ mHealth system was co-created with older adults with a hip fracture, their family caregivers and health professionals. Co-creation is a step considered essential for uptake, usage and sustainability of this type of intervention [114]. A more detailed information about ActiveHip+ has been published elsewhere [170]. Therefore, the aim of the present study was to evaluate the feasibility of implementing the ActiveHip+ mHealth system in older adults after hip surgery following hip fracture or hip osteoarthritis, in an orthopaedic setting and within two different healthcare systems.

METHODS

Design

The present feasibility study was international and multicentre involving participants with osteoporosis and osteoarthritis from (i) three hospitals from the southern Spain (Andalusian) Public Healthcare System and (ii) three hospitals located in the Belgian north-west region, from the hospitals company Algemeen Ziekenhuis Delta (AZ Delta) hospitals in Belgium. The project followed the guidelines established by the Helsinki Declaration and Law 14/ 2007 on Biomedical Research. This study was approved by the Ethics Committee of Research Ethics Committee Granada (CEI Granada), (21/07/2022), the Ethics Committee of Katholieke Universiteit Leuven (S65606) and AZ Delta (S65606). Informed consent was obtained from older adults and family caregivers.

Participants

The current study included 69 (36 from Spain and 33 from Belgium) older adults admitted to the Orthopaedic services who had undergone hip surgery and their family caregivers. The participants were recruited (i) from September to December 2020 in three different hospitals of the Andalusian Public Healthcare System; namely, the Virgen de las Nieves University Hospital (Granada), Puerto Real University Hospital (Cádiz) and Jerez de la Frontera University Hospital (Cádiz) and (ii) from July to October 2021 in three different hospitals of the Belgian company AZ Delta; namely Campus Rumbeke (Rumbeke), Campus Rembert Torhout (Torhout) and Campus Brugsesteenweg Roeselare (Roeselare).

The inclusion criteria were: (i) to have undergone hip surgery to treat a hip fracture or osteoarthritis, (ii) to be, at least, 60 years of age, (iii) to be authorised weight-bearing on the operated limb 48 hours after the surgery, (iv) to have been functionally independent before surgery measured with the Functional Independence Measure (FIM) i.e., overall FIM score of 90 points or higher a week before surgery, (v) to be discharged to their own home or to a relative's home and (vi) to have internet access and the ability of using mobile phone (vii) or in cases where the older adults did not have the ability, to have a caregiver with internet access and the ability of using mobile phone. The exclusion criteria were: (i) to have severe cognitive impairment (i.e., to make, at least, 4 mistakes for literate older adults or 5 mistakes for illiterate in the Short Portable Mental State Questionnaire, (ii) to be discharged to an institution or nursery home, (iii) to have post-surgery complications precluding the start the rehabilitation and (iv) to be diagnosed with a terminal disease.

Recruitment and follow-up

Older adults after hip surgery and family caregivers were offered to participate in the study during their hospital stay. Those who agreed were assessed and trained in the use of the ActiveHip+ mHealth system 1 or 2 days before hospital discharge. During the training, the research team of this study downloaded the app in the participants' mobile phone to check that everything worked. They also explained the different sections of the app and showed how to perform the tele-rehabilitation sessions The exercises of the first tele-rehabilitation sessions were explained to the older adults and their family caregivers. In addition, the most complicated exercises were practiced before hospital discharge. The explanation and follow-up of the subsequent sessions were conducted during the videoconferences. Thus, participants of this study had time to practice, resolve doubts and optimise their digital literacy in order to improve their experience of use before hospital discharge. Additionally, participants receive a leaflet with instructions on how to use the application in case they have any doubts. Moreover, the research team of the study reminded participants that they could ask questions through the messaging section of the application. In some cases where older adults did not have the ability to use a mobile phone and their caregiver was not in the hospital due to the Covid-19 restrictions, the explanation and subsequent training with the caregiver was made via phone call or video call. Participants of this study were contacted regularly, at least once every other week, to solve any issues during their experience using the ActiveHip+ m-Health system. All the assessments were conducted at the hospitals, the first before they started using the ActiveHip+ system, and the last at 12 weeks (end of the program use).

ActiveHip+ m-Health system

A detailed description of the ActiveHip+ program is available elsewhere [170]. The ActiveHip+ mHealth system [170] is comprised of: (i) a mobile application for older adults after hip surgery and family caregivers, who play an essential role to help older adults to use mHealth and (ii) a webpage for health professionals, where they can monitor and adjust the evolution of the older adults in their recovery process.

The contents of the educational health and tele-rehabilitation program delivered through the ActiveHip+ mHealth system for older adults after hip surgery and family caregivers are grouped into two main sections. Firstly, the health educational section was composed of five modules for older adults and family caregivers, and two additional specific modules for family caregivers. The modules offered relevant information about the hip recovery process (e.g., type of surgery, medication, overview of the recovery process during hospital stay and at hospital discharge, supporting devices for the development of the activities of daily living since the first day after surgery, keys to the physical and mental well-being) and keys for prevention of secondary fractures. This section was provided through videos, one for each module, which were translated and cross-culturally adapted for older adults and family caregivers from both Spain and Belgium. Between each module, there is a brief summary of the content they have just watched and an introduction to the next module. These summaries were created to facilitate the participants' learning and to allow them to stop at some points if they needed to continue the educational section at a different time. The total duration of the 5 and 7 modules was one hour and one and a half hours respectively. Secondly, the rehabilitation section, where older adults can perform two sessions of physical exercise and one session of occupational therapy per week for 12 weeks. The rehabilitation sessions were delivered through pre-recorded videos with a voice-over to describe each exercise. The physical exercise sessions consist of a warm-up, the main training and a cool-down. These sessions have 18-20 exercises depending on the level of difficulty and include balance, resistance, upper body, step and other exercises. The duration of the physical exercise sessions ranges from 25 minutes to an hour. The occupational therapy sessions are composed of the body of the session (ranging from 5-7 activities and a cool down with a choreography to improve the mobility. Activities such as mobility in bed, transfer with and without supporting devices, or walking among others. The duration of the sessions ranges from 25 minutes to 50 minutes. The tele-rehabilitation intervention was asynchronous due to requests of older adults and family caregivers during the co-creation process. The asynchronous delivery allows them both to adapt the sessions to their daily routine and set their own pace. At the end of each session, older adults respond to three questions regarding pain, effort and satisfaction with the session. This information is accessible through the health professional´s webpage to individualise the rehabilitation program of the participant adapting the difficulty level of the sessions to the condition of the older adults. Moreover, there is an alert system on the website for health professionals to notify them if any value of these 3 questions is inadequate, i.e., pain>5, so that they can contact the participants quickly. Although asynchronous delivery does not allow for real-time follow up, we set the aforementioned alert system and a video call system. Through these video calls, health professionals could check in real-time the how older adults were progression, how they were performing the most complicated exercises and answer questions doubts about the recovery. Additionally, the app contains videos showing how to perform the activities of daily living (ADL) safely (i.e., dressing, bathing, up and down stairs). These videos are available anytime to the participants. The follow-up is based on messages and videoconferences between health professionals, older adults and caregivers, using a two-way communication system. The two-way communication system is composed of a messaging system in which older adults and caregivers can send messages to health professionals and vice versa. It also allows the possibility of making video calls in order to improve communication for older adults, family caregivers and health professionals.

Feasibility outcomes

To measure the feasibility of the ActiveHip+ mHealth system for older adults after hip surgery, the following measures were collected and analysed:

Adoption: Proportion of older adults agreeing to use ActiveHip+ out of the total number of older adults eligible to participate in the project. This information has been extracted from the register of the eligible and finally included participants.

Usage: The rate of older adults who access the mobile application at least half of the days of the health educational and tele-rehabilitation program delivered through the ActiveHip+ mHealth system. We measured the number of times older adults and their caregivers access the application through: (i) the number of interactions through the logging data and (ii) the number of tele-rehabilitation sessions performed through the activity register, where health professionals could check the date and the time spent for each session.

Satisfaction with the app: The Mobile App Rating Scale (MARS) is an easy-to-use and reliable tool to measure the quality of several aspects of health care mobile applications [278].

Perceived quality of the app: The Net promoter Scale (NPS) is a tool used to measure the satisfaction of the users of a mobile application through the question "how likely would you recommend this mHealth tool to other older adults like you?" It scores from 0 to 10 points, scores are interpreted as indicating dissatisfaction (≤ 5 points) and satisfaction > 5 points) [279].

Clinical Outcomes

Functional status: The functional level was assessed using the Functional Independence Measure (FIM). In the first assessment conducted during the first week after surgery, older adults were asked to report their functional status at two different times; i) a week before surgery (i.e., to evaluate an inclusion criterion), and ii) at the moment of the assessment, which was during the week after surgery (i.e., pre-intervention measure). The FIM consists of 18 items, of which 13 concern physical activities divided into four categories: self-care, sphincter control, transfers, and locomotion [122]. The remaining five items relate to cognitive and social functioning aspects 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 psychometric properties of the

FIM are adequate [177]. The FIM has been used previously during the follow-up of older adults after hip surgery, both during their hospital stay [176] and after hospital discharge [280].

Physical performance: The Short Physical Performance Battery (SPPB) assessment has previously been used to evaluate older adults and older adults with hip fracture[178,179,281]. This tool consists of three tasks: balance, walking, and chair stands [178]. The SPPB evaluates the ability to maintain balance for 10 seconds in certain positions, time to walk 4 meters, and time required to sit and stand up from a chair 5 times. We considered 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 psychometric properties of the SPPB are adequate [180,282].

Pain: The numeric rating scale for Pain (NRS) test is a fast and convenient way to evaluate the intensity of pain perceived by the patient.The patient indicates the perceived pain by pointing out on a physical scale a value from 0 (without pain) to 10 (maximum pain) [283]. Psychometric properties of the NRS-pain are adequate [283].

Statistical Analysis

The normal distribution of the data was checked with the Kolmogorov-Smirnov test. When variables did not show a normal distribution, the Blom formula was performed [284]. Descriptive characteristics of the sample are presented as mean and standard deviation (SD) or frequency and percentage when appropriate.

The Acceptability of both the MARS and the NPS have been calculated. In both of them the overall mean score of the scale and the standard deviation have been calculated and provided, as well as the mean score of each of the categories which compose the MARS scale.

To examine the effects of the ActiveHip+ mHealth system, we conducted a repeated measures ANCOVA, where the hospital stays assessment and the assessment 3 months after the surgery were the repeated measures to estimate the intra-subject effect. A previous stepwise regression was performed to decide the inclusion of the cofounders (i.e., age, gender, level of studies, Body Mass Index (BMI), falls during last year, hospital stay, number of sessions and number of interactions) in the model which are the best predictors (i.e., explain the largest proportion of the variance) of functional status (subjective through the FIM scale and objective through the SPPB) [285]. All analyses were performed using Statistical Package for Social Sciences (SPSS, IBM Corporation version 25.0; Armonk, NY) and the level of significance was set at $p < 0.05$.

RESULTS

In Spain, from 125 older adults admitted to the orthopaedics settings, 55 were identified as eligible participants who met the inclusion criteria. Of them, 47 accepted to participate in the ActiveHip+ study and were recruited and trained in the use of the app. Out of these 47 participants who accepted, 36 were included in the final analysis. In Belgium, from 105 older adults admitted to the traumatology department in the AZ Delta hospitals, 48 met the inclusion criteria. Of them, 34 accepted to participate in the ActiveHip+ study. Out of these 34 participants who accepted, 33 were included in the final analysis. The exclusion and dropouts of older adults in both countries are detailed in the CONSORT 2021 flowchart (Figure 13).

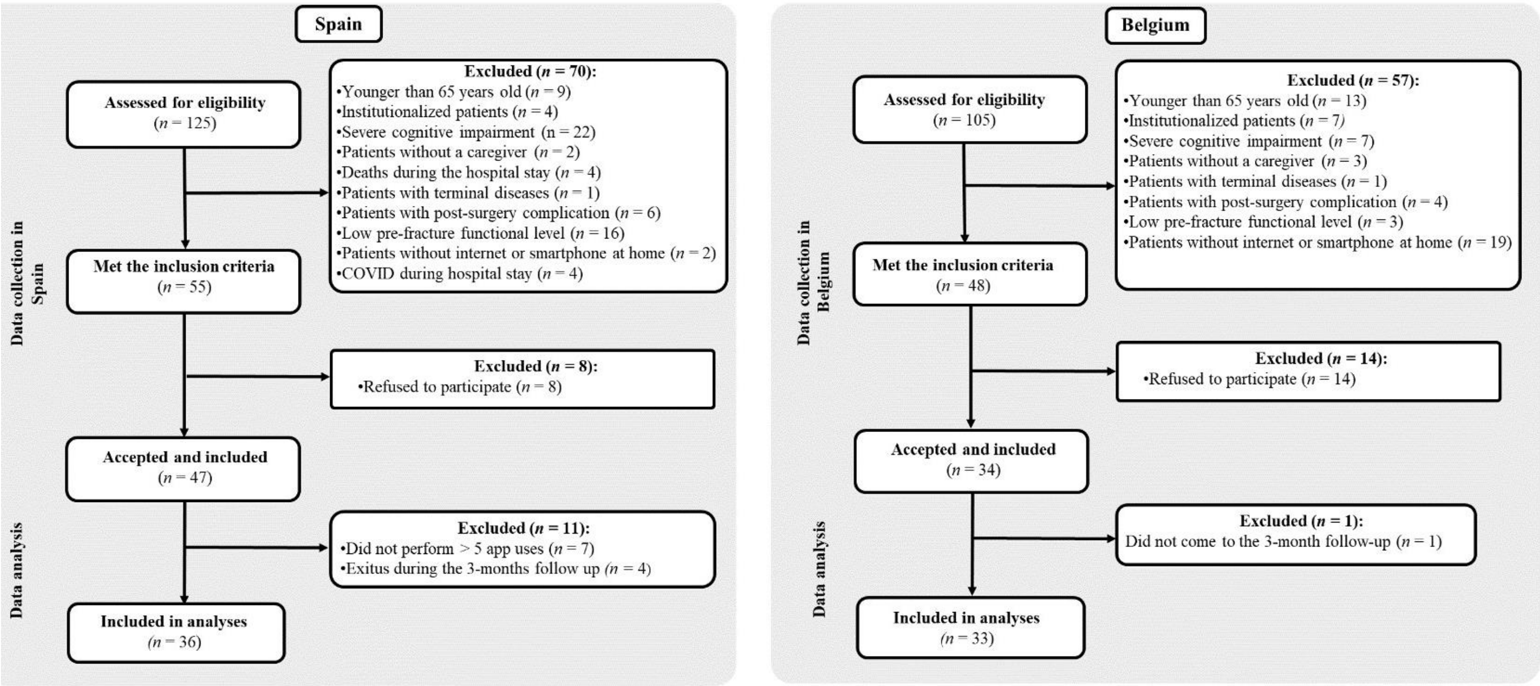

Figure 13. Flowchart of the sample in Spain (left panel) and Belgium (right panel).

Table 9 shows the descriptive characteristics of the ActiveHip+ sample by country. In Spain, most of sample had hip fracture (86%). In Belgium, most of the sample had osteoarthritis (85%).

Table 9. Baseline characteristics of the older adults who used ActiveHip+ mHealth system.

Variable	Spain (*n* = 36)	Belgium (*n* = 33)
Age, (years), Mean (standard deviation)	80.3 (8.9)	71.1 (5.6)
Gender, *n* (%)		
Women	29 (80)	16(49)
Men	7 (20)	17 (51)
Body Mass Index (kg/ m2) categories, *n* (%)		
Underweight (<18.5)	2 (6)	4 (12)
Normal (18.5 to 24.9)	7 (19)	17 (52)
Overweight (≥25)	27 (75)	12 (36)
Educational level, *n* (%)		
Without formal education	17 (47)	2 (6)
Primary school	15 (42)	17 (52)
Secondary school	3 (8)	12 (36)
University	1 (3)	2 (6)
Type of injury, *n* (%)		
Fracture Cervical Femoral (Intracapsular)	5 (14)	1(3)
Fracture Trochanteric (Extracapsular)	26 (72)	24 (12)
No fracture, but degeneration	5 (14)	28 (85)
Type of surgery, *n* (%)		
Prosthesis	10 (28)	30 (91)
Screw Plate	7 (19)	0 (0)
PFN-A Nail	18 (50)	3 (9)
Others	1(3)	0(0)
Falls in the previous year, *n* (%)		
Yes	17 (42)	11 (33)
No	19 (53)	22 (67)
Pre-fracture residence, *n* (%)		
Own home	34 (94)	33 (100)
Nursing or relative´s home	2 (6)	0 (0)
Change of residence at hospital discharge, *n* (%)		
Yes	12 (33)	3 (9)
No	24 (67)	30 (91)
Support at hospital discharge, *n* (%)		
Formal caregiver	8 (22)	2 (6)
Informal caregiver (relative or friend)	28 (78)	31 (94)

PFN-A= Proximal Femoral Nail

Feasibility Outcomes

Adoption: The ActiveHip+ adoption rate was 85% in Spain, meaning that 47 out of 55 older adults who were offered to participate accepted to use the ActiveHip+. The adoption in Belgium was 82%, with 34 out of 48 participants accepting to participate in the study.

Dropout: The rate of dropout in Spain was 15% (7/47). In addition to the 7 dropouts, 4 patients died during the first week after accepting to participate in this study. In Belgium, the dropout rate was 3% (1/34).

Usage: The usage of the ActiveHip+ mHealth system has been measured in two ways, the number of interactions with the app to watch any of the resources available in the different sections and the number of sessions of tele-rehabilitation performed.

Regarding the number of interactions with the app, the usage rate in Spain was 64%. It means that 23/36 older adults included in the analysis had at least 42 interactions with the app, which is half of the 84 days that the health educational and tele-rehabilitation program delivered through the ActiveHip+ mHealth system lasts. The usage rate in the Belgian sample was 84%, with 28/33 performing the minimum interactions with the app.

Regarding the number of tele-rehabilitation sessions performed the usage rate in Spain was 25%. It means that 9/36 older adults included in the analysis have performed at least 10 tele-rehabilitation sessions. Concerning the Belgian sample, the rate of video-recorded sessions performed is 9%. It means that 3/33 older adults performed at least 10 sessions during the ActiveHip+ intervention.

MARS and NPS score: Figure 14 presents, for each country the users perception of the quality of the app. In Spain, the mean of the overall MARS scale was 4.42/5 (SD 0.42), whereas in Belgium, the overall mean score was 3.51/5 (SD 0.39). Regarding the score of the different categories, in the Spanish sample all of the scores are similar, ranging from the lowest, 4.40/5 (*Information)* to 4.44/5 (*Functionality).* Nevertheless, in the Belgian sample, there are differences, the most valued category is *Engagement* (3.70/5), whereas the worst rated category is *Information* (2.54/5).

Concerning the NPS, the Spanish sample overall score was positive 8.86/10 (SD 1.00), whereas the Belgian overall score was less positive, 5.16/10 (SD 1.97).

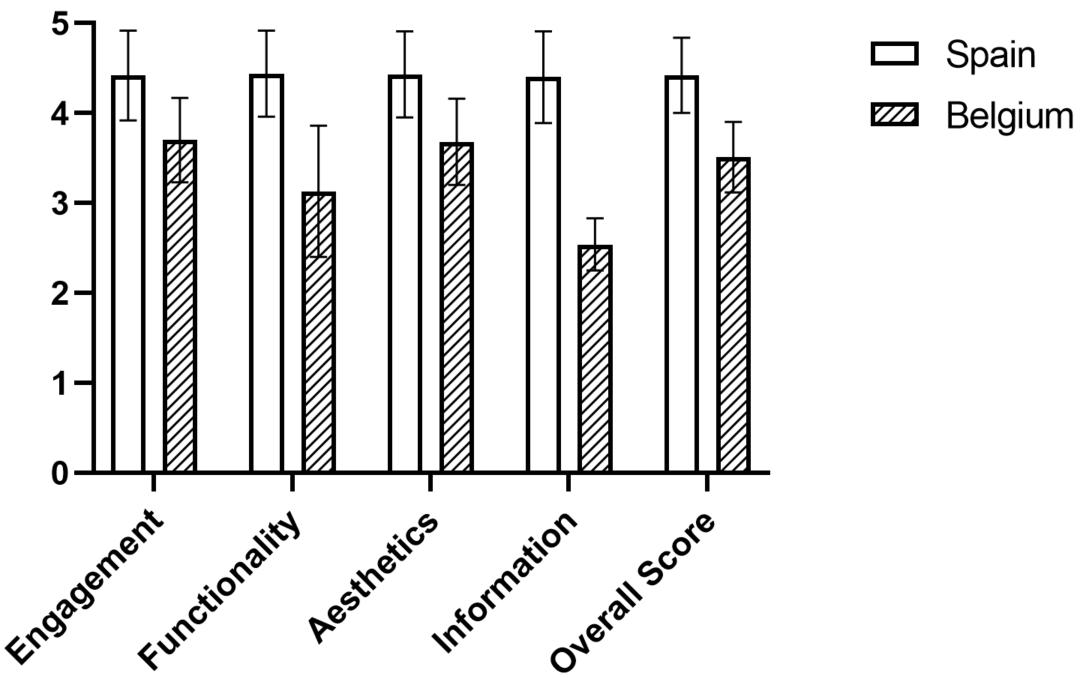

Figure 14. Quality assessment of the ActiveHip+ app by older adults and caregivers, divided by country. The evaluation was conducted using the Mobile App Rating Scale (MARS).

Clinical Outcomes

<u>Functional Status</u>: The ANCOVA model including the variables age, body mass index (BMI), level of studies and existence of previous falls during last year as covariate, performed on the functional status showed statistical differences the pre-post intervention analysis of the FIM scale in both countries after using the ActiveHip+ mHealth system. In Spain the pretest score (assessed in the first week after surgery) was 68.30 (95%CI: 62.16 - 74.46) and the post-test score was 109.20 (95%CI: 106.04 - 112.34). In the Belgian sample, the pretest score (assessed in the first week after surgery) was 105.73 (95%CI: 102.609 -108.85) and the post-test score was 121.21 (95%CI: 119.65 - 122.77). The results of the pre-post intervention analyses of the FIM older adults are provided in Figure 15.

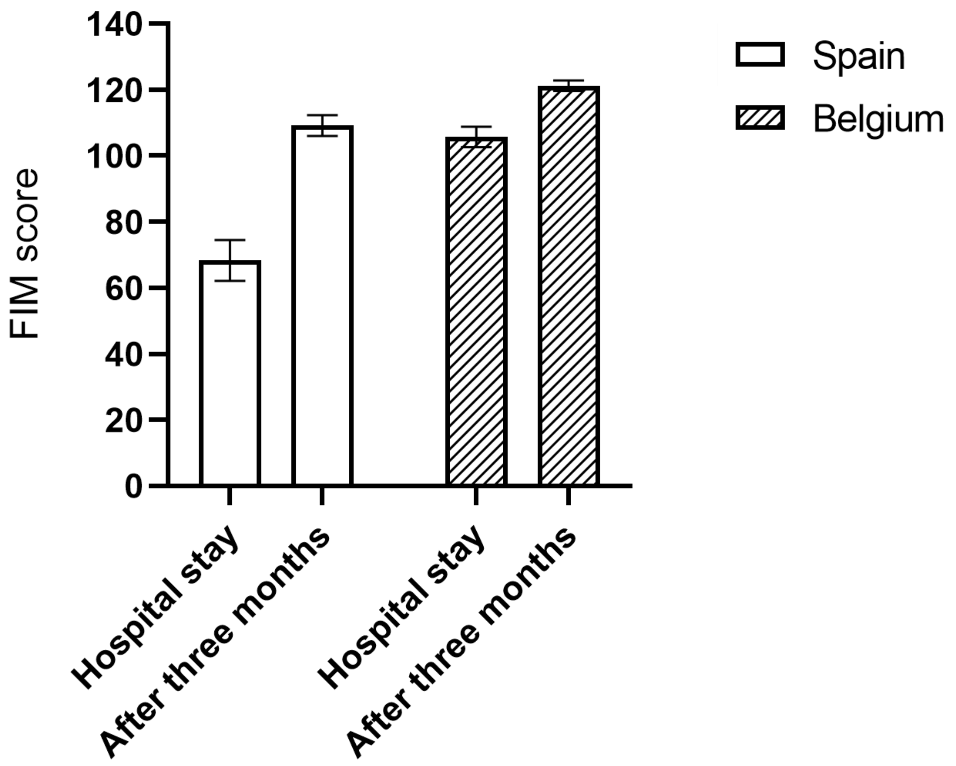

Figure 15. Evolution of older adults functional status after using the ActiveHip+ app, divided by country. Functional status was measured using the Functional Independence Measure (FIM).

Physical Performance: The ANCOVA model including the variable n° of tele-rehabilitation sessions performed as covariate, performed on the physical performance showed statistical differences in the pre-post intervention analysis of the SPPB results in both countries after the health educational and tele-rehabilitation program delivered through the ActiveHip+ mHealth system. The results of the analyses pre-post intervention of the SPPB older adults are provided in figure 4. The pretest score of the Spanish sample was 3.14 (95%CI: 2.40 - 3.89) and the post-test score was 7.22 (95%CI: 6.40 - 8.05). In Belgium, the pretest score of the SPPB scale was 3.36 (95%CI: 2.72 - 4.01) and the post-test score was 6.85 (95%CI: 5.94 - 7.76). The results of the analyses pre-post intervention analyses for SPPB are provided in Figure 16.

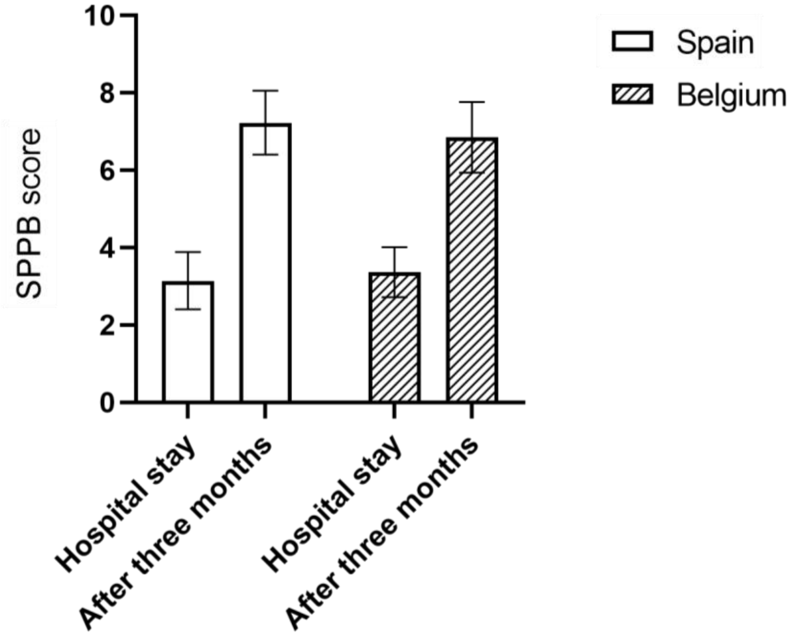

Figure 16. Evolution of older adults' physical performance after using the ActiveHip+ app, divided by country. Physical performance was measured using the Short Physical Performance Battery (SPPB).

<u>Pain</u>: The ANCOVA model including the variable n° of interactions with the app performed as covariate, performed on the pain showed statistical differences the pre-post intervention analysis of the NRS results in both countries after the health educational and tele-rehabilitation program delivered through the ActiveHip+ mHealth system. In Spain the pretest score was 5.28 (95%CI: 4.36 - 6.20) and the post-test score was 2.14 (95%CI: 1.36 - 2.91). In the Belgian sample, the pretest score was 5.21 (95%CI: 4.34 - 6.08) and the post-test score was 3.06 (95%CI: 2.43 - 3.67). The results of the analyses pre-post intervention of the NRS older adults are provided in Figure 17.

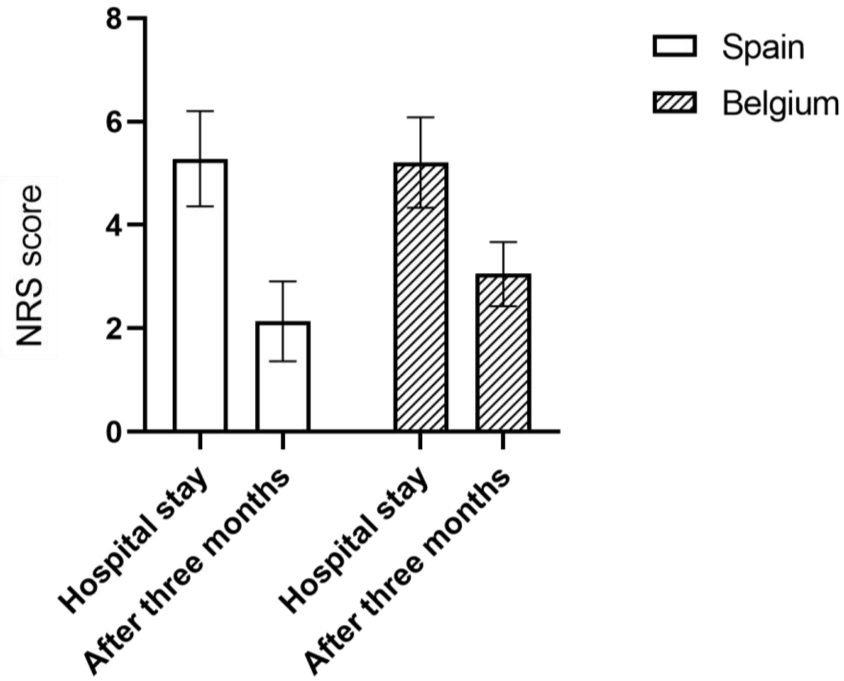

Figure 17. Evolution of older adults' level of pain after using the ActiveHip+ app, divided by country. The level of pain was measured using the numeric rating scale (NRS).

DISCUSSION

The aim of the present study was to evaluate the feasibility of implementing the ActiveHip+ mHealth system for older adults after hip surgery in an orthopaedic setting and in two different healthcare systems. Our findings suggest that the ActiveHip+ mHealth system is feasible in older adults after hip surgery. The health educational and tele-rehabilitation program delivered through the ActiveHip+ mHealth system may improve functional status, physical performance and pain level, which should be tested in appropriately designed randomized controlled trials.

In the present study, the adoption rate was high (78% combining both samples), which is in line with previous studies in the field of tele-rehabilitation [272]. This high adoption rate could be associated with the absence of treatment alternatives due to the COVID-19 restrictions, especially concerning for older adults with comorbidities, as our sample [286]. The dropout rate of this study is similar to previous studies [113]. This rate is higher in the Spanish sample (11/47) than the Belgian sample (1/34). We speculate that differences in the characteristics of the sample, due to restrictions on surgeries during COVID-19 [287,288] waves, may explain this discordance in the dropout rate. For instance, the Spanish sample is older than the Belgian sample (78 years vs. 66 years) since it is comprised mostly by people with osteoporotic hip fractures, an orthopedic disease that usually occur in advanced ages [289]. Hip osteoarthritis is more predominant in the Belgian sample and these patients are typically younger [290]. It should be noted that in the Spanish sample there were 4 deaths, in line with previous studies who established a strong relationship of this injury with a high mortality rate [291].

In the present study, the percentage of older adults who regularly used the app was high (74% combining both samples), indicating that the ActiveHip+ is a promising tool to consider in the recovery after hip surgery. The usage rate based on the interactions is similar to the results of previous studies [113]. In comparison to the Spanish sample, the usage ratio of the Belgian sample was higher (64% vs. 84%). As we mentioned before, the Belgian sample is younger and it is associated with a higher use of smartphones and, therefore, mHealth systems [200,292]. Regarding the usage rate based on the number of video-recorded sessions of rehabilitation performed is low (25% in Spain, 9% in Belgium). To understand the results, it is important to describe the context of both samples. The Spanish sample was recruited during one of the worst periods of the COVID-19 [293]. As some older adults were alone during their hospital stay, explanation and training in the use of the app was done via calls and videocalls, which may negatively affect the usage rate. Moreover, some family caregivers did not go to the older adults' homes to avoid contagion due to the patient's clinical condition after surgery [294]. The key role of caregivers in mHealth use needs to be taken into account. In an older sample as included in this study, it is easier to understand the inferior than expected nº of sessions performed in the Spanish sample [295]. Regarding the usage rate in terms of video-recorded sessions performed by the Belgian older adults, it is essential to know that the Belgian healthcare system provides patients with a rehabilitation program of 3 to 5 in-person sessions at home per week after the surgery. This means that no further video-recorded sessions are necessary. Despite the fact that the usage rate is lower than expected, 25% is a promising result, especially considering the average age of our sample and the conditions under which this study was conducted. Belgian participants have considered the ActiveHip+ mHealth systems an educational and informative resource. The ActiveHip+ mHealth system was co-created to answer the need of older adults and caregivers to be an active element in the recovery process and receive information [198,199]. This informative use of the ActiveHip+ mHealth system is also shown in the MARS rating of the Belgian users, who scored lower in the informative category than the Spanish sample. We hypothesize that future intervention after the COVID-19 pandemic would have more satisfactory results in terms of usage if the explanation is made in-person during their hospital stay. These results also show the need of developing a close follow-up during the first week of their participation to ensure a better adherence. Furthermore, during the final assessment, older adults and caregivers have explained that once they considered that they were recovered, which they do after about 2 months of using the application, they do not consider the need for further sessions, so they do not continue. This information could be useful for future studies on the use of tele-rehabilitation, which could use shorter periods of rehabilitation and focus more on educational aspects of prevention once they are recovered.

With regard to the acceptability of the app, measured once users finish the 12-weeks program, the results of the two samples were different. This may be due to the existence of family caregivers found in Spain but not in Belgium and who were able to support the use of mHealth. Also, the usefulness of the app when in-person rehabilitation was not available. The result, (3,99/5 combining both samples) is over the limit of 3.73 established in previous articles measuring the quality of different mHealth apps to be considered a good app[296]. In addition, letting users evaluate the mobile app support some of the suggestions to explore the opinion of key stakeholders to improve mHealth interventions[297].

Due to the differences in the two samples detailed throughout this study, there were differences in pre-intervention functional status through the ActiveHip+ mHealth system. Despite these differences, we found statistically significant improvements in functional status and physical performance according to FIM and SPPB respectively in both groups. This is in line with previous studies in this field [109,110,113]. For example, Li et al. [109] obtained significant improvements in the ADL performance compared with the control group. Similarly, Kalron et al. [110] showed improvements in different mobility tests comparing the results of their tele-rehabilitation intervention group with the control group. Moreover, Ortiz et al. [113], in a predecessor of the current ActiveHip+ study, showed that the tele-rehabilitation participants reported higher scores in their functional status measured by FIM and physical performance measured with the Timed Up and Go test compared with the older adults allocated to the control group. However, an unexpected finding of this study was a greater recovery in the Spanish sample in terms of SPPB score. This could be explained by the higher number of video-recorded sessions performed by the Spanish older adults, which were focused on the tests included in the SPPB (balance, walking and standing up) among others, whereas in Belgium there is no standard in-person rehabilitation, so it is possible that the exercises the patients performed at home were different. On the other hand, the significant decrease measured by the NRS support previous results showed by Azma et al. [298], where people with osteoarthritis showed statistically significant lower level of pain after a tele-rehab intervention. While our results seem to be promising, they should be carefully interpreted due to the limitations of the present feasibility study. Thus, appropriately designed randomized controlled trials are required to accurately test the effects of the ActiveHip+ mHealth system in clinical outcomes.

The present study has limitations. First, this study was designed to test the feasibility of the ActiveHip+ mHealth system. The potential effects of the intervention in clinical outcomes should be carefully interpreted because of several reasons, including for instance the inclusion of a relatively small and heterogeneous sample. Thus, the implementation of the ActiveHip+ mHealth system is not recommended until its effectiveness has been demonstrated in appropriately designed randomized controlled trials. Second, the app was available in mobile phones only and not in tablets. Third, the inability to record older adults' pain medication may have affected the data reported in this study. Third, a further limitation of this study has been the technical problems encountered, associated with the pilot phase of the app. Lastly, it has not been possible to measure the time spent using the different sections of the app other than the tele-rehabilitation section. This study also has strengths. First, the feasibility of the intervention has been demonstrated in two considerably different healthcare systems. Second, to our knowledge, this is the first study testing the feasibility of a mHealth system created to deliver a health educational and tele-rehabilitation program for the recovery of older adults with hip fracture and hip replacement.

CONCLUSIONS

This study showed that a mHealth system is a feasible option in the recovery of older adults after hip surgery. While our results in clinical outcomes seem to be promising, they should be carefully interpreted due to the limitations of the present feasibility study. Thus, appropriately designed randomized controlled trials are required to accurately test the effects of the ActiveHip+ mHealth system in clinical outcomes in older adults after hip surgery.

Study VI

Effectiveness of the ActiveHip+ mHealth system on functional status, pain and fear of falling in older adults with hip fracture: A randomised controlled trial

INTRODUCTION

The incidence of hip fracture incidence is high. In Europe, for instance, there are 250 fractures out of 100,000 people [6], a figure that is steadily increasing [14]. Hip fracture also negatively impacts functional status [113], fear of falling [42] and pain [47]. In fact, hip fracture is the leading cause of morbidity in older adults, those over 65 years of age [299]. Hip fracture makes patients highly dependent, which subsequently affect their relatives' health, who become their main caregivers [300]. Hip fracture is a sudden event, which is stressful for the caregivers because their lack of time and information to fulfil their role [59,157]. Collectively, there is a need to improve how hip fracture is managed in clinical settings [37].

In hip fracture, the main goal of rehabilitation is to recover the pre-fracture functional status [37]. Higher functional status, as perceived by the patients, is related to more participation in meaningful activities [44,187]. In addition to functional status, other important outcomes in the rehabilitation of hip fracture are pain and fear of falling [42,301]. On the one hand, poor pain management is associated with delayed gait recovery, higher levels of depression as well as poorer adherence to rehabilitation interventions [302,303]. On the other hand, fear of falling is considered a psychological symptom that causes older adults with hip fractures to be more disabled than even those who fall [304]. In fact, fear of falling reduces the social participation of older adults with hip fracture, a component considered as the highest level of functional status [49]. Accordingly, it is essential to design adequate rehabilitation interventions targeting functional status, fear of falling and pain in older adults with hip fracture.

Although international guidelines for the management of hip fracture highlight the importance of multidisciplinary approaches [305] and early rehabilitation [96], some patients are not offered such programmes after discharge because of the constrained healthcare resources [84]. Thus, a priority in clinical settings is to improve the accessibility to rehabilitation of hip fracture [84]. Accordingly, digital health, the use of Information and Communication Tools (ICT) to support health provision, seems to be a promising alternative because they are more widely accessible than traditional in-person rehabilitation [97]. Specifically, mobile health (mHealth), the use of mobile devices to support health promotion [99], due to the widespread use of smartphones worldwide. Digital health has evolved from traditional procedures as websites or recorded videos [110,113,169] to mobile apps [109,111]. Previous studies provide hip fracture patients with a mobile app to conduct rehabilitation for 3 weeks and 3 months respectively [109,111]. However, to the best of our knowledge, there are just 2 randomised controlled trials confirming the effectiveness of mHealth systems in the recovery of the older adults with hip fracture [109,111] and further research is needed. Accordingly, we developed ActiveHip+, a mHealth system to provide a tele-rehabilitation and educational program for older people with hip fracture supported by their family caregivers [170]. The ActiveHip+ mHealth system was co-created with main stakeholders (older adults with hip fracture, caregivers and health providers) to enhance acceptance and experience of its use [306]. We have previously demonstrated that the ActiveHip+ mHealth system is feasible [307]. Next, the aim of this study was to experimentally test the effectiveness of the ActiveHip+ mHealth system on the functional status, pain and fear of falling pain in older adults with hip fracture.

METHODS

Study design

The present study is a multicentre randomised controlled trial (RCT), conducted following the guidelines established by the Helsinki Declaration and Law 14/2007 on Biomedical Research. The ActiveHip+ project was approved by the Ethics Committee of the Research Centre of Granada (CEI-GRANADA) and it was also pre-registered in Clinicaltrials.gov (NCT04859309).

Sample

A total of 104 older adults with hip fracture and their family caregiver were recruited, being randomly allocated to the intervention group (n=51) or to the control group (n=53).

The inclusion criteria of the present study were: (i) To have a hip fracture; (ii) To be, at least 65 years of ager; (iii) To have a high prefracture functional status a week before surgery (i.e., Functional Independent Measure (FIM) overall score >90 points); (iv) to be allowed weight-bearing at 48 hours after the surgery; (v) To be discharged to your own home or to a relative's home; (vi) To have an informal caregiver with Internet access and (vi) To sign the informed consent. The exclusion criteria were: (i) to have severe cognitive impairment (Pfeiffer test score >4) (ii) to be discharged to a nursing home (iii) to have postoperative complications that prevent the start of rehabilitation in the first postoperative week.

Recruitment, allocation, blinding and follow up

The present study involves older adults with hip fracture and their family caregivers recruited in three hospitals of the Andalusian Public Healthcare System: Virgen de las Nieves University Hospital (Granada), Jerez de la Frontera University Hospital (Cádiz) and Puerto Real University Hospital (Cádiz), located all of them in southern Spain. The recruitment was conducted between June to December 2021. Older adults with hip fracture and their caregivers who met the inclusion criteria were invited by the research team to participate in the study during the hospital stay. If agree, researchers explained the main characteristics of the program and ask them to sign the informed consent was signed, participants were assigned to the intervention or control group using sealed numbered envelopes.

Older adults and caregivers included in the study were not blinded since they were aware that they were conducting rehabilitation through the ActiveHip+ m-Health system. Regarding the research team blinding, researchers who conducted the assessment of the participants included and those who analysed study data were blinded to the group. Furthermore, the researchers assessing the outcomes were not the same at the hospital stay assessment and at the 12 weeks assessment to ensure an optimal blinding strategy and thus avoid potential risk of bias during the assessment process.

Intervention

A part of the intervention was common to the older adults recruited to this group, irrespective of which group they belonged to, the tele-rehabilitation group or the control group. During the hospital stay, all older adults underwent the standard care established by the Andalusian Public Healthcare System for a hip fracture, which is composed of a few rehabilitation sessions during weekdays (no weekends). In addition, all participants were given a booklet during their stay in the hospital with recommendations and some exercises to do during the first days of the recovery process.

<u>Intervention group</u>

Older adults allocated in this group used the ActiveHip+ mHealth system, an educational and a multidisciplinary tele-rehabilitation program delivered through a mobile app for 12 weeks. A detailed description of the ActiveHip+ mHealth system is provided [170]. An educational program for older adults with hip fracture and their family caregivers was also provided through the ActiveHip+ app. Five modules were available to older adults and seven modules were available to caregivers with information on the hip fracture recovery process and prevention tips. In addition, the ActiveHip+ application had a set of general recommendations and an on-demand daily life activities section to be used when needed.

During the 12 weeks, older adults with hip fracture could perform three video-recorded sessions each week (two of physical exercise and one of occupational therapist) with help of their caregivers. For those patients who finished the three sessions a week, and showed their motivation, an extra session was enable, called "bonus session". Both the physical exercise and the occupational therapy program are divided in four levels of difficulty, based on the older adults with hip fracture´s physical and functional level evolution. Older adults with hip fracture allocated in the intervention study were contacted regularly so as to solve possible doubts about the use of the ActiveHip+ mHealth system.

<u>Control group</u>

The participant assigned to the control group, received the usual rehabilitation offered so far by the Andalucian HealthCare System. It was composed of 5-10 in face sessions delivered by physiotherapists or occupational therapist at patient´s home. These sessions focused on general recommendations to improve balance and functional status. Furthermore, participants allocated to this group were provided with an informative leaflet with recommendations on physical exercise to do at home.

All patients enrolled in the study were assessed at the hospital at two moments: during their hospital stay after the surgery and at 12 weeks after the surgery, at the end of the intervention.

Feasibility outcomes

The feasibility of the ActiveHip+ mHealth system for older adults with hip fracture was measured through the following variables:

<u>Adoption</u>: Proportion of older adults agreeing to use ActiveHip+ out of the total number of older adults invited to participate. This information has been extracted from the register of the invited and finally included participants.

<u>Usage</u>: Rate of older adults who access the app at least half of the days 12 weeks of intervention. We measured the number of times older adults and their caregivers access the application through: (i) the number of interactions and (ii) the number of rehabilitation sessions performed.

<u>Satisfaction with the app:</u> The Mobile App Rating Scale (MARS) is an easy-to-use and reliable tool to measure the quality of several aspects of healthcare mobile applications [278].

Perceived quality of the app: The Net promoter Scale (NPS) is a tool used to measure the satisfaction of the users of a mobile application through the question "how likely would you recommend this mHealth tool to other older adults like you?" It scores from 0 to 10 points, scores are interpreted as indicating dissatisfaction (≤ 5 points) and satisfaction > 5 points) [279].

Clinical outcomes

Functional status: The functional level was assessed using the Functional Independence Measure (FIM) and the New Mobility Score Spanish Version (NMS-ES). In the first assessment conducted during the first week after surgery, to fill the FIM, older adults were asked to report their functional status at two different times; i) a week before surgery (i.e., to evaluate an inclusion criterion), and ii) at the moment of the assessment, which was during the week after surgery (i.e., pre-intervention measure). The FIM consists of 18 items, including items related with development of Activities of Daily Living (ADLs) (e.g., self-care or transfers) as well as social and cognitive items (e.g., communication) [122]. The total FIM score range is between 18 and 126 points. Higher scores indicate a higher level of independence. The NMS is composed of three questions regarding walking mobility across ADLs in three different contexts: indoor walking, outdoor walking, and walking during shopping [124]. Its overall score ranges from 0 to 9 points. The psychometric properties of the both scales are adequate [91,177]. The FIM has been used previously to monitor older adults with hip fracture [176,280]. The NMS-ES has been recommended to measure the pre-fracture functional ability of older adults with hip fracture [132].

Pain: The numeric rating scale for Pain (NRS) test is a fast way to evaluate the intensity of pain perceived by the patient. The patient indicates the perceived pain by pointing out on a physical scale a value from 0 (without pain) to 10 (maximum pain) [283]. Psychometric properties of the NRS-pain are adequate [283].

Fear of falling: We measure the fear of falling through the Short Falls Efficacy Scale-International (SFES-I), a reliable (Cronbach's α = 0.92) and feasible [174] tool to measure the fear of falling in older adults. The SFES-I is also a quick and easy-to-use tool, which is considered as critical to be used in the health providers´ daily practice. It is comprised by 7 items relating to some ADLs inside and outside the home. Each of the SFES-I item has a score between 1 (not worried about the possibility of fall) and 4 (extremely worried about the possibility of fall). The overall score ranges from 7 (not worried at all about falling) to 28 (extremely worried about falling).

Sample size

We used the G*Power V.3.1.7 software (Franz Faul, Christian-Albrechts-Universitätzu Kiel) (version 3.0.1) to estimate 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 tele-rehabilitation intervention on the main outcomes; i.e., physical performance and functional status. We considered an 80% power, an alpha error of 5%, and a dropout rate of 15%, the ActiveHip+ project. In total, 104 participants (52 participants per group) were estimated as the appropriate sample size.

Statistical Analysis

The normal distribution of the data was checked with the Kolmogorov-Smirnov test. When variables did not show a normal distribution, the Blom formula was performed [284]. Descriptive characteristics of the sample are presented as mean and standard deviation (SD) or frequency and percentage when appropriate.

The Acceptability of both the MARS and the NPS have been calculated. In both of them the overall mean score of the scale and the standard deviation have been calculated and provided, as well as the mean score of each of the categories which compose the MARS scale.

To test the effectiveness of the ActiveHip+ mHealth system, we conducted a repeated measures analyses of variance (ANOVA) including two time points (i) pre-intervention (baseline) assessment at the hospital stay and (ii) post-intervention (follow-up) assessment 3 months after the surgery. Within subjects Cohen's d has been calculated as effect size indicator using the formula Cohen's d = Mean difference / pooled SD. As effect size indicators they can be interpreted according to the standard benchmarks, i.e. a value around 0.2 is considered a small effect size, 0.5 is considered a medium effect size and 0.8 is considered a large effect size [182]. All analyses were performed using Statistical Package for Social Sciences (SPSS, IBM Corporation version 25.0; Armonk, NY) and the level of significance was set at $p < 0.05$.

RESULTS

In Spain, 233 older adults with fracture were admitted to the hospital to undergo hip surgery. Out of the 124 potential participants who were invited to participate in this study, 110 accepted to use ActiveHip+ study. Half of them were randomly allocated to intervention group and half of them to the control group. In the intervention group, out of these 55 participants who accepted, 51 older adults with hip fracture were included in the final analysis. In the control group, 53 were included. The exclusion and dropouts of older adults in both countries are detailed in the CONSORT 2021 flowchart (Figure 18).

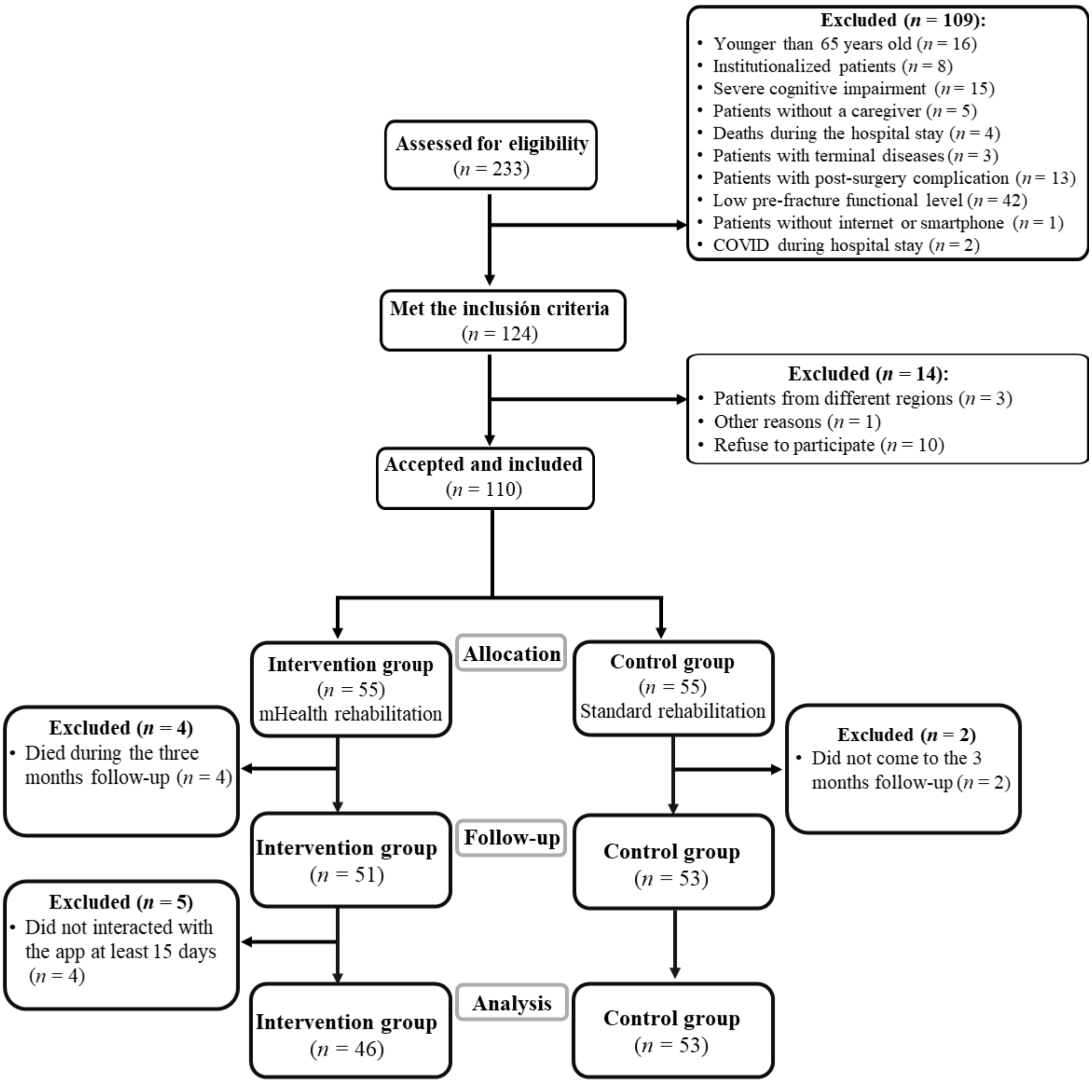

Figure 18. Consort flowchart of the sample recruited for this study.

Table 10 shows the sociodemographic characteristics of the participants by allocation groups. There were no statistically significant differences in any of the clinical outcomes shown in Table 10.

Table 10. Baseline characteristics and pre-interventions raw of sample divided by groups.

Variable	Intervention group (n = 46)	Control group (n = 53)	P
Age (years), Mean (SD)	79.70 (7.2)	79.94 (7.8)	0.73
Sex, n (%)			0.83
Women	33 (72)	37 (70)	
Men	13 (28)	16 (30)	
Type of injury, n (%)			0.58
Fracture Cervical Femoral (Intracapsular)	21 (46)	22 (42)	
Fracture Trochanteric (Extracapsular)	20 (43)	23 (43)	
No fracture, but degeneration	5 (11)	8 (15)	
Type of surgery, n (%)			0.94
Prosthesis	14 (65)	13 (25)	
Screw Plate	30 (31)	35 (66)	
PFN-A Nail	1 (2)	5 (9)	
Others	1 (2)	0 (0)	
Falls in the previous year, n (%)			0.93
Yes	16 (35)	11 (33)	
No	30 (65)	22 (67)	
Pre-fracture residence, n (%)			0.28
Own home	45 (98)	53 (100)	
Nursing or relative´s home	1 (2)	0 (0)	
Post-fracture residence, n (%)			0.67
Own home	42 (91)	47 (89)	
Nursing or relative´s home	4 (9)	6 (11)	
Hospital stay (days), Mean (SD)	6.83 (4.2)	5.64 (3.3)	0.08
Functional status at hospital discharge			
FIM (Total score 18-126) Mean (SD)	78.13 (19.23)	75,26 (13,39)	0.36
NMS-ES (Total score 0-9) Mean (SD)	5.89 (2.31)	6.58 (1.73)	0.26
Fear of falling at hospital discharge			
SFES-I (Total score 7-28) Mean (SD)	19.37 (7.2)	20.08 (5.18)	0.58
Pain level at hospital discharge			
NRS (Total score 0-10) Mean (SD)	5.89 (2.31)	6.58 (1.73)	0.91

n = sample size; SD = standard deviation; PFN-A = Proximal Femoral Nail; FIM = Functional Independence Measure; NMS-ES = New Mobility Score Spanish version; SFES-I = Short Falls Efficacy Scale; NRS = Numeric rating scale

Feasibility Outcomes

Adoption: The adoption rate was 88%. A hundred and ten out of 124 older adults with hip fracture invited to participate in this study accepted to use the ActiveHip+ mHealth system.

Dropout: The dropout rate of the ActiveHip+ mHealth system was 7% (4/55). All the dropouts were older adults with hip fracture who died during the 12 weeks of follow-up.

Usage: It has been measured both the number of days accessing the contents of the app and the number of tele-rehabilitation sections. Regarding the number of interactions with the app, the rate was 82%. It means that 38/46 older adults with hip fracture included in the analysis interacted with the app for at least 42 days, which is half of the 12-week duration of the tele-rehabilitation and health education intervention provided through the ActiveHip+ app. Regarding the number of tele-rehabilitation adherence, the rate was 37%. This data means that 17/46 older adults with hip fracture recruited have performed at least 10 tele-rehabilitation sessions through the ActiveHip+ mHealth system.

MARS and NPS score: Figure 19 shows the ActiveHip+ mHealth system quality perceived by the users. The overall MARS scale was 4,3/5 (SD 0,35). Regarding the categories which compose the MARS scale, the average of all the categories ranges from 4,19/5 (*Information)* to 4,48/5 (*Aesthetics*).

Concerning the score of the NPS, the overall score was positive 8,35/10 (SD 0,97)

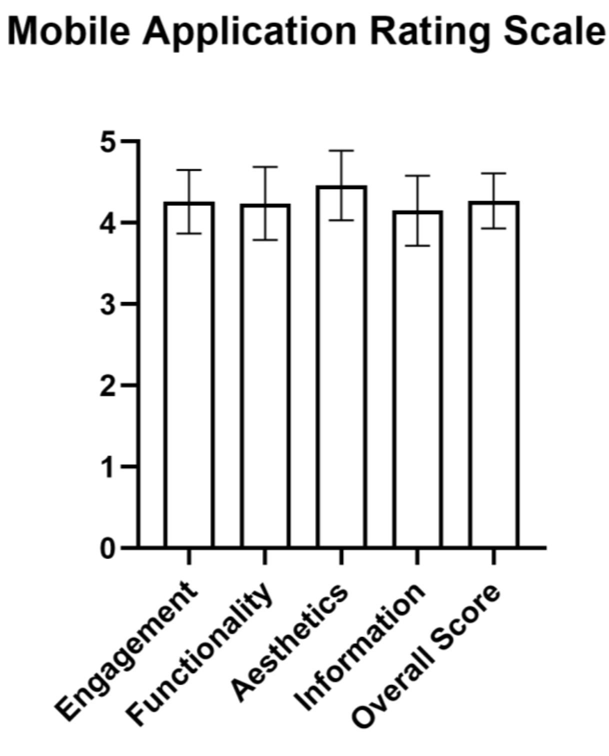

Figure 19. ActiveHip+ quality assessment perceived by older adults and caregivers. The assessment was carried out through the Mobile Application Rating Scale (MARS).

Clinical Outcomes

Table 11 shows the per-protocol analysis, which shows the differences between the intervention and control groups three months after surgery adjusting for baseline values. The functional status measured by both the FIM and NMS-ES of participants allocated to the intervention group (those using the ActiveHip+ mHealth system) had a statistically significant greater recovery than that of participants in the control group at the follow-up of 3-months (medium effect size: 0.70 Cohen's d; p = 0.02) and (medium effect size: 0.62 Cohen's d; p = 0.03) respectively. However, there were not statistically significant differences between group. In addition, the level of pain reported by the participants of the intervention group was statistically significant lower than those in the control group (medium effect size: 0.45; Cohen's d p = 0.03). Regarding the fear of falling, although the fear of falling in the intervention group showed a decreasing trend compared to the control group, there was no statistically significant difference (medium effect size: 0.32 Cohen's d; p = 0.17). All these results are graphically presented in Figure 20.

Table 11. Intervention effects of the ActiveHip+ mHealth system considering baseline and 3-month assessments (per-protocol analysis).

	Adjusted mean (95% CI)			*P*
	Tele-rehab. (*n* = 30)	Control group (*n* = 34)	Groups difference (Rehab – Control)	
Functional status				
FIM				
Raw score	114.90 (112.16 to 117.65)	110.61 (108.05 to 113.17)	4.29 (0.53 to 8.06)	0.02
NMS				
Raw score	6.86 (6.45 to 7.26)	6.01 (5.63 to 6.39)	0.85 (0.29 to 1.40)	0.03
Fear of Falling				
SFES-I				
Raw score	11.72 (10.11 to 13.32)	13.46 (11.75 to 14.74)	-1.53 (3.73 to -0.67)	0.17
Pain				
NRS				
Raw score	1.21 (0.64 to 1.78)	2.065 (1.54 to 2.59)	-0.86 (-0.08 to -1.63)	0.03

CI = confidence interval; *n* = sample size; FIM = Functional Independence Measure; NMS-ES = New Mobility Score Spanish version; SFES-I = Short Falls Efficacy Scale; NRS = Numeric rating scale.
A one-way analysis of variance (ANOVA) was used to test raw differences between the intervention and control group at the post-intervention, adjusting for basic pre-intervention values. Adjusted means and confidence intervals of the mean are represented. Differences between groups are presented as: post-intervention mean minus pre-intervention mean. Significant differences ($p < 0.05$) are highlighted in bold.

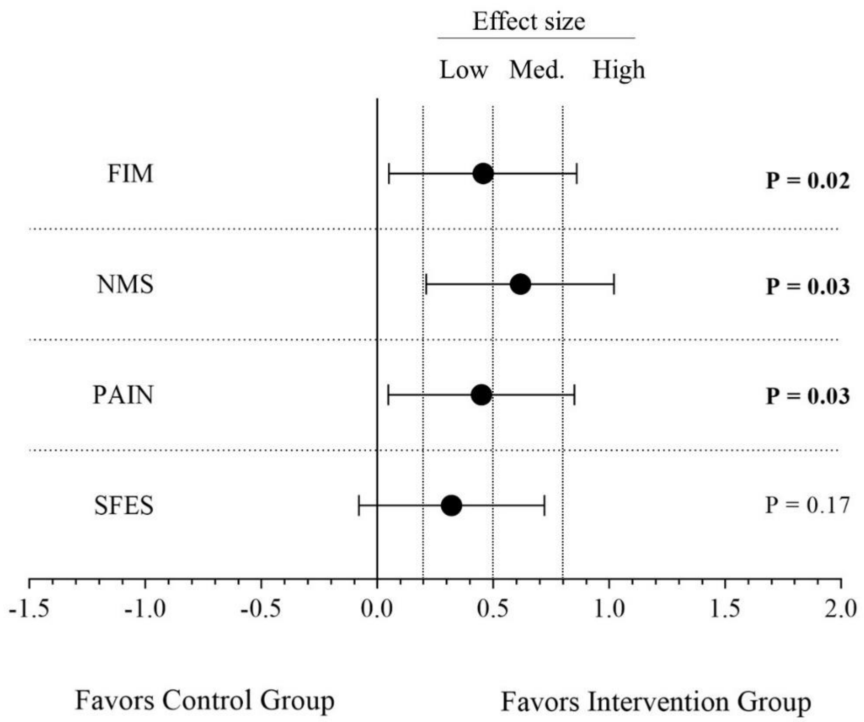

Figure 20. Effect sizes of the ActiveHip+ mHealth system in the functional status, pain and fear of falling (per-protocol analysis).

DISCUSSION

The aim of the present study was to determine the effectiveness of the ActiveHip+ mHealth system in increasing the functional status and decreasing fear of falling and pain in older adults with hip fracture. We found that the ActiveHip+ mHealth system is effective to recover the previous functional status and to reduce pain but not to reduce fear of falling.

In the present study, the older adults who followed the educational and tele-rehabilitation program delivered through the ActiveHip+ mHealth system had a significantly higher recovery of the functional status than those who received standard rehabilitation for a hip fracture provided by the Andalusian Public Healthcare system. These results support previous studies where older adults with hip fracture using apps during rehabilitation showed a higher recovery in their functional status in comparison to those receiving the usual care [109,111]. Because older adults with hip fracture identify functional status as their main recovery goal [22], the findings of the present study are important.

In this study, we found that those participants using the ActiveHip+ mHealth system reported significantly lower levels of pain than participants in the control group. These results confirm the preliminary finding from the ActiveHip+ feasibility study, where older adults with hip fracture using the system showed lower level of pain [307]. However, a previous study showed that an intervention consisting of occupational therapy tele-rehabilitation sessions performed during 3 weeks was not effective to lower pain in older adults with hip fracture [109]. This may be explained by the fact that, unlike this previous study, the ActiveHip+ mHealth system offers both a tele-rehabilitation and educational program. Indeed, some aspects of pain management (e.g., medication) are included in the ActiveHip+ educational section, which may lead to a better understanding and self-management of pain [308,309].

In the present study, the ActiveHip+ mHealth system did not prove to be effective for reducing fear of falling in older adults with hip fracture. To the best of our knowledge, there are no previous studies testing mHealth interventions for reducing fear of falling in hip fracture [183]. Our finding is in line with a systematic review showing that in-person interventions are effective to decrease fear of falling in older adults with hip fracture [184]. Because there is evidence describing the relationship of fear of falling with a higher avoidance of ADLs [43], which is related with a worse functional status [186], further mHealth systems should make a stronger emphasis in targeting fear of falling.

The adoption rate of the present study (88%) was higher than previous studies of digital health [272], which may be related to the highly restricted usual care offered to older adults with hip fracture. The usability results showed that, 82% of the participants in the intervention group used the ActiveHip mHealth system during at least 50% of the days and 37% of them performed at least 10 tele-rehabilitation sessions. These results are higher than those observed in our previous feasibility pilot study, where usage rate in terms of interactions and tele-rehabilitation sessions were 64% and 25% respectively [307]. Our results in terms of adherence are inferior to previous studies [109]. This may be explained by two facts. First, at some points of the recruitment, the training sessions in the use of the app before hospital discharge with older adults with hip fractures and family caregivers were not conducted in person with caregivers due to their restricted access to the hospital because of the epidemiological situation of COVID-19 [310]. Second, the intervention of the present study was 12 weeks, while previous interventions were considerably shorter (e.g., 3 weeks [109]. The overall satisfaction of the users (4.3/5) is considered good because it was higher than the cut-off value of 3.73 established for mobile health applications [296].

Limitations and strengths

This study has limitations. First, a mHealth system for the recovery of older people with hip fracture may not be generalisable because of potential barriers for some of them such as lack of skills or cognitive impairment [306]. This barrier could be overcome by the inclusion of family caregivers to support the older adults with the use of the app [112], as it was an inclusion criterion to have at least one caregiver with basic mobile phone skills. Second, we did not measure the participation of these caregivers in the recovery process in both the intervention and control groups, which may have influenced the older adults with hip fracture participation in rehabilitation [96]. The present study has also strengths. The main strength is its experimental design. Indeed, it is the first RCT study testing the effectiveness of a mHealth system developed to deliver a tele-rehabilitation program and an educational program both for older adults with hip fracture and their family caregivers.

CONCLUSIONS

This multicentre RCT study demonstrates that the ActiveHip+ mHealth system improves functional status and reduces pain in older adults with hip fracture. Nevertheless, the ActiveHip+ mHealth system was not effective in the decrease of the fear of falling in older adults with hip fracture. It should be acknowledged that the effectiveness of the ActiveHip+ mHealth system may be limited to older adults with hip fracture who have good IT skills and cognitive performance. Because mHealth enhances accessibility to rehabilitation and helps to address the existing overload in most healthcare systems, implementation of the ActiveHip+ mHealth system seems particularly relevant in older adults with hip fracture.

General discussion

This thesis aimed at improving the quality of care in older adults with hip fractures and their family caregivers using digital health interventions. This thesis includes 6 studies. Study I provides a quick and easy-to-use assessment tool (the New Mobility Score, Spanish version) needed by health providers in their daily clinical practice. Using this tool, health providers are able to tailor and individualise the patient's rehabilitation. Study II shows that tele-rehabilitation is effective in decreasing the fear of falling in older adults with a hip fracture. Moreover, study V demonstrates that a mHealth system is feasible in the recovery of older adults with hip fracture, which is particularly important in those patients with difficulties to receive rehabilitation. Similarly, study VI provides preliminary evidence supporting the effectiveness of the above mHealth system in improving the functional status of older adults with hip fracture as well as in reducing pain. It should be noted that, to develop feasible tools, it is essential to give stakeholders an active role during the different phases of the co-creation and implementation process of an mHealth system. Study IV described some of the needs to be implemented in digital health tools perceived by patients, caregivers and health providers to adapt tools to their reality, which can increase acceptance and adherence. Furthermore, study III evidences, on the one hand, the essential role of caregivers during the first months of recovery, as they can promote the active participation of patients in their own rehabilitation. On the other hand, this study highlights the need for caregivers to be included in the recovery process, receiving information on how to deal with the sudden situation of hip fracture. Table 12 shows the main findings of this thesis and its clinical implications.

Table 12. Summary of the main findings of the studies included in this thesis and its implications for clinical practice.

		Main findings	Implications for clinical practice
Section 1	Study I	- The Spanish version of the New Mobility Score (NMS-ES) is a reliable and valid tool to assess the functional status of older adults with hip fracture. - NMS-ES is a quick and easy-to-use tool to measure the functional status of older adults with hip fracture, both inside their home and outside.	- Health providers can use a quick and easy-to-use tool to assess the functional status, which can decrease their clinical practice burden without neglecting follow-up. - Facilitating follow-up of the functional status to health providers may increase the adaption and individualisation of the rehabilitation interventions.
Section 2	Study II	- Tele-rehabilitation decreases the fear of falling in older adults with hip fracture, but not in family caregivers´ fear of falling. - The fear of falling of older adults with hip fracture decrease is strongly related to the improvement in their functional status.	- Tele-rehabilitation is an option to be included in the clinical practice to decrease the fear of falling in older people with a hip fracture. - Decreasing older adults with a hip fracture' fear of falling may lead to increase their participation in their own activities of daily living (ADLs). - Intervention designed for the decrease of fear falling in older adults recovering after a hip fracture should be comprehensive. For this, they should be comprised by physical activity oriented to improve the development of ADLs, which could increase their self-efficacy. - Specific contents and interventions should be designed and developed for family caregivers to decrease their fear of falling.
	Study III	- @ctivehip tele-rehabilitation program was perceived as useful by family caregivers. They were highly satisfied with the intervention. - Family caregivers demand more communication with health providers during the process of recovery of their relatives. They also ask for a wide variety of exercises to avoid drop-outs due to repetitiveness.	- The use of tele-rehabilitation by older adults with hip fracture must be supported by family caregivers, who are younger and have better skills in using mobile phones or tablets. - Despite of the fact that the @ctivehip tele-rehabilitation is time-consuming, it was not perceived as burdensome. - Tele-rehabilitation intervention can bridge the communication gap between older adults and caregivers with health providers. To this end, future tele-rehabilitation interventions should include a channel to facilitate the communication and follow-up, as well as to be adapted to the older adult´s progression.

Section 3	Study IV	- Key stakeholders (older adults with a hip fracture, family caregivers and health providers) consider necessary to be included during the development process of a mHealth system. - MHealth systems for older adults with a hip fracture have to be user-friendly and simple. - Family caregivers of older adults with a hip fracture need to receive the information progressively and not all of it before discharge from hospital. - MHealth systems should include encouraging and positive messages as well as lived experiences of people with the same condition and a communication channel. - Information has to be on-demand so that older adults with a hip fracture and their family caregivers can use it exactly when they need it.	- Co-creating a mobile health (mHealth) system for the recovery of older adults with a hip fracture with the Key stakeholders is essential to improve the uptake and adherence. - MHealth systems can be an educational tool to provide appropriate information for the different phases of the recovery process. - Motivating older adults with a hip fracture through contents and notifications of an mHealth system can be an option to increase their participation in their recovery process in an active way.
	Study V	- The ActiveHip+ mHealth system is a feasible option for providing rehabilitation to older adults after hip surgery. - The ActiveHip+ mHealth system has been perceived as a good app in two different healthcare systems: with patients not having in-person rehabilitation and with patients who do.	- The ActiveHip+ mHealth system is a feasible option to be used during the recovery process of older adults after hip surgery in the clinical practice. - The ActiveHip+ mHealth system can be used as an educational tool in settings where in-person rehabilitation is available. - An extended in-person explanation during hospital stay is needed for better adherence and experience of use of mHealth systems in older adults after hip surgery and their family caregivers. - During the first weeks using an mHealth system, more intensive follow-up by health providers is required.
	Study VI	- The ActiveHip+ mHealth system is an effective option to undergo rehabilitation for older adults with hip fracture. - The ActiveHip+ mHealth system statistically significantly outperformed standard rehabilitation for a hip fracture.	- The ActiveHip+ mHealth system is a feasible option to be used during the recovery process of older adults after hip surgery in the clinical practice. - In-person training before hospital discharge is needed to overcome some barriers related with experience of use.

Characteristics of the sample

The sample of the studies II, V and VI of this thesis comprised older adults with hip fracture recruited in different periods, hospitals and countries, with an average age of about 75 years. The average age is lower than in previous studies conducted in older people with hip fracture [110,223], an injury whose average age ranges from 80-85 years [289]. This lower age may explain the high feasibility of the digital health interventions included in this thesis because younger patients tend to have higher their skills in the use of electronic devices are [200,292]. In this thesis, 70% of the sample are women, which is similar to the sex distribution of previous studies [109,113]. Additionally, we did not include older adults with hip fracture who had severe cognitive impairment. All the older adults with hip fracture recruited for studies II, V and VI were previously independent, so they may be more willing to engage in digital health rehabilitation in order to recover their previous functional status [22,311]. The rationale to include older adults without cognitive impairment and a previous high functional status was that both interventions, the @ctivehip tele-rehabilitation program and the ActiveHip+ mHealth system, were supervised by family caregivers at home and remotely supported by health providers. Thus, we considered those patients with a higher likelihood to attend to their family caregivers` instructions. In view of the aforementioned, it should be noted that the digital health interventions provided by this thesis may not be generalisable to all the population of older adults with hip fracture.

The importance of measuring functional status in older adults with hip fracture (Study I)

In hip fracture, functional status is a critical aspect for the recovery of older adults for a number of reasons. First, after hip fracture, there is a severe decrease in functional status [48]. Second, older adults consider their ability to carry out their daily life activities independently as a priority [22]. Last, functional status is a predictor of the recovery success [312]. Given the importance of the functional status of older adults with hip fracture, it is essential to be able to measure it adequately. To do so, it is necessary to provide health care providers with validated tools to measure it adequately. Nevertheless, one of the aspects to be improved during the recovery process of a hip fracture is the follow-up [54,157], which is limited due to the lack of resources [313] and the COVID-19 pandemic [85]. As health providers do not have enough time for each patient, inappropriate assessment and monitoring of hip fracture are common in older adults. We therefore developed the NMS-ES, a Patient Reported Outcomes Measure (PROM). This tool is reliable and valid to measure the functional status both inside and outside the home [91]. Moreover, the NMS-ES is quick and easy-to-use, which is considered essential in the daily clinical practice of health providers. The NMS-ES may help to improve the assessment and monitoring of functional status in older adults with hip fracture, contributing to individualise their rehabilitation.

The involvement of key stakeholders in designing and developing digital health interventions (Study IV)

It is well-known that involving key stakeholders during the development and implementation of digital health for rehabilitation [314,315] may enhance uptake and adherence because it ensures that the intervention is well aligned with the reality of patients, caregivers and health providers [114,115].

Thus, in study IV we aimed to obtain the perspectives and needs of key stakeholders of the hip fracture recovery process (patients, caregivers and health providers) on the use of digital health for the recovery. We aimed to obtain the perspectives of all key stakeholders as the recovery process involves a number of changes and responsibilities not only for patients, but also for caregivers and health providers. The benefits attributed to providing patients with an active role in their own recovery process have been reported [316], an approach considered necessary by the healthcare systems in different countries [317]. Nevertheless, scarce research has been conducted including older adults with hip fracture actively in the recovery process [93]. Moreover, as reported in study III caregivers also play an essential role in the recovery of older adults with hip fracture [247]. On the one hand, they are the main support of older adults with hip fracture, not only physically but also psychologically, since the older adult becomes totally dependent and usually depressed as they see their functional status after the surgery [22]. On the other hand, as caregivers share a great deal of time during the recovery process, they establish a strong relationship with older adults with hip fracture [60,207]. Due to this relationship, caregivers are extremely important in promoting participation in physical activity, Activities of Daily Living (ADLs) and rehabilitation programs for older adults with hip fracture [51]. In addition, health providers also play a critical role as they are expected to help older adults with hip fracture to regain their previous functional status [318]. Thus, interventions should not take only the patient into account [319] but also their caregivers [93,212] and health providers [320,321].

Some of the aspects we obtained in study IV were that mHealth systems have to be user-friendly and not burdensome to fit into daily life, which is line with the results of the study of Braun et al. [234]. In addition, the stakeholders highlighted the need of providing specific information for caregivers, a piece of advice previously reported in the literature [61,157]. Other key finding of study IV was that the information provided for patients and caregivers should be available on-demand, so that they can access it after hospital discharge when it is perceived as more necessary [247]. This piece of advice is in line with the existing evidence indicating that the caregivers' burden increases after hospital discharge, when they have to replace health providers as the main support of the patients [207]. Understanding how stakeholders need mHealth systems to be used effectively and sustainably could help to optimally develop tools to address complex hip fracture care [250,251].

Digital health: an option for older adults with hip fracture and their family caregivers (Studies II, V and VI)

In hip fracture rehabilitation, the priority is the recovery of the patients' previous both functional status and social life [66]. Although guidelines have been provided [83,322], the most common scenario is that there is a lack of resources that precludes following such guidelines in the rehabilitation of hip fracture [84]. In this context, digital health is a promising alternative to overcome accessibility-related barriers [323]. Before widely implementing digital health tools, their feasibility and effectiveness need to be demonstrated. Study II showed that the @ctivehip tele-rehabilitation program is effective in decreasing the fear of falling in older adults with hip fracture. Although previous studies did not test the effects of tele-rehabilitation in the fear of falling of older adults with hip fracture [183], there was evidence on the effects of tele-rehabilitation in other outcomes (e.g., functional status and the quality of life) [113,171]. The results of study II are in line with a previous systematic review where in-person rehabilitation was effective in reducing fear of falling of older adults with hip fracture [184]. Collectively, Study II adds a favourable evidence to the scarce literature on the use of tele-rehabilitation in older adults with hip fracture [211].

To decrease fear of falling is important because it is a common symptom in older adults with hip fracture and results in ADLs avoidance [43]. ADLs avoidance is related to a decrease in self-efficacy [45], which may lead to poorer recovery outcomes [192,193]. Therefore, it is necessary to find the best approach to decrease fear of falling. In this context, Study II showed that the decrease in fear of falling is mediated by recovery of functional status. This finding suggests that future interventions targeting fear of falling should be comprehensive, including physical activity aimed to improve the performance of ADLs, as they promote an increase in self-efficacy of older adults with hip fracture [45]. To test the effects of digital health interventions, a comprehensive evaluation of outcomes should be followed. Study II suggests that the inclusion of both objective (e.g., performance-based such as the SPPB) and subjective (e.g., PROMs such as the NMS-ES) seems to be advisable, which is in line with previous literature [194,195]. However, this requires that health providers have validated assessment tools of both types, which underlines the need for the study I of this doctoral thesis. In addition, study II also reported that the @ctivehip tele-rehabilitation program is not effective in decreasing caregivers' fear of falling. One possible explanation was that the @ctivehip tele-rehabilitation program did not focus on caregivers, which also underlines the need to include caregivers during the recovery process, as indicated in the studies III and IV [247,306]. Moreover, including caregivers in the recovery is necessary as their participation is a predictor of better recovery outcomes [207].

The ActiveHip+ mHealth system is the continuation of the @ctivehip program [170] developed following the co-creation process described in study IV of this thesis and the experience of the @ctivehip program described in studies II and III. Study V demonstrated that the ActiveHip+ mHealth system is a feasible option for delivering an educational and tele-rehabilitation program for older adults after hip surgery and their caregivers in two different healthcare systems (Spain and Belgium). It should be noted that the Spanish sample was comprised by older adults with osteoporotic hip fractures, meanwhile the Belgian sample was comprised by older adults hip osteoarthritis. The type of injury could be the main reason why the Spanish sample was older than the Belgian one [289]. In comparison to previous studies, the overall adoption rate of the ActiveHip+ mHealth system was high (78%) [272]. The overall acceptability of the app was also good (4/5) [296]. Although usability and satisfaction trends were similar in both samples, there were some differences between them that were probably driven by the sociodemographic characteristics of the two samples. The overall usability rate was higher in the Belgium than in Spain. This may be explained by the fact that the Belgian sample was younger, which is related to better skills in using mobile devices [200]. However, the usage rate in terms of the number of performed tele-rehabilitation sessions was higher in Spain. This may be explained by the fact that older adults after hip surgery are offered in-person rehabilitation in Belgium but not in Spain. Collectively, the ActiveHip+ seems to be feasible for older adults after hip surgery regardless of whether they are offered in-person rehabilitation (i.e., in Belgium) or not (i.e., in Spain).

Despite of the fact that the overall usage rate to tele-rehabilitation sessions was low, we are enthusiastic about the ActiveHip+ for a number of reasons. First, it was the pilot feasibility study which allowed us to get the experience of real users to fine-tune it, before developing the RCT of study VI. Second, it was conducted during one of the worst waves of COVID-19 [293], which did not allow in-person training with patients and their caregivers because the access to hospitals was highly restricted [294]. Considering the lack of skills with mobile devices of older adults with hip fracture [112], the absence of caregivers who are the main support using it, as reported on study IV, may have decreased the number of tele-rehabilitation sessions conducted [295]. However, we interpret these results highlighting the importance of training the patient and caregiver in the use of tele-rehabilitation tools prior to hospital discharge.

In terms of clinical outcomes, ActiveHip+ appears to be a promising option for the recovery of older adults after hip surgery. There were statistically significant improvements in both functional status and pain which supports previous studies showing digital health as an effective option in the recovery of older adults after hip surgery [109,110,113]. Accordingly, we developed study VI, a RCT to confirm the effectiveness of the ActiveHip+ mHealth system in the recovery of older adults with hip fracture. The ActiveHip+ mHealth system has been shown as effective in the recovery of the functional status, which is in line with previous studies implementing mHealth in the recovery of older adults with hip fracture [109,111]. Thus, mHealth can be an alternative to remotely support rehabilitation following an user-centered design, as the functional status is the main goal recovery of the own older adults with hip fracture [22]. We also observed that levels of pain were lowered in those patients using the ActiveHip+ mHealth system, which was not in line with a previous study showing similar post-intervention pain in the intervention and control groups [109].

Towards implementing digital health for the recovery of a hip fracture: barriers and facilitators (Studies III and IV)

Studies III and IV describe some of the barriers and facilitators perceived by the key stakeholders for implementing tele-rehabilitation and mHealth systems in the recovery of older adults with hip fracture and their family caregivers. The process of exploring the users' experience and including suggestions of stakeholders may improve the adoption and usage rate of digital health interventions, which is one of the biggest barriers [252]. Using in-depth interviews, Study III explored the experience of family caregivers of older adults with hip fracture who participated in study II. Participants were similar to previous studies, as the caregivers were offspring of the older adults with hip fracture [62,207], mainly daughters [157,300], middle-aged [52,60] and had support for caregiving [160,324]. Nevertheless, most caregivers of study III were employed at the time of the fracture, unlike a previous study [94].

Caregivers interviewed were highly satisfied with the @ctivehip tele-rehabilitation program. They found it useful and not burdensome, as was the case in other studies using ICTs focused on improving caregivers' communication and management skills [104,221]. Caregivers were concerned during the early days of the process that older adults with hip fracture may not recover their previous functional status. This is a fact to consider when addressing hip fracture recovery, as it has been reported previously [157] and is a concern shared by both the caregiver and the patient [45].

In studies III and IV, tele-rehabilitation and mHealth systems were perceived as possible options to provide older adults with hip fracture and their caregivers with information about the recovery process. This perception can contribute to overcome the existing evidence highlighting the need of providing patients and caregivers with information [105,318]. Information provision is noted as a beneficial approach for several reasons. First, it is described as a way to increase self-management of the injury in older adults with hip fracture [248], supporting the user-centered approach in rehabilitation [250]. Second, it has also been described as a way to decrease the burden and stress on caregivers due to the sudden situation [157]. Lastly, providing information allows caregivers to actively participate in the recovery process, which has been demanded previously [209,212].

However, it was reported on study IV that the provision of information must be tailored, individualised and on-demand, as it can increase the burden if it is not harmonised with the user's daily life, which is consistent with the results of study III [247]. It was stated that digital health has to be user-friendly, simple, which is consistent with a previous study implementing this type of delivery [242]. Implementing user feedback in development to follow a user-centered design approach is regarded as an approach to improve user adoption and experience [114,244].

Moreover, studies III and IV considered tele-rehabilitation and mHealth systems as options to improve the communication between patients and caregivers with health providers during the recovery process. Communication is essential during the transition to home after hospital discharge [104] as at this point, patients are totally dependent and caregivers have to assume most of the responsibility [22]. Nevertheless, it is needed to be integrated in the health providers daily clinical practice to ensure sustainability [246].

Despite some facilitators reported, studies III and IV also reported some of the barriers perceived by stakeholders. The main barrier was the high average age of older people with hip fracture, which has been stated in other studies. However, there is evidence supporting the use of digital health in older people [166,232], as the studies II and V of this thesis. Furthermore, this barrier can also be overcome with the help of family caregivers, as it is shown previously [113] in which a tele-rehabilitation program was delivered to older adults with hip fracture who were assisted by their caregivers. In addition, caregivers interviewed on study III highlighted two important findings: the need of a greater variety of exercises and the need of individualise the finishing of rehabilitation according to the condition of each older adult with hip fracture. In spite of the wide range of existing interventions for hip fracture recovery, there is no consensus or gold standard [325]. This may be explained by the fact that there are differences among older adults with hip fracture at the geographic level and at the socio-demographic level (e.g., level of education, social support) [14]. The success of digital health interventions in older adults with hip fractures depends to a large extent on a user-centered approach tailored to the user's context [225,254].

Limitations and strengths

A summary of the limitations and strengths of the present thesis is provided on Table 13.

Table 13. Limitations and strengths and of the studies included in this thesis.

		Limitations	Strengths
Section 1	Study I	- Despite reviewers being blinded during the assessment to the other reviewer´ rating, both reviewers were present during the assessment.	- Widely accepted protocol was followed to cross-culturally adapt and translate the scale. - A heterogeneous sample of older adults with hip fracture was included.
Section 2	Study II	- Allocations based on participants preference. - Results may not be generalisable to those patients with cognitive impairment or poor pre-fracture functional status. - Caregivers' involvement in the recovery was not measured. - The long-term effects of the program are unknown	- Longitudinal design. - First tele-rehabilitation intervention aiming to decrease the fear of falling.
	Study III	- Interviews with caregivers were conducted 3-6 months after they complete their tele-rehabilitation program. - Psychosocial factors of the caregivers were not analysed.	- User-centered design to explore the caregivers' experience after using the tele-rehabilitation intervention, which has served as a baseline for our next steps.
Section 3	Study IV	- Older adults having impairment after a hip fracture were not included in the focus groups. - Different categories of stakeholders were not mixed	- The inclusion of the three different group of stakeholders since the first phase for the co-creation process.
	Study V	- The study was not randomised. - The app was developed only for mobile phones. - Time spent in sections other than rehabilitation was not measured.	- The feasibility of the ActiveHip+ was tested in two different healthcare systems.
	Study VI	- The exclusion of patients with cognitive impairment and pre-fracture functional limitations may have resulted in selection bias. - The involvement of family caregivers in the recovery process was not measured.	- Design: randomised controlled trial.

Scalability and transference of this Doctoral Thesis

One of the strengths of the present thesis doctoral is the process beyond the development of a digital health tool for older people with hip fracture and their family caregivers focused on the implementation in real healthcare systems. The members of the @ctivehip and ActiveHip+ projects have developed an international dissemination network with different types of audiences, such as healthcare systems, hospitals, patients' organisations and some of the most scientifically valuable organizations involved in hip fracture, such as, the Fragility Fracture Network and the International Osteoporosis Foundation. During the development of the digital health project described in this thesis, 7 Intellectual Property Registries have been done. Our hope is that the digital health tools included in this thesis will be considered as an option for health providers in their daily practice so that a higher number of older people with hip fracture, family caregivers and health providers can benefit from it.

Within the framework of the projects described in this thesis, a collaboration agreement was established with the pharmaceutical company Amgen SA. This agreement enabled the ActiveHip+ project to reach secondary fracture prevention units. Consequently, the ActiveHip+ mHealth system has been implemented in several healthcare systems, as illustrated in Figure 21. Health providers of the following hospitals were trained to use in their clinical practice the ActiveHip+ mHealth system:

- Virgen de las Nieves University Hospital (Granada, Spain)
- Jerez de la Frontera University Hospital (Cadiz, Spain)
- Puerto Real University Hospital (Cadiz, Spain)
- Cruz Roja Hospital (Gijon, Spain)
- Sant Pau Hospital (Barcelona, Spain)
- Sureste Hospital (Madrid, Spain)
- Manises Hospital (Comunidad Valenciana, Spain)
- El Escorial Hospital (Madrid, Spain)
- Navarra University Hospital (Pamplona, Spain)
- Valle de los Pedroches Hospital (Cordoba, Spain)
- Valme Hospital (Seville, Spain)
- North Lisbon University Hospital Center (Lisbon, Portugal)
- AZ Delta Complex Hospitals (Leuven, Belgium)
- AZ Delta Complex Hospitals (Rumbeke, Belgium)
- AZ Delta Complex Hospitals (Torhout, Belgium)

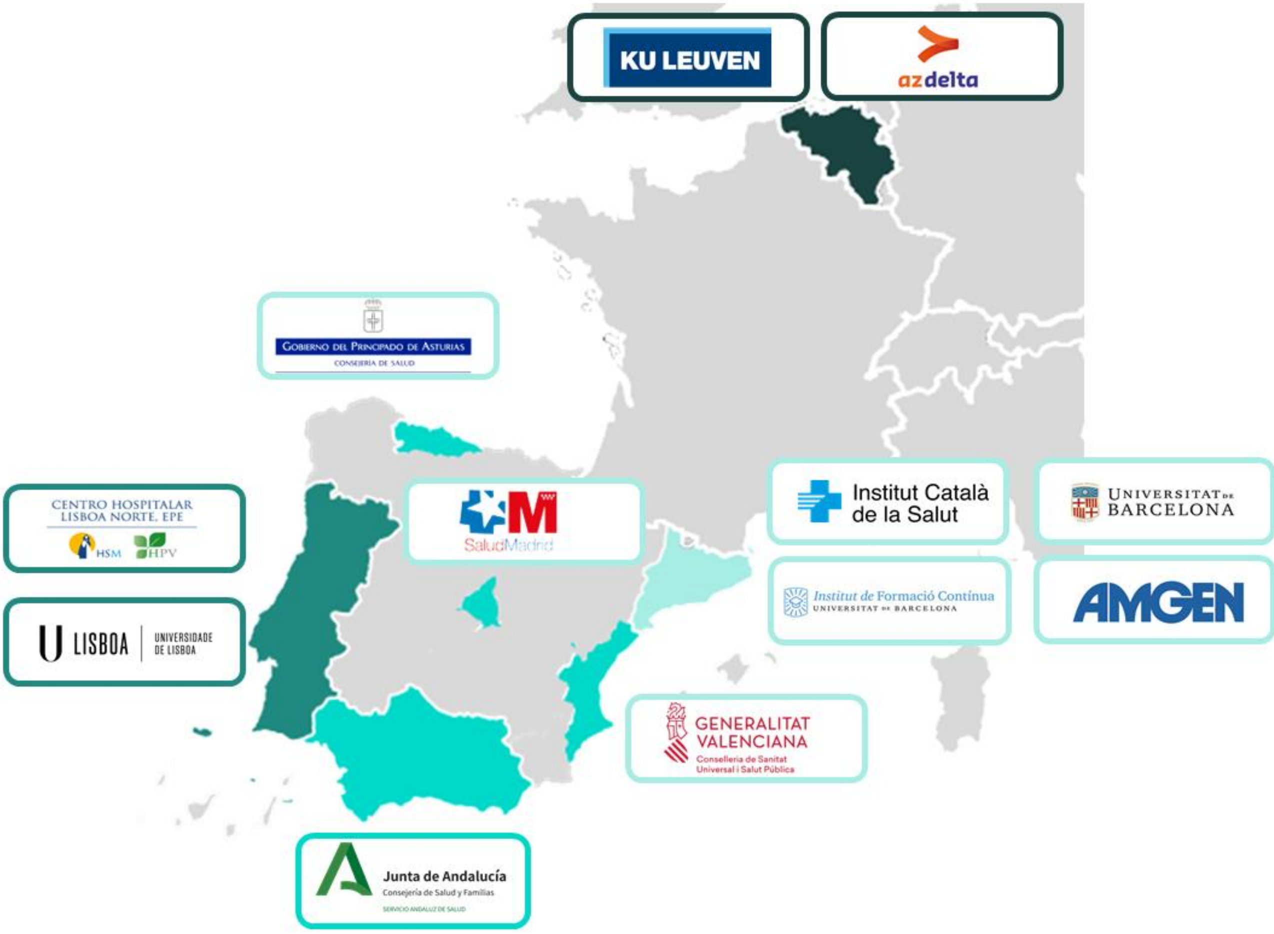

Figure 21. Geographical location of healthcare systems where the ActiveHip+ mHealth system has been implemented.

As a results of the collaboration with patient's organisations such as the Spanish Association for Osteoporosis and Osteoarthritis (AECOSAR) and the Osteoarthritis Foundation International (OAFI), we have developed a guide to be offered to older adults with hip fracture and their family caregivers. This guide describes (through text, illustrations and videos linked to QR codes) the process of recovering from a hip fracture, from the first days in hospital (before and after surgery) to the first days after discharge from hospital and some tips on how to prevent secondary fractures. Additionally, this guide provides information on how caregivers can take such a role. This guide was developed to complement the information provided through the ActiveHip+ mHealth system, as requested by some older adults and caregivers who preferred paper-based materials. To increase the population that can benefit from this guide, it can be printed and delivered in hospitals or downloaded from the ActiveHip+ project landing page https://www.activehipplus.com/.

Moreover, in this webpage and in the ActiveHip YouTube channel, there are more than 200 videos available about the recovery process of a hip fracture. These videos inform about aspects such as training of activities of daily living with and without the support of a caregiver, general recommendations explained by health providers regarding the recovery process (e.g., supporting devices, environmental adaption, physical activity) as well as strategies and tools to promote physical and mental well-being for both older adults with hip fracture and caregivers.

In order to increase the outreach of the ActiveHip+ mHealth system, we have developed a certified course for health providers to train them online in the use of the ActiveHip+ mHealth system. This course is certified by the Andalusian Healthcare Quality Agency (ACSA), which allows a greater number of health providers to be trained without the need of lectures, because the modality of the course is self-training. This may increase the number of older adults with hip fractures and family caregivers who benefit from the ActiveHip+ mHealth system.

In Annex 1 are provided some screenshots of the dissemination and implementation process.

Conclusions

General conclusion

The @ctivehip tele-rehabilitation program and the ActiveHip+ mHealth system are feasible and effective digital health tools which improve the quality of care of in older adults with hip fracture and their family caregivers. These both digital health tools have shown positive effects in essential aspects during the recovery process such as functional status or pain. However, for better performance and adherence to digital health in hip fracture recovery, it is necessary to analyse the experience of use as well as to include potential stakeholders (older adults with hip fracture, family caregivers and health providers) in the development process to include their needs and adapt the tools to them. Digital health tools are expected to be easy to use, to facilitate communication with the health providers as well as to provide individualised interventions and information related to both the recovery process and the prevention of future fractures.

Specific conclusions

Section I: Validation of the New Mobility Score Spanish version.

* Study I

- The New Mobility Score was translated and cross-cultural adapted into Spanish.

- The New Mobility Score Spanish version is a valid and reliable tool to be used to assess the functional status of older people with a hip fracture during the clinical practice of health providers.

Section 2: The @ctivehip tele-rehabilitation program for older adults with a hip fracture.

* Study II

- The @ctivehip tele-rehabilitation program was effective reducing the fear of falling of older adults with a hip fracture in comparison with the standard care for hip fracture recovery. Nevertheless, @ctivehip tele-rehabilitation program was not effective decreasing the fear of falling of family caregivers of older adults with hip fracture.

* Study III

- Family caregivers of older adults who used the @ctivehip tele-rehabilitation program were satisfied with it.

- @ctivehip tele-rehabilitation program is considered by family caregivers as a not burdensome and effective intervention for the hip fracture recovery process.

- The @ctivehip tele-rehabilitation program is a possible option to provide caregivers with information related to the intervention received by older adults with a hip fracture.

Section 3: The ActiveHip+ mHealth system for older adults with hip fracture and their family caregivers.

* Study IV

- Key stakeholders (older adults with a hip fracture, family caregivers and health providers) stated their perceptions about key elements to be included to develop appropriately a mHealth system.

- The mentioned elements were included in the ActiveHip+ mHealth system as the final step of the co-creation process.

* Study V

- The ActiveHip+ mHealth system is a feasible alternative to be considered in clinical practice to recover older adults after hip surgery.

* Study VI

- The ActiveHip+ mHealth system is effective in the recovery of the functional status and the decrease of the pain in older adults with hip fracture. Nevertheless, the ActiveHip+ mHealth system was not effective decreasing the fear of falling of older adults with hip fracture.

Conclusiones

Conclusión general

El programa de tele-rehabilitación @ctivehip y el sistema de salud móvil ActiveHip+ son herramientas de salud digital factibles y efectivas que mejoran la calidad asistencial de las personas mayores que sufren una fractura de cadera y sus cuidadores informales. Estas herramientas de salud digital han demostrado efectos positivos en aspectos esenciales del proceso de recuperación como la funcionalidad o el dolor. No obstante, para mejorar el rendimiento y adherencia de la salud digital en la recuperación de una fractura de cadera, es necesario que se analice la experiencia de uso y que se incluya a las personas implicados en el uso de este tipo de herramientas (personas mayores con fractura de cadera, cuidadores informales y profesionales sanitarios) durante el proceso de desarrollo, de forma que se incluyan sus necesidades. Para las personas implicadas, es esencial que las herramientas de salud digital se adapten a ellos. Estas herramientas deben ser fáciles de usar, facilitar la comunicación con los profesionales sanitarios y proporcionar tanto una intervención individualizada como información relativa al proceso de recuperación y a la prevención de futuras fracturas.

Conclusiones específicas

Sección 1: Validación de la versión española del New Mobility Score

* Estudio 1

- El New Mobility Score fue traducida y adaptada al castellano.

- La versión española del New Mobility Score es una herramienta valida y fiable para medir la funcionalidad de personas mayores con fractura de cadera durante la práctica clínica de los profesionales sanitarios.

Sección 2: El programa de tele-rehabilitación @ctivehip para personas mayores con fractura de cadera

* Estudio II

- El programa de tele-rehabilitación @ctivehip fue efectivo en la reducción del miedo a la caída en personas mayores con fractura de cadera en comparación con el cuidado estándar para una fractura de cadera. Sin embargo, el programa de tele-rehabilitación @ctivehip no fue efectivo en la reducción del miedo a la caída de los cuidadores informales de personas mayores con fractura de cadera.

* Estudio III

- Los cuidadores informales de personas mayores con fractura de cadera que usaron el programa de tele-rehabilitación @ctivehip se mostraron satisfechos con dicho programa.

- El programa de tele-rehabilitación de @conocimiento es considerado por los cuidadores familiares como una intervención no sobrecargante y efectiva para el proceso de recuperación de la fractura de cadera.

- El programa de tele-rehabilitación @ctivehip es una opción posible para proporcionar a los cuidadores información relacionada con la intervención que reciben los adultos mayores con fractura de cadera.

Sección 3: El sistema de salud móvil ActiveHip+ para personas mayores con fractura de cadera y sus cuidadores informales

* Estudio IV

- Las personas implicadas en la recuperación de una fractura de cadera (personas mayores con fractura de cadera, cuidadores informales y profesionales sanitarios) expusieron su opinión acerca de qué elementos consideraban necesarios incluir para desarrollar adecuadamente un sistema de salud móvil.

- Los elementos mencionados se incluyeron en el sistema de salud móvil ActiveHip+ como paso final del proceso de co-creación.

* Estudio V

- El sistema de salud móvil ActiveHip+ es una alternativa factible a considerar en la práctica clínica para la recuperación de personas mayores tras una cirugía de cadera.

* Estudio VI

- El sistema de salud móvil ActiveHip+ es efectivo tanto en la recuperación de la funcionalidad como en la disminución del dolor en personas mayores con fractura de cadera. Sin embargo, no fue efectivo en la disminución del miedo a la caída de personas mayores con fractura de cadera.

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Annexes

Annex 1. Summary of the dissemination network

Image 1. Lecture at the 2022 Xpatient Barcelona Congress.

Image 2. Lecture 3rd Conference on Innovation at the Virgen de las Nieves University Hospital, Granada, Spain.

Image 3. Lecture at the XXV Congress of the Spanish Society for Bone and Mineral Metabolism Research.

Image 4. Training sessions with health providers of the Hospital Cruz Roja, Gijon, Spain.

Image 5. Session at the 2022 European Researchers' Night.

Image 6. Collaboration with the Spanish Association for Osteoporosis and Osteoarthritis (AECOSAR) so that the guide developed in the ActiveHip+ project is available at their webpage.

Image 7. Training sessions with health providers of the North Lisbon University Hospital Centre, Lisbon, Portugal.

Image 8. Home of the certified online course developed to train health providers of the Andalusian Public Healthcare System in the use of the ActiveHip+ mHealth system.

Image 9. Landing page of the ActiveHip+ webpage where all the contents have been uploaded to be on-demand for anyone who is interested.

Image 10. Leaflet provided to patients and caregivers to facilitate the use of the app.

Curriculum Vitae

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