Programa @ctivehip: implicaciones en la sobrecarga de los cuidadores informales de pacientes mayores con fractura de cadera

@ctivehip programme: implications on family caregiver burden of older adults with hip fracture



UNIVERSIDAD DE GRANADA

Programa de Doctorado en Medicina Clínica y Salud Pública

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Granada, 2023

Editor: Universidad de Granada. Tesis Doctorales Autor: María Fernández González ISBN: 978-84-1195-192-0 URI: <u>https://hdl.handle.net/10481/89808</u> La doctoranda María Fernández González y los directores de la tesis Mario Lozano Lozano y María Patrocinio Ariza Vega

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ABSTRACT

Introduction: Hip fractures globally affect the elderly, with rising prevalence due to an aging population. Thus, it is anticipated to become a more significant problem in the coming years. Such fractures present as sudden events, impacting both the elderly and their family caregivers. While family caregivers play a crucial role during the recovery process after a hip fracture, providing substantial functional, emotional and support they often face unrecognized burdens and mental health challenges. Emerging technologies, like tele-rehabilitation, promise to enhance functional recovery for elderly individuals with hip fractures, yet their effects on caregivers remain underexplored.

Objective: To determine the impact of a tele-rehabilitation program, called *@ctivehip*, *on* caregiver burden, mental health, and physical activity levels in family caregivers assisting older individuals with hip fractures.

Methodology: In this non-randomized controlled trial, participants were family caregivers of older people with hip fractures. The tele-rehabilitation group (n=30) engaged in a 12-week multidisciplinary program using *@ctivehip*, while the control group (n=32) received traditional in-person rehabilitation from the Andalusian Public Health System. Measured variables included: i) caregiver burden using the Zarit Burden Interview, ii) anxiety and depression with the Hospital Anxiety and Depression Scale (HADS), and iii) self-perceived physical fitness level with the International Fitness Scale (IFIS).

Results: This study revealed no statistically significant differences in caregiver burden between those utilizing the @ctivehip tele-rehabilitation program and those receiving face-to-face rehabilitation, although there was a trend towards lower values [Mean (95%CI); 14.73 (9.09 to 20.37) vs 16.03 (10.63 to 21.43) points; p=0.771]. Informal caregivers in the @*ctivehip* group exhibited lower levels of anxiety and depression [5.66 (3.21 to 8.78) vs 11.19 (8.52 to 13.86); p=0.022] and slightly better physical fitness scores, though not statistically significant [19.37 (17.94 to 20.81) vs 17.15 (15.77 to 18.53); p=0.055].

Conclusion: Utilizing *@ctivehip* tele-rehabilitation program is not associated with an increase in caregiver burden. Furthermore, the *@ctivehip* program is linked to lower levels of anxiety and depression compared to in-person rehabilitation. Finally, there is no association with respect to physical fitness levels.

RESUMEN

Introducción: la fractura de cadera es un problema a nivel global que se produce en mayor parte en personas mayores. Debido al aumento de edad de la población, es un problema que se espera, sea mayor en los próximos años. La fractura de cadera es un evento inesperado para pacientes mayores y sus cuidadores informales. Durante el proceso de recuperación tras la fractura de cadera, los cuidadores informales adquieren un papel fundamental. Este papel es de gran importancia en la recuperación funcional y el apoyo emocional y social que los cuidadores informales dan a los adultos mayores. A pesar de la gran importancia de los cuidadores informales en el proceso de recuperación, estos no se encuentran reconocidos y apoyados durante el proceso. A veces, muestran sobrecarga y una peor salud mental. El uso de nuevas tecnologías ha emergido como una opción para mejorar la recuperación funcional de las personas mayores con fractura de cadera, pero no hay evidencia a cerca de los cuidadores en este sentido.

Objetivo: determinar si el uso de un programa de tele rehabilitación llamado @ctivehip para personas mayores con fractura de cadera, llevado a cabo con el apoyo de los cuidadores informales, puede aumentar la sobrecarga y afectar en su salud mental y nivel de actividad física.

Metodología: en este ensayo controlado no aleatorizado, los participantes fueron los cuidadores informales de personas mayores con fractura de cadera. El grupo de tele rehabilitación (n=30) llevó a cabo un programa multidisciplinar de 12 semanas, de tele rehabilitación con el uso de @ctivehip. El grupo control (n=32) recibió la rehabilitación cara a cara por parte del Sistema Público Andaluz de Salud. Las variables que se midieron fueron; i) sobrecarga del cuidador con el Zarit Burden Interview, ii) Ansiedad y depresión con la escala Hospital Anxiety and Depression Scale (HADS), y iii) el nivel auto percibido de forma física con Internacional Fitness Scale (IFIS).

Resultados: este estudió mostró que no hubo diferencias estadísticamente significativas en la sobrecarga de los cuidadores que utilizaron el programa de tele rehabilitación (activehip frente a aquellos que siguieron la rehabilitación cara a cara, aunque hubo una tendencia hacia valores más bajos [Mean (95%CI); 14.73 (9.09 a 20.37) vs 16.03 (10.63 a 21.43) puntos; p=0.771]. Los cuidadores informales del grupo que utilizó (activehip mostró niveles menores de ansiedad y depresión [5.66 (3.21 a 8.78) vs 11.19 (8.52 a 13.86); p=0.022] y mejores puntuaciones en el nivel de forma física, aunque este último no mostró valores estadísticamente significativos [19.37 (17.94 a 20.81) vs 17.15 (15.77 a 18.53); p=0.055].

Conclusión: el uso del programa de tele rehabilitación @ctivehip no está relacionado con el aumento de la sobrecarga del cuidador. Además, el programa @ctivehip se asocia con menores niveles de ansiedad y depresión frente a aquellos que siguieron la rehabilitación cara a cara. Finalmente, no existe una asociación con respecto al nivel de forma física.

ABREVIATIONS

ADLs	Activities of Daily Living
BMI	Body Mass Index
CI	Confidence Interval
FIM	Functional Independence Measure
ICT	Information and Communications Technologies
ОТ	Occupational Therapist
РТ	Physiotherapist
SPPB	Short Physical Performance Battery
TUG	Time Up and Go

INTRODUCTION

Hip fracture represent a significant public health issue due to four key factors: (i) its elevated incidence rate, (ii) high mortality, (iii) loss of functional autonomy for performing Activities of Daily Living (ADLs), and (iv) substantial economic consequences linked to the care process (1). These fractures not only disrupt the lives of the older adults but also significantly impact their environment, including their family caregivers (2,3).

HIP FRACTURE PROBLEMATIC

Incidence

Globally, the incidence of hip fracture exceeds 14.2 million cases annually (4). Notably, over 70% of fractures occur in females, and more than 40% affect individuals aged 85 years or older (5). The incidence of hip fracture increases exponentially with age (6), with projections indicating a marked increase by 2050 (7). As reported by the World Health Organization (WHO) (8), this is partly due to the anticipated 4.5-fold increase in the global population aged over 85 years by that year, which is expected to lead to a rise in hip fracture cases, reaching 6.26 million cases (9).

In Europe, hip fracture cases are reaching 830,00 cases per year (10), with variations in incidence across different countries. Northern European countries report a higher number of cases (11). In Spain, the risk of hip fracture is considered moderate, with a total of nearly 40,000 hip fractures per year (12,13), being almost entirely in people over 65 years (14). Andalusia (351.52/100,000 inhabitants*year) ranks fifth among Spain's 19 regions in terms of incidence, with the highest incidence after Ceuta (356.71/100,000 inhabitants*year), Castilla la Mancha (359.64/100,000 inhabitants*year), Catalonia (361.79/100,000 inhabitants*year) and Valencia (363.13/100,000 inhabitants*year) (15).

Similar to the global trends, most of the hip fractures in Spain occur in women (76,5%), with a median age at the time of fracture of 86,88 years (16).

Spain boasts one of the highest life expectancies among countries (17). By 2037, it is projected that a significant 26% of the Spanish population will be individuals aged 65 and above (18). Moreover, the number of centenarians is anticipated to quadruple within the next 15 years. Spain's high life expectancy, associated with the fact that the incidence rate in people over 85 years of age is increasing by 0.58% (19) per year presents hip fracture as a major challenge to health and social care systems.

Mortality

Globally, the median one-year mortality rate following a hip fracture is 22.8 (20). When comparing by geographical regions, Europe exhibits a higher one-year mortality rate (23%) compared to Asia (15%), despite both regions having a similar median age for hip fracture occurrences (21). In Spain, 8.9% of older people die within 30 days of suffering a hip fracture (16). As the incidence of hip fracture rises, a corresponding increase in mortality rates is observed (22,23). Notably there has been a 2% annual increase in the one-year mortality rate (24).

Among older adults who undergo surgery, the one-year post-fracture mortality rate is nearly 24% (25), compared to 11% for healthy individuals with similar characteristics (26). Besides, surgical complications increase the risk of early mortality (27). Incidence is higher in women, but mortality is higher in men, ranging from 30 to 60% one year after hip fracture. In addition to gender and surgical complications, there are other factors that influence the increase of mortality in people who undergo a hip fracture: the presence of cognitive impairment (28–30), cardiovascular diseases (29,31), comorbidities (32), and a

low functionality level before de fracture occurs (28,30). So, frailty can be considered the main predictor of one-year mortality after hip fracture (33).

Loss of Functional Autonomy

Older adults experiencing a hip fracture can suffer a functional decline of up to 50% in the initial month compared to their prior functional status. This is followed by a 25% decline at three months and a 12% decline after one year (34). Such a significant restriction in functionality adversely affects the older adult's occupational performance (35). Between 60% and 80% of these individuals require assistance with basic daily activities, such as dressing or toileting (36). One year post-fracture, 50% of older adults encounter challenges in walking independently (37), while another 50% fail to regain their former function in ADLs (38,39). Hence, the primary objective for patients during the recovery process is to restore pre-fracture functionality (40), and the final aim is to recover their previous life, including social participation.

The reduction of the functional status is the most evident lost after a hip fracture and it is related to several factors. Advanced age is a predictor of both, mortality and poor functional outcomes (41). Older adults with dementia and delirium have been associated with a lower probability of recovering their previous functional level and with poor functional outcomes (42,43). Also, their pre-fracture functional status is a predictive factor to functional recovery in elderly patients after hip fracture (44). All this factors are associated with a functional recovery in short (<6 months) and long term (\geq 6 months) (44). Residing from residential care, along with other factors, may also reduce the chances of recovering the previous functional status (45) in short and long term (44). Pre fracture independence in basic ADLs are associated with recovery of function in short

(eating, bathing and bladder management) and long term (bathing) as instrumental ADLs independence is associated to long term recovery (44).

Also, other aspects will be affected by the loss of function. Hip fractures influences the routines and social connections of older adults who suffer them, conducting patients into isolation, a reduction of social participation (3) and a decline of quality of life (34,46). Additionally, their mental state is influenced by the prolonged recovery process and the abrupt shift towards dependency (40).

Economic cost

The economic impact of hip fractures includes both direct and indirect costs. The main direct costs are related to hospitalization, the recovery period and potential referrals to nursing homes (7). On overage, the cost of hospitalization for individuals with hip fractures is approximately 9,133 \in , escalating to 39,911 \in when considering the entire year-long recovery process (47,48). In Europe, hospitalization cost is different depending on the location, ranged from 5,306 \in in Slovenia (49) to more than 68.000 \in in Norway, which is the highest (50). The notably higher healthcare costs in Norway are primarily due to its extensive and comprehensive post-hospital care, including thorough medical monitoring, rehabilitation, and home assistance, which demands considerable investment in resources and personnel (50).

In Spain, patients who suffer a hip fracture spend an average of 10.29 days at hospital and long rehabilitation periods are required (40). The total cost of a hip fracture in our country is around 9.700 \in (14). Although, as in the case of Europe, the cost of hip fractures in Spain depends on the Region in which they occur (14). Differences of economic cost in regions are mainly caused by the length of the stay and the follow-up outpatient care,

which is longer in Madrid or Galicia. (51) Within the total expenditure on each hip fracture, most of it, is spent on hospital care, and only 9% on home care (52).

Short hospital stays in regions such as Andalucía, may suggest that out-of-hospital care is provided by informal caregivers (52). The time and activities carried out by informal caregivers have a large economic cost that is often not reflected in analyses, but it has been recently quantified as a monetary valuation ranging from 18,871 million \in to 53,299 million \notin per 4193 million hours of informal caregiving (53). The indirect cost are related to the impact of the hip fracture on the older adult life and their family caregivers, who usually have to make the care of their relatives compatible with their work and other responsibilities (54).

RECOVERY PROCESS

Older adults

When a hip fracture occurs, surgical repair is usually the primary treatment option(55). Surgery has a high success rate and positive clinical outcomes, reducing mortality and morbidity when it is provided during the first 24 hours (55–58). After hip fracture surgery, early rehabilitation is of vital importance (59), both during hospital stay and after hospital discharge (60), which is recommended by clinical practice guidelines (61–63). This early and continuous rehabilitation aims to recover the previous functional status having a positive impact on social participation and quality of life (37,60,64).

There are some fundamental aspects related to recovery process (61). As mentioned above, one of the key factors is to start rehabilitation in the acute phase (65), therefore it is recommended to weight bear in the same day of surgery or in the following 24 hours (66). Another important aspect is to have a multidisciplinary management after hip fracture (67,68). This team can carry out rehabilitation treatment combining physical exercise (69,70) and occupational therapy, focusing on training in ADLs (71–73). Also, exercise training emerged as the most effective intervention for promoting the safety of older adults after hip fractures on returning home (74). Occupational therapy interventions have demonstrated that improves health perception and emotions (75). However, the limited resources make it challenging to continue rehabilitation posthospital discharge, having only a few session during hospital stay (76).

Key role of family caregivers

In Spain, half of the older adults who suffer a hip fracture return home after hospital discharge (16). Once home, they often find themselves dependent and in need of assistance to perform their ADLs (40), so caregiver availability has emerged as an important predictor of home discharge (3). In countries like Spain, caregiving is predominantly provided by an "informal caregiver", i.e. a family member or relative of the patient (54), who does not receive financial remuneration (77). Family caregivers play an essential role during recovery process, providing substantial, physical, emotional and social support (46,78). Moreover, not only do they encourage participation in rehabilitation (79), also provide a sense of safety to the older adults, which is crucial for improving their mobility and activity levels (80).

Hip fracture occurs unexpectedly and, therefore, family caregivers has very little time to adapt to their new responsibilities and role (54), without the necessary knowledge or skills in most of the cases (81). The impact of a hip fracture on family caregivers' lives has been reported in the literature. Near to 90% of family caregivers need to change their routines and reorganize their daily tasks (54), even apply for a reduction of work time. Only 50%

of family caregivers maintain full time jobs (8 hours) (81). In addition to burden, family caregivers experience physical and mental health problems, such as anxiety and depression (82,83), leading to a decreased quality of life (84). The quality of life and depression status of family caregivers tend to deteriorate substantially in the first 3 months (85) following the fracture, but is even worse one year after (47). More of 40% have problems in combining the care of their relative with hip fracture and their own personal activities (83). For those reasons, hip fracture has a direct impact on the health of family caregivers (86).

The need to address the issue of informal caregivers has been reported, especially in those countries where the age of the population is expected to increase, as Spain (87). The psychological well-being of the family caregiver is closely linked to the mental health of the older adult with hip fracture; improvements in one often boost the well-being of the other, and vice versa, (88). A better preexisting relationship between patient and family caregiver means a lower caregivers burden (89). Even family caregivers mental health is an important predictor of patients' institutionalization (90). Also there is a relationship between family caregivers' mental health and recovery outcomes of elderly patients with hip fracture (91). Caregiver burden also adversely affects their own physical and mental health perception (92).

Despite the essential role of informal caregivers in the recovery process, they are not recognized and supported during this period (81). They are sometimes described as "hidden patients" who need to be integrated into the hip fracture treatment pathway (85). Family caregivers have demanded more information about the older adults' transition to home (93) and to be more involved in the decision-making process during the hospital stay of their relatives, and care transitions (93,94). They have also suggested the use of technology to improve communication and dissemination of knowledge (95), and despite

some existing interventions (96,97), it is necessary to create more resources and tools that can respond to their needs, playing a more active role in the acute phase (78,83).

USE OF NEW TECHNOLOGIES IN HIP FRACTURES

One of the key factors in improving and accelerating the recovery process of older adults with hip fracture is the inclusion of a rehabilitation programme in the short and medium terms (98). Digital health, defined as "the use of information and communication technologies (ICT) in medicine and other health professions to manage illnesses and health risks and to promote well-ness", encompasses mobile health, telerehabilitation, telehealth, wearable devices, health information system, and telemedicine (99). Cost-effective digital health tools allow caregivers to reduce and manage public expenses related to hospitalization and long-term services and support (100).

Telerehabilitation, understood as the provision of rehabilitation services at distance (101), has emerged as an option that can facilitate the follow up by health professionals, reduce the need for hospital visits and allow patients to undergo rehabilitation at home (102). Another benefit of telerehabilitation is that it encourages patient engagement in their own treatment (65) and helps them identify difficulties in ADLs at home, enhancing their sense of security (103,104).

Telerehabilitation is more effective than traditional rehabilitation in managing various musculoskeletal disorders (105), and there is well-established scientific evidence in relation to diseases as cognitive impairment (106), dementia, cancer (107), late life disability (108)and heart disease (109) in relation to patients outcomes . However, there is limited information on how telerehabilitation might help or burden family caregivers. Scientific evidence shows that caregivers do not pose a burden when carrying out this

telerehabilitation in stroke patients (110,111). There have been a few studies on the use of telerehabilitation in hip fracture (112,113), also including caregivers as an essential part of the treatment (114), but no outcomes were reported yet on them.

SUMMARY OF THE CONTRIBUTION OF THIS THESIS

In this context, we developed @*ctivehip*, a telerehabilitation programme for older adults with hip fracture in which family caregiver had a very active role, supporting them at home (115). This approach was informed by the findings and caregiver demands identified in a previous study we conducted in Spain (116). The role of family caregivers was essential to assist older adults in using new technologies and ensure their safety during the performance of the exercises and activities at home (117). Nevertheless, one of our main concerns was how the programme, which has been useful in improving the functional recovery and quality of life of older adults (118,119), could have affected the overall health of their family caregivers.

Addressing this gap in the literature, this International Doctoral Thesis seeks to contribute by providing knowledge about:

- The description of caregiver burden, psychological factors and physical fitness of family caregivers of older adults with hip fracture during the first three months after surgery.
- The effects of a telerehabilitation programme for older adults with hip fracture on caregiver burden, psychological factors and physical fitness of their family caregivers.

AIMS

The general aim of this International Doctoral Thesis is to analyze the effects of a telerehabilitation programme for older adults with hip fracture called *@ctivehip*, carried out with the support of their family caregivers on the overall health (understood as a state of complete physical, mental, and social wellbeing) (8) of this family caregiver.

Related to the general aim of this International Doctoral Thesis, we differentiate a series of specific objectives detailed below:

Specific objective 1: to analyze the association in relation to caregiver burden on those who follow the *@ctivehip* telerehabilitation programme versus those who follow face-to-face rehabilitation.

Specific objective 2: to analyze the association in relation to caregiver's psychological factors on those who follow the *@ctivehip* telerehabilitation programme versus those who follow face-to-face rehabilitation.

Specific objective 3: to analyze the association of caregivers' fitness level on those who follow the *@ctivehip* telerehabilitation programme versus those who follow face-to-face rehabilitation.

Specific objective 4: to assess the influence of other characteristics on the different outcomes studied both, in the use of *@ctivehip* telerehabilitation programme and in face-to-face rehabilitation.

OBJETIVOS

El objetivo general de esta Tesis Doctoral Internacional es analizar los efectos de un programa de tele-rehabilitación para personas mayores con fractura de cadera llamado *@ctivehip*, el cual es llevado a cabo con el apoyo de sus cuidadores informales en la salud general (comprendida como un estado de bienestar físico, mental y social) (8) de dichos cuidadores informales.

En relación con el objetivo general de esta Tesis Doctoral Internacional, se diferencian una serie de objetivos específicos detallados a continuación:

Objetivo específico 1: analizar la asociación en relación con la sobrecarga de los cuidadores que siguen el programa de tele-rehabilitación @*ctivehip* frente a aquellos que siguen el sistema de rehabilitación cara a cara.

Objetivo específico 2: analizar la asociación en relación con los factores psicológicos de aquellos cuidadores que siguen el programa de tele-rehabilitación @*ctivehip* frente a aquellos que siguen el sistema de rehabilitación cara a cara.

Objetivo específico 3: analizar la asociación en relación con el nivel de forma física de aquellos cuidadores que siguen el programa de tele-rehabilitación @*ctivehip* frente a aquellos que siguen el sistema de rehabilitación cara a cara.

Objetivo específico 4: evaluar la influencia de otras características en las variables medidas tanto en el uso del programa de tele-rehabilitación @*ctivehip* como en la rehabilitación cara a cara.

METHODS

To achieve the objectives, set out in the previous section of this International Doctoral Thesis, the following methodology is described.

STUDY DESIGN

This single-blinded, non-randomized clinical trial was carried out at the Orthopedic acute care unit of the "Virgen de las Nieves" University Hospital (Granada, Spain), and it was approved by the Research Ethics Committee of Granada Research (CEI-GRANADA). The protocol was registered at ClinicalTrials.gov (Identifier: NCT02968589). The trial was developed according to the established guidelines by the Helsinki Declaration and Law 14/2007 on Biomedical Research. This clinical trial was mainly design for older adults with hip fracture and took into account their preferences (120) as we wanted to test the results after the implementation in their real daily routines. However, the important role of family caregivers, in the task of supporting their relatives during the use of the tele-rehabilitation programme was a key meeting to conduct the present study. A nonrandomized design was chosen due to some factors: a) telerehabilitation was new for these patients (121) and required access to a computer and the internet, so the use of ICTs could be a major challenge; and b) the ethical issue linked to the number of rehabilitation sessions these patients would receive at home was considered, as patients using the rehabilitation programme would benefit from more sessions, even if these were supervised by family caregivers rather than health professionals. The study design did not resolve the ethical issue as despite offering rehabilitation to participants who did not undergo rehabilitation at the end of the study, the first three months after fracture are the most important in terms of functional recovery (34).

POPULATION

Participants in the present study were the family caregivers of older adults with hip fracture who participated in the afore mentioned clinical trial. All older adults and their family caregivers were invited to enroll in the study if the older adults met the following inclusion criteria: (1) had undergone hip fracture surgery; (2) aged 65 years or older; (3) reported a high pre-fracture functional level (Functional Independence Measure (FIM) index > 90 points) in the week prior to the fracture; (4) allowed weight-bearing within 48 hours post-surgery; (5) discharged to their own (or their relative's) home following hospitalization, not to an institution; (6) had a family caregiver; (7) had internet access and/or a family caregiver with internet access; and (8) agreed to participate in the study by signing the informed consent form. Older adults were excluded if they (1) had severe cognitive impairment (Score below 24 points on the Mini-mental State Examination) (122); (2) had a terminal illness with which they were not expected to live beyond 6 months; or (3) had any post-surgery complications that made it impossible to begin rehabilitation during the first week after surgery. Family caregivers of excluded older adults were not invited to participate in the study.

RECRUITMENT, ALLOCATION AND BLINDING

The recruitment was conducted at the "Virgen de las Nieves" University Hospital of Granada, from January 2017 to July 2018. Eligible older adults, along with their family caregivers were invited to join the study by an occupational therapist (OT) or a physiotherapist (PT) associated with the study. Older adults with a hip fracture and their family caregivers were presented with two allocation options:

- Telerehabilitation group: this included a) usual care during hospital stay (2-5 rehabilitation sessions), b) an educational workshop, and c) the @*ctivehip* telerehabilitation programme (maximum of 60 sessions).
- 2. Comparative group: participants in this group received a) usual care during hospital stay (2-5 rehabilitation sessions), b) an educational workshop, and c) the usual post-discharge rehabilitation provided by the Andalusian Public Healthcare System, consisting of face-to-face rehabilitation at home (5-15 sessions).

Due to the study design, and the fact that the older adults and their family caregivers personally selected their preferred group, blinding them to group allocation was not feasible. However, to maintain objectivity in data collection and analysis, the OT, the PT and the sport scientist who collected data were blinded to the group allocation. At the same time, the statistician, the OT and the PT that performed the data analysis were also blinded to group allocation.

INTERVENTION

Common elements for Both Groups: Usual Care during Hospital Stay and Caregiver's Workshop.

a. Usual care during hospital stay: older adults in both groups following a hip fracture, received the usual care during the hospital stay. This included 2-5 rehabilitation sessions. Besides, an informative leaflet with (imagen 1) recommendations and home exercises were given to the older adults and their family caregivers during the hospital stay.



Image 1. Informative leaflet with recommendations and home exercises

- b. Caregiver's Educational Workshop family caregivers from both groups were also invited to participate in educational workshops conducted at the hospital. These workshops, led by an OT and a PT, were held twice weekly. Family caregivers had the flexibility to attend as many sessions as desired during their relative's hospitalization. The workshops included two main components using the teachback method based on a previous study (123):
 - Background knowledge, information and recommendations for hip fracture recovery including mobilization, nutrition or home environment recommendations.
 - Practice of caregiver's hand-on skills such as supporting older adults during walking, climbing stairs, transferring and performing other activities of daily living (e.g., bathing, dressing, toileting).

A typical workshop included 8 participants and lasted approximately one hour. The workshop concluded with a group discussion. To reinforce learning, health professionals provided written materials and links to online videos, and material to family caregivers to complement the workshop material. A detailed description of the contents provided in the workshops is provided in table 1.

1 <i>uit</i> 1. Duo	nground knowledge (35 minutes)
1. Common beliefs about hip fracture (10 minutes)	This section provided the opportunity for the health professionals to understand family caregivers' knowledge of hip fracture (e.g., mortality, functional recovery) and to encourage dialogue on misperceptions, countered with presentation of current evidence.
2. Brief description of hip anatomy and biomechanics, classification of hip fracture, surgery, and postoperative mobility prescription (2 minutes)	This section provided general information, including an overview of activities to avoid early after surgery for hemiarthroplasty.
3.Pain management (3 minutes) (124–127)	Here, health professionals engaged family caregivers on "typical" patterns of pain experience after hip fracture. There was a general discussion on analgesic medication and its use specifically before walking practice. An emphasis was placed on controlling pain but remaining active. Family caregivers were encouraged to consult with the doctor and nurses if pain persisted.
4. Mobilization after surgery (5 minutes) (124,127,128)	This section generated discussion on early mobilization (walking) and completion of ADLs 24 hours after surgery (if indicated). The emphasis was on supporting older adults to do as much as possible, even though tasks may take longer to complete in the first few days. The health professionals offered practical advice for encouraging the return to independence in functional activities.
5. Rest (2 minutes) (124)	This section emphasized the importance of rest in recovery: both rest periods during the day and sleep hygiene at night.
6. Hydration and nutrition (3 minutes)	There was discussion on the importance of maintaining adequate hydration and optimal nutrition to support the recovery process.
7. Supportive devices for ADLs and mobility (5 minutes) (128)	Health professionals explained, with examples, some ADL devices (e.g., long shoehorn, raised toilet seat, bath transfer bench) and walking aids (e.g., walker, rollator, elbow crutches, and cane).
8. Home environment recommendations (5 minutes) (128)	safe home environment: one that supported older adults to move but considered reducing fall risk factors, such as encouraging the adoption of clear paths between rooms, adequate handrails, and supportive lighting.

Part 1. Background knowledge (35 minutes)

Part 2. Practice session (30-40 minutes)

This section of the workshop was aimed to develop caregiver knowledge, skill, and confidence to support their family member/friend with hip fracture. An emphasis was placed on caregivers' watching their own health and biomechanics to avoid back and other related injuries. The health professionals had a 2-step process of knowledge transfer and skill development. First, they explained the activity/exercise (with 1 caregiver who volunteered to act as a "patient"). Following this, caregivers formed pairs (dyads) to practice the activities. In these practice dyads, one caregiver took on the role of an older adult with hip fracture, and the other was the caregiver. Then, the caregivers switched roles and completed the activities again. This was done intentionally so that caregivers gained experience from different perspectives. The health

professionals circulated between the dyads and offered suggestions to improve the delivery of care in a safe manner. Practical components included a demonstration and discussion of:

1) moving/transferring in and out of bed; 2) walking using different walking aids; 3) ascending and descending stairs; 4) basic ADLs (dressing, showering, bathing, etc.); and 5) balance and strength exercises.

Telerehabilitation Group (@ctivehip)

The older adults in the telerehabilitation group participated in a 12-week multidisciplinary telerehabilitation programme called @*ctivehip*, supported by their family caregivers at home. The programme included physical exercise and occupational therapy sessions as well as recommendations, supportive devices information or information about prevention for older adults and their family caregivers provided through the now-inactive website (www.activehip.es).



Image 2. Recommendations for patients and family caregivers on the website
Older adults following the programme could complete up to five online sessions weekly, each lasting from 30 to 60 minutes through *the @tivehip* online platform. The programme comprised.

- Three physical exercise sessions: including lower and upper body strengthening, balance, and cardiovascular exercises.
- Two occupational therapy sessions: focused on self-care activities and walking aids, the safest way to perform activities of daily living, and options for creating a safer home environment to prevent new falls.

The @*ctivehip* programme has four levels of difficulty. Older adults were assigned to one level based on the Functional Independence Measure and Time Up and Go test performed at baseline assessment. A detailed description of the programme is provided in Tables 2 and 3. Older adults were able to change difficulty level as they progressed based on three questions related to pain, fatigue, and perceived difficulty of the session. Each session was performed at home including written instructions and pre-recorded instructional videos with activities and exercises appropriate to the older adults' functional status. Older adults and their family caregivers were able to watch videos as many times as they needed.

Table 2. Description of activities to train in sessions of Occupational Therapy according to programme level



movements that could contribute to falls.

Transfers

- Dressing
- Activities to do: Bathing/showering
 - Use of walking aids
 - Climb and descend stairs

improve balance and muscular strength.

Sweep

Activities to do:

Change position of objects (from one shelf to another of different height) Climb up and descend stairs with increased weight-bearing on the affected limb

Clean windows

Remove dishes from the dishwasher

FIM, Functional Independence Measure. Levels 1-3 are defined based on the older adults' score on the FIM subscales: Transfer to toilet, transfer to shower, dressing lower body, bathing/ showering, walking, and climb up/descend stairs, with scores 90 were classified as Level 4

Table 3. Description of activities to train in sessions of Physical Exercise according to programme levels



TUG, Time UP and Go Test. All sessions consist of: 1) an initial warm-up of three exercises, 2) performance of 9–10 exercises with a minimum of 10 repetitions per exercise and a maximum of 24 (depending of the week training during the 12-week program), and 3) a relaxation exercise to end the session.

Before starting the programme older adults and their family caregivers received a training on using the *@ctivehip* online platform and were provided with the necessary equipment to perform the programme. The role of the family caregivers was to support and supervise the older adults during the home-based sessions and to maintain communication with the health care providers through videoconferences and text messages. Thus, family caregivers played a key role during the use of the telerehabilitation programme.



Image 3. @ctivehip website

Comparative group (Usual care)

Similar to the telerehabilitation group, older adults in the comparative group received the standard care during the hospitalization, the educational workshops and the informative leaflet previously mentioned. Upon discharge from the hospital, older adults in the comparative group received the usual rehabilitation programme provided by the Andalusian Public Healthcare System. This programme comprised 5-15 post-discharge sessions of face-to-face rehabilitation sessions at home, conducted by an OT and/or PT.

PROCEDURES

The older adults and their family caregivers, who enrolled in the study were assessed two times: (1) before hospital discharge, (first week after surgery); and (2) three months postdischarge, (at the end of the telerehabilitation programme). They were provided the opportunity to report any adverse or serious event via phone, videoconference or through self-reporting on the online platform, which was monitored weekly by an OT.

At the beginning of the study, sociodemographic data was collected such as age, gender, body mass index (BMI), relationship with the older adult, employment status, support from other caregivers, and the number of caregivers. This information was gathered through interviews with the older adults and their family caregivers. The main outcomes are described below.

OUTCOMES

Family Caregivers

Caregiver burden. The Zarit Burden Interview (129) was employed to assess the perceived burden among family caregivers. This self-reported instrument comprises 22 items that cover a wide range of aspects related to caregiving, including emotional challenges, physical status, economic situation, and social state, as well as the caregiver's feelings in providing care to the patient. The response scale is designed to capture the frequency of these challenges, ranging from 0 ("never") to 4 ("almost always"): 0 = never, 1 = almost, 2 = sometimes, 3 = quite often and 4 = almost always. The maximum score is 88, a score below 46 is usually considered indicative of "no burden", scores between 47 and 55 indicates "moderate burden" and a score above 56 is indicative of "severe burden". This scale vas adapted and validated for Spanish population in 1996 by Martín et al (130). Internal reliability for Spanish version is good with a with a Cronbach's $\alpha =$ 0.92 (131).

Anxiety and depression. The psychological well-being of family caregivers, specifically their levels of anxiety and depression, was assessed using the Hospital Anxiety and Depression Scale (HADS) (132). It comprises 14 items, split into two subscales: one dedicated to anxiety and the other to depression. Each item on the scale presents four possible answers, scored from 0 to 3 points. Each subscale encompassing 7 questions. The total achievable score on the scale is 42 points, with each subscale allowing for a maximum of 21 points. In both subscales, a score above 11 indicates the presence of anxiety or depression (133). The overall scale boasts a Cronbach's α of 0.90, demonstrating its reliability in capturing the essence of these psychological states. The subscales further attest to this reliability, with the depression subscale having a Cronbach's α of 0.84 and the anxiety subscale a slightly higher α of 0.85 (133). Moreover,

the reliability of HADS extends beyond clinical populations to encompass healthy individuals as well. Both Pearson and Spearman correlations, alongside interclass correlation coefficient assessments, have yielded results ranging between 0.85 and 0.91 (134).

Fitness level. The fitness level of the family caregivers was measured by the International Fitness Scale (IFIS). The IFIS scale is a nuanced, self-administered questionnaire designed to gauge an individual's perception of their own physical fitness. It comprises five key dimensions, namely general physical fitness, cardiorespiratory fitness, muscular strength, agility, and flexibility conditions. Each question on the IFIS is structured as a Likert-type item, allowing caregivers to rate their fitness on a scale ranging from 1 to 5. The scoring system is straightforward yet insightful: a score of 5 points shows an excellent perception of fitness. Consequently, the cumulative score across all domains can range from 5 to 25 points. The validity and reliability of the IFIS have been tested in different demographic groups. In studies involving youth, the IFIS demonstrated a high level of internal consistency, with a Cronbach $\alpha = 0.80$ (135). Furthermore, its effectiveness in categorizing fitness level among older adults has been well-documented (136). The test-retest reliability measured by the average weighted Kappa (K), stands at 0.45 (101).

Older adults

Functional level. The Functional status of the older adults with hip fracture was assessed using a self-reported scale (Functional Independence Measure (FIM) (137)). The FIM is a clinician-rated outcome that assesses the level of assistance a person requires for daily activities. The FIM is an 18-items scale, with 13 items dedicated to assessing physical activities divided into four domains:

- 1. Self-care: this includes basic activities like eating, grooming, bathing, dressing, and toileting.
- 2. Sphincter control: it focuses on bladder and bowel management.
- 3. Mobility: this category assesses movement abilities such as transferring from bed to chair, to toilet, and to shower.
- 4. Locomotion: It evaluates the ability to walk, use a wheelchair, and going through stairs.

The remaining 5 items of the FIM are related to cognitive and social functions, divided into two categories:

- 1. Communication: this encompasses comprehension and expression abilities.
- Social cognition: It includes assessing social interaction, problem solving, and memory.

Each item on the FIM is scored on a scale from 1 to 7, where a lower score indicated a higher dependence. The total FIM score ranges from 18 (totally dependent) to 126 (totally independent). The FIM's robustness is evidenced by its excellent internal consistency, with a Cronbach's α of 0.95 (138).

Physical performance. The Short Physical Performance Battery (SPPB) (139) has been widely used to measure the physical performance of older adults with hip fracture (139,140). It consists of three subscales: balance, walking and chair standing. These subscales collectively provide a comprehensive overview of an individual's mobility and physical capabilities. The SPPB score ranges from 0 (indicating severe impairment) to 12 points (reflecting excellent mobility). The high internal consistency of the SPPB, with a Cronbach's α of 0.87, underscores its reliability as a measurement tool in this demographic (141).

SAMPLE SIZE

The present International Doctoral Thesis shows the secondary results of the clinical trial mentioned above. The sample size was calculated using the functional status of older adults with hip fracture, which is the main outcome of the clinical trial, as described in the protocol (142). Finally, a total of 70 participants, (35 in the telerehabilitation group and 35 in the usual care group) were included to obtain an 80% statistical power and an α error of 5% using a two-sample t-test. It is crucial to underscore that one of the key objectives of our study was to ensure that the caregiver burden did not increase as a result of the intervention, so the low statistical power achieved for the caregiver burden variable further supports these results. The software Epidat: software for epidemiological data analysis. Version 4.2, July 2016. Consellería de Sanidade, Xunta de Galicia, España; Organización Panamericana de la salud (OPS-OMS); Universidad CES, Colombia, was used.

DATA ANALYSES

All analyses were performed using the SPSS software (version 25.0, IBM © SPSS © Statistic), and the level of significance was set at p < 0.05.

Before performing the analysis, continuous variables were checked for normal distribution by visual inspection of histograms together with the Kolmogorov-Smirnov test and to determine which kind of analysis to carry out.

An independent t-test was used to determine baseline differences between the telerehabilitation and the usual care groups for continuous variables in relation to sociodemographic data. Sex was the only categorial binomial variable, so an X^2 test was

used to determine the difference. Sample data are presented as mean values and Standard Deviations or percentages.

To carry out **specific objectives 1, 2 and 3**, an analysis of covariance (ANCOVA) was used to determine relationship of the telerehabilitation programme. In Model 1 the postrehabilitation outcomes were used as dependent variables, the group (i.e., telerehabilitation vs. usual care) as a fixed factor and the baseline outcomes as a covariate. Sample data are presented as mean values and Standard Deviations or percentages.

To perform **specific objective 4** and to test the influence of potential confounders a sensitive analysis in Model 2 was performed. The variables that demonstrated an additional predictive capacity in Model 1 (number of rehabilitation sessions, caregiver's depression status, older adults' age, and older adults' FIM and SPPB scores) were included as covariables in Model 2, along with the baseline outcomes. Sample data are presented as mean values and Standard Deviations or percentages.

Differences between both groups were tested with two approaches for specific objectives, per-protocol, and intention to treat. The per-protocol approach, which included those participants who met the following criteria: (1) to have valid data in both the pre- and the post-intervention assessments and (2) to have completed at least 10 sessions of the telerehabilitation programme, a criterion that only applied to the telerehabilitation group. For the intention-to-treat approach, all participants (N = 69) were included and those without valid data were imputed through multiple imputations.

RESULTS

For the clinical trial, a total of 401 older adults with hip fracture and their family caregivers were identified to be eligible for the study. Finally, 69 older adults and their family caregivers were enrolled in the present study and assigned to either the telerehabilitation group (n=35) or the usual care group (n=34). A total of 62 family caregivers (30 in the telerehabilitation group and 32 in the usual care group) were included in the per-protocol analysis, while all 69 family caregivers were included in the intention-to-treat analysis. The CONSORT 2010 flow chart (Figure 1) shows the reasons for exclusion and dropouts during the study. The main reasons for exclusion were severe cognitive impairment (n=82) and those who had low pre-fracture level (n=67). There were no adverse events or deaths in either group during the study.



PER-PROTOCOL ANALYSIS RESULTS

Sociodemographic and clinical data

Table 4 shows the baseline characteristics of family caregivers and older adults by mean and standard deviation (SD) or frequencies with percentages, as appropriate, divided into the telerehabilitation and the usual care groups. In relation to family caregivers, most of them were women (73.3% in telerehabilitation group; 62.5% in usual care group) being daughters of the older adults with a hip fracture (85.7% in telerehabilitation group; 70.5% in usual care group). Half of the caregivers (57.1% in telerehabilitation group; 58.8% in usual care group) had support of other caregivers (1.09 \pm 1.17 telerehabilitation group; 1.41 \pm 1.65 usual care group) during the recovery process of the older adults.

In most of the baseline outcomes, no statistically significant differences were observed between the groups. However, exceptions were noted in terms of age for both the family caregivers and the older adults. The age difference was 8 years among the family caregivers (p= 0.019), and 4 years among the older adults (p = 0.002), with the telerehabilitation group being the younger in both instances.

Outcomes	Telerehabilitation	Usual Care	р		
Caregiver					
-	(n= 30)	(n = 32)			
Age (years)	47.53±8.44	54.94±14.67	0.019		
BMI (kg/m ²)	(n= 17) 25.44±4.64	(n= 20) 26.43±4.69	0.524		
Sex					
Men	8(26.7%)	12(37.5%)	0.423		
Women	22(73.3%)	20(62.5%)	0.423		
Relationship					
Partner/spouse	1 (2.9%)	6 (17.7%)			
Son/daughter	30 (85.7%)	24 (70.5%)	0.116		
Other	4 (11 4%)	4 (11.8%)			
relatives/friends	(11.170)	(11.070)			
Employment					
Full-time	10 (28.6%)	7 (20.6%)	0 604		
Part-time	13 (37.1%)	12 (35.3%)	0.001		
Unemployed	12 (34.3%)	15(44.1%)			
Support of other					
caregivers			0.611		
Yes	20 (57.1%)	20 (58.8%)	0.011		
No	15 (42.9%)	14 (41.2%)			
Number of other	1.09 ± 1.17	1 41+1 65	0 347		
caregivers	1.07 ± 1.17	1.41±1.05	0.547		
Baseline Outcomes					
Zarit	16.07±9.35	17.75 ± 14.41	0.590		
HADS					
Depression	2.47 ± 2.46	2.72 ± 3.14	0.728		
Anxiety	5.77±4.13	6.41±4.71	0.573		
Total	8.23±5.91	9.13±7.41	0.604		
IFIS	17.97 ± 3.06	18.81±3.38	0.307		
Older adults					
	(n=30)	(n=32)			
Age (years)	75.77±5.67	80.38±5.70	0.002		
BMI (Kg/m ²)	26.27±3.79	28.60 ± 3.92	0.021		
Men	8(26.7%)	6(18.8%)	0 330		
Women	22(73.3%)	26(81.3%)	0.550		
Baseline Outcomes					
FIM	78.10±4.29	78.16±6.73	0.969		
SPPB	3.17±1.32	2.62 ± 1.47	0.128		

Table 4. Baseline characteristics of family caregivers and older adults divided by the telerehabilitation and usual care groups.

Baseline: after hip fracture surgery and before rehabilitation; BMI: Body Mass Index; FIM: Functional Independence Measure; HADS: Hospital Anxiety and Depression Scale; IFIS: International Fitness Scale; n: sample size; SD: Standard Deviation; SPPB: Short Physical Performance Battery. Values are presented as mean \pm SD or percentages. P-value was obtained by the independent samples T-test for continuous variables, and by the chi-square test for categorical variables.

Outcomes

The results of the per-protocol analysis are detailed in Table 5. This table presents the means and mean differences, each with a 95% confidence interval, for both the telerehabilitation and usual care groups, three months post-hip fracture. These values are first adjusted for baseline values (Model 1). A further adjustment is made in Model 2, which is adjusted for additional variables: the number of rehabilitation sessions, pre-intervention depression status (measured using the HADS), older adults' age, and the

older adults' FIM and SPPB scores.

Statistical Models Outcomes	Telerehabilitation group n=30	Usual Care group n=32	Mean Differences Telerehab-Usual	р
	Mean (95% CI)	Mean (95% CI)	Care (95% CI)	
Model 1				
Zarit	14.16 (9.17 to 19.15)	16.57 (11.73 to 21.40)	- 2.41 (-9.36 to 4.55)	0.492
HADS				
Anxiety	4.66 (3.27 to 6.05)	7.35 (6.00 to 6.70)	-2.69 (-4.62 to -0.75)	0.007
Depression	1.90 (0.87 to 2.94)	3.34 (2.34 to 4.34)	-1.35 (-2.88 to 0.01)	0.051
Total	5.59 (4.33 to 8.85)	10.64 (8.45 to 12.83)	- 4.05 (-7.20 to -0.90)	0.013
IFIS	19.50 (18.28 to 20.72)	17.03 (15.85 to 18.21)	2.47 (0.77 to 4.18)	0.005
Model 2				
Zarit	14.73 (9.09 to 20.37)	16.03 (10.63 to 21.43)	-1.30(-10.22 to 7.63)	0.771
HADS				
Anxiety	4.48 (2.76 to 6.21)	7.51 (5.86 to 9.16)	-3.02 (-5.77 to -0.27)	0.032
Depression	1.44 (0.18 to 2.70)	3.77 (2.57 to 4.98)	-2.33 (-4.32 to -0.33)	0.023
Total	5.66 (3.21 to 8.78)	11.19 (8.52 to 13.86)	-5.19 (-9.62 to -0.76)	0.022
IFIS	19.37 (17.94 to 20.81)	17.15 (15.77 to 18.53)	2.22 (-0.05 to 4.49)	0.055

Table 5. Differences between @ctivehip telerehabilitation programme and the usual care on the burden, psychological factors, and physical fitness of family caregivers.

CI: Confidence Interval; HADS: Hospital Anxiety and Depression Scale; IFIS: International Fitness Scale; n: sample size. Differences between the telerehabilitation and usual care groups at post-intervention adjusted for basic preintervention values are shown in Model 1. In Model 2, differences are adjusted for number of rehabilitation sessions, the caregiver's pre-intervention depression status measured with the HADS, patient's age, and patient's FIM (Functional Independence Measure) and SPPB (Short Physical Performance Battery) scores. Mean differences between groups are presented as telerehabilitation group adjusted mean minus usual care group adjusted mean. In examining the burden experienced by family caregivers, it was observed that those supporting older adults through the @*ctivehip* telerehabilitation programme did not report a higher burden compared to those who received the usual care, both at baseline and 3-month follow-up. In fact, caregivers using the @*ctivehip* programme reported a somewhat lower burden. However, this difference did not reach statistical significance in either model 1 (p=0.492) or model 2 (p=0.771), as illustrated in figure 2.



Figure 2. Evolution of caregiver burden (Zarit score) by groups.

The levels of anxiety and depression among family caregivers were notably lower in the *@ctivehip* group compared to those in the usual care group. In the analysis using model 1, significant statistical differences emerged only in the area of anxiety (p=0.007) and in the HADS total score (p=0.013). However, when applying model 2, there were significant statistical differences in anxiety (p= 0.032), depression (p= 0.023) and HADS total score (p= 0.022). Figure 3a, 3b and 3c.





anxiety (HADS score) by groups.

Figure 3b. Evolution of caregiver depression (HADS score) by groups.



Figure 3c. Evolution of caregiver total punctuation (HADS score) by groups.

In assessing the self-perceived physical fitness levels of family caregivers, those participating in the @*ctivehip* telerehabilitation programme showed higher scores compared to those participating in the usual care group. This difference was statistically significant in model 1 (p= 0.005). In model 2, while telerehabilitation group showed a higher score compared to the usual care group, this difference did not reach statistical significance (p= 0.055). Figure 4.



Figure 4. Evolution of caregiver self-perceived physical condition (IFIS score) by groups.

INTENTION-TO-TREAT ANALYSIS RESULTS

Sociodemographic and clinic data

Table 6 shows the baseline characteristics of family caregivers and older adults by mean and standard deviation (SD), or frequencies with percentages, as appropriate, divided into the telerehabilitation and the usual care groups. Baseline characteristics of family caregivers are very similar in both analyses. Most of them were women (71.4% in telerehabilitation group; 61.8% in usual care group) being daughters of the older adults with hip fracture (85.7% in telerehabilitation group; 70.5% in usual care group). Half of the caregivers (57.1% in telerehabilitation group; 58.8% in usual care group) had support of another caregiver (1.09 \pm 1.17 telerehabilitation group; 1.41 \pm 1.65 usual care group) during the recovery process.

Outcomes	Telerehabilitation	Usual Care	р
Caregiver			
0	(n = 35)	(n = 34)	
Age (years)	47.74±8.00	55.09±14.35	0.010
BMI (Kg/m ²)	(n=20) 25.64±15.12	(n=21) 4.49±4.58	0.601
Sex			
Men	10(28.6%)	13(38.2%)	0.450
Women	25(71.4%)	21(61.8%)	
Relationship			0.116
Partner/spouse	1 (2.9%)	6 (17.7%)	
Son/daughter	30 (85.7%)	24 (70.5%)	
Other relatives/friends	4 (11.4%)	4 (11.8%)	
Employment			0.604
Full-time	10 (28.6%)	7 (20.6%)	
Part-time	13 (37.1%)	12 (35.3%)	
Unemployed	12 (34.3%)	15(44.1%)	
Support of other			
caregivers			
Yes	20 (57.1%)	20 (58.8%)	0.611
No	15 (42.9%)	14 (41.2%)	
Number of other	1.09 ± 1.17	1.41±1.65	0.347
caregivers			
Baseline Outcomes			
Zarit	16.69±9.76	$17.44{\pm}14.11$	0.796
HADS			
Depression	2.34 ± 2.33	2.71±3.07	0.581
Anxiety	5.71±3.95	6.50 ± 4.64	0.451
Total	8.06 ± 5.60	9.21±7.27	0.464
IFIS	17.66±2.96	18.56±3.46	0.248
Older adults			
	(n=35)	(n=36)	
Age (years)	76.71±6.04	80.72±5.59	0.005
\mathbf{BMI} (Kg/m ²)	26.75±3.93	28.52±3.71	0.055
Men	9(25.7%)	9(25%)	1.000
Women	26(74.3%)	27(75%)	
Baseline Outcomes		· (· - · · /	
FIM	77.46±5.48	78.22±6.48	0.593
SPPB	3.03±1.32	2.61±1.41	0.202

Table 6. Baseline characteristics of family caregivers and older adults divided by telerehabilitation and usual care group

Baseline: after hip fracture surgery and before rehabilitation; BMI: Body Mass Index; FIM: Functional Independence Measure; HADS: Hospital Anxiety and Depression Scale; IFIS: International Fitness Scale; n: sample size; SD: Standard Deviation; SPPB: Short Physical Performance Battery. Values are presented as mean \pm SD or percentages. P-value was obtained by the independent samples T-test for continuous variables, and by the chi-square test for categorical variables. There were no statistically significant differences between groups in most baseline outcomes. However, exceptions were observed in the ages of both the family caregivers and the older adults. The caregivers in the telerehabilitation group were, on average, 8 years younger (p= 0.010), while the older adults in this group were 4 years younger (p= 0.005), compared to their counterparts in the other group.

Outcomes

The results of the intention-to-treat analysis are detailed in Table 7. In the same way as in the per-protocol analysis, this table presents the means and mean differences, each with a 95% confidence interval, for both the telerehabilitation and usual care groups, three months post-hip fracture. These values are first adjusted for baseline values (Model 1). A further adjustment is made in Model 2, which is adjusted for additional variables: number of rehabilitation sessions, pre-intervention depression status (measured with the HADS), older adults' age, and the older adults' FIM and SPPB scores (Model 2).

The caregiver burden, as assessed by Zarit scale, was lower in the telerehabilitation group compared to the usual care group. This was observed despite the implementation of @*tivehip*, yet the difference was not statistically significant in model 1 (p=0.626).

Statistical Models Outcomes	Telerehabilitation group n=35	Usual Care group n=34	Mean Differences Telerehab-Usual	р
	Mean (95% CI)	Mean (95% CI)	Care (95% CI)	
Model 1				
Zarit	14.54 (9.90 to 19.17)	16.16 (11.45 to 20.86)	-1.62 (-8.23 to 4.99)	0.626
HADS				
Anxiety	4.97 (3.69 to 6.26)	7.15 (5.84 to 8.45)	-2.17 (-4.01 to -0.34)	0.021
Depression	2.15 (1.17 to 3.14)	3.25 (2.25 to 4.25)	-1.10 (-2.50 to 0.31)	0.123
Total	7.16 (5.03 to 9.28)	10.34 (8.18 to 12.50)	-3.18 (-6.22 to -0.15)	0.040
IFIS	19.19 (18.09 to 20.28)	16.84 (17.73 to 17.96)	2.35 (0.78 to 3.91)	0.004
Model 2				
Zarit	14.73 (9.85 to 19.61)	15.95 (10.99 to 20.91)	-1.22 (-8.81 to 6.37)	0.749
HADS				
Anxiety	5.05 (3.59 to 6.51)	7.07 (5.58 to 8.55)	-2.01 (-4.30 to 0.27)	0.083
Depression	2.16 (1.04 to 3.28)	3.25 (2.11 to 4.38)	-1.09 (-2.83 to 0.65)	0.216
Total	7.27 (4.85 to 9.69)	10.22 (7.76 to 12.68)	-2.95 (-6.73 to 0.83)	0.124
IFIS	18 87 (17 67 to 20 07)	17 16 (15 95 to 18 38)	1 704 (-0 16 to 3 57)	0.073

Table 7. Differences between @ctivehip telerehabilitation programme and the usual care on the burden, psychological factors and physical fitness of family caregivers

CI: Confidence Interval; HADS: Hospital Anxiety and Depression Scale; IFIS: International Fitness Scale; n: sample size. Differences between the telerehabilitation and usual care groups at post-intervention adjusted for basic preintervention values are shown in Model 1. In Model 2, differences are adjusted for number of rehabilitation sessions, the caregiver's pre-intervention depression status measured with the HADS, patient's age, and patient's FIM (Functional Independence Measure) and SPPB (Short Physical Performance Battery) scores. Mean differences between groups are presented as telerehabilitation group adjusted mean minus usual care group adjusted mean.

Regarding the HADS scale, both the subscale scores and total scores were lower in telerehabilitation group. Statistically significant differences were showed in the anxiety subscale (p=0.021) and the total score (p=0.040) in model 1. Additionally, the self-perceived physical fitness was higher in the telerehabilitation group compared to the usual care group, with this difference reaching statistical significance (p=0.004) in model 1.

In model 2, which involved an intention-to-treat analysis, no statistically significant differences were observed in any outcome: Zarit scale (p=0.749), HADS anxiety subscale (p=0.0083), HADS depression subscale (p=0.124), total HADS score (p=0.124) and IFIS scale (p=0.073).

DISCUSSION

The current International Doctoral Thesis evaluates whether the use of the @*ctivehip* telerehabilitation programme, designed for the recovery of older adults with hip fractures and administered with the assistance of a family caregiver, increases caregiver burden, and influences caregiver's anxiety, depression, and physical fitness compared to traditional face-to-face rehabilitation at home (usual care). The findings indicate that the implementation of the @*ctivehip* telerehabilitation programme does not increase caregiver burden when compared to usual care. Furthermore, the psychological factors (anxiety and depression) of family caregivers improved among those utilizing the telerehabilitation programme. Nevertheless, there is no observed correlation between telerehabilitation and the perceived physical fitness level of family caregivers.

CHARACTERISTICS OF THE SAMPLE

Demographic profile of family caregivers in our study closely aligns with those in prior researches (54,83,143–147), predominantly consisting of middle-aged adult daughters (54,83,143–147) of older adults with hip fracture. Notably, the age of family caregivers, particularly in the telerehabilitation group, was slightly younger in our study. In Spain, only 56% of older adults use the internet daily, a figure that rises to 90% in middle age (148,149). This decline in ICT usage with age might explain the age disparity between groups in our study, that was selected by choice. Furthermore, the younger population has greater skills in handling technologies, which would encourage their preference for ICT use (150,151).

Concerning employment status, our findings reveal that the majority of family caregivers were employed, aligning with Tsakiri et al.'s similar study (144). In contrast, studies conducted by Martín-Martín et al. (152) and Parry et al. (153) observed that more than

60% of the family caregivers were unemployed. The older age and reduced functional and cognitive status of the older adults included in those studies (152,153) could explain why those caregivers had to deliver more intensive care, rendering them unable to work concurrently or possibly receiving less support from other caregivers (152) than the caregivers in our study. Liu et al. (139) reported an 86,2% of caregivers with support while in our study, only the middle of caregivers had the support of another caregiver. Family caregiver's mental health was better among those with additional caregiver support. This may indicate that caring of an older adult with hip fracture results in less strain if carried out by more than one caregiver.

It is important to bear in mind that the caregiver profile may evolve due to societal cultural changes. These changes have not yet been tested in the scientific literature, as caregivers have only been studied for a few years. As mentioned earlier, in the study by Martín-Martín, the unemployment rate was 60%, whereas in our study, it hovers around 35/40%. Both studies were conducted in the same city with a 6-year gap between them. This leads us to consider that cultural changes, especially in the role of women in society, could contribute to the continuous evolution of the caregiver profile. Moreover, the caregivers' profile can be influenced by the available resources in each region. In Spain, there are seventeen different Health Care Systems with different type of hospitals and health care centres. For example, in regions such as Catolonia and Madrid, most older adults are discharged to socio-health hospitals, where they stay between four to six weeks receiving intensive rehabilitation. The main aim of the stay in those hospitals is to achieve a functional status that let older adults to perform basic ADLs in order to manage themselves when they come back home. In contrast, in regions such as Galicia, Valencia, Extremadura or Andalucia, most older adults are discharged from the orthopedic units to their homes or relatives' homes directly (14). In these regions, the role of family

caregivers is essential for the management of the older adults at home and for the sustainability of the Health Care System. Therefore, the profile and needs of family caregivers differ between regions, and these differences should be considered when designing new interventions during the recovery process after a hip fracture.

CAREGIVER BURDEN

The caregiver burden in our study, compared with previous research (96,116), was initially low in both groups. This divergence may stem from the profile of older adults in our study, characterized by a high pre-fracture functional level and no cognitive impairment, suggesting minimal prior care needs. Additionally, these factors facilitate enhanced functional recovery, social integration for older adults with hip fractures (154) and a reduced caregiver burden (116,155). Moreover, caregiver burden level was reduced in both groups post-intervention in our study. This can be attributed to factors such as the remarkable functional recovery of older adults in the clinical trial (reported FIM scores at 3 months: 120.54 points for telerehabilitation, 108.29 points for face-to-face rehabilitation) (118). Furthermore, the workshops on postoperative patient management and home recommendations given to both groups during the hospital stay (118), and the resolution of question before hospital discharge may have influenced the reduced caregiver burden. The workshops had a theoretical basis, which has been shown to be more successful than those without (156). These aspects contributed to improve caregiver's knowledge and skills, which could be related to improved caregiver selfefficacy. Lin et al. highlighted that lower self-efficacy was correlated with a higher burden (157). However, improving self-efficacy requires more than the provision of knowledge. In this sense, the teach-back method used in a previous study (123) was also included during the delivery of the workshops in the hospital, and during the follow up of the health providers through videoconferences and text messages while they used the telerehabilitation programme. The lack of an increased burden on who supported older adults using the *@ctivehip* programme reinforce the need to include family caregivers on the recovery process giving them an active role. Moreover, their skills in using ITC could be an opportunity to overcome the barriers faced by older adults and facilitate the use of telerehabilitation programmes.

This reduction in caregiver burden also underscores the transformative impact of integrating modern technology into healthcare practices. The utilization of the @*ctivehip* telerehabilitation programme not only modernized the rehabilitation process but also democratized access to quality care, allowing caregivers, irrespective of their location or time constraints, to effectively contribute to the rehabilitation process. The flexibility and accessibility of telerehabilitation programmes represent a significant shift in how care can be delivered, especially in scenarios where traditional rehabilitation methods may pose logistical challenges. Furthermore, the integration of technology in caregiving has the potential to bridge the gap between professional healthcare providers and family caregivers, fostering a more collaborative and informed approach to patient care. By empowering caregivers with the tools and knowledge to effectively manage the rehabilitation process, telerehabilitation can significantly enhance the quality of life for both caregivers and patients, promoting a more sustainable and holistic approach to healthcare.

PSYCHOLOGICAL FACTORS

The levels of anxiety and depression were also lower in our study compared to others (144,146,158), with notably lower levels in the telerehabilitation group than in the control

group. Differences between our study and others could be based on variations in the social and healthcare systems. In Spain, the Public Healthcare Systems covers all medical costs (e.g., surgery costs, medical appointments, rehabilitation, and commute to and from appointments), which can reduce caregivers' concerns, including concern for economic problems. Tsakiri at al. (144) conducted a study in Greece in which no differences in caregiver burden were found based on economic level, contrarily to the study by Siddiqui et al., which identified economic factors as a stressor for caregivers (158). This suggests that, regardless of the family's prior economic status, potential expenses related to hip fractures are highly relevant and may contribute to caregivers' burden. The reduced anxiety and depression levels in our study may also be due to the older adults' high prefracture functional level, absence of cognitive impairment, and support from other family caregivers. Furthermore, the differences between groups in our study could be attributed to the proactive involvement of family caregivers supporting older adults through the @ctivehip telerehabilitation programme. Their proactive participation in the recovery process, along with close communication with health professionals (78,82) likely contributed to the enhancement of psychological factors for family caregivers.

Additionally, the findings of our study highlight the broader implications of integrating telerehabilitation into the caregiving process. The use of technology-based rehabilitation methods, such as the *@ctivehip* programme, not only facilitates a more efficient and personalized recovery process for the older adults but also appears to have a positive psychological impact on the caregivers themselves. By enabling caregivers to be more actively and effectively involved in the recovery process from the comfort of their homes, telerehabilitation can alleviate the stress and anxiety commonly associated with traditional caregiving roles. This approach also offers caregivers a sense of empowerment and control over the situation, which can significantly reduce feelings of helplessness and

subsequent mental health challenges. The ease of access to professional guidance and the ability to track and monitor the patient's progress through technological means provide an additional layer of support, further alleviating the psychological burden on caregivers. These aspects underscore the potential of telerehabilitation programmes not only in enhancing patient care but also in improving the overall well-being of caregivers, thereby suggesting a beneficial model for future healthcare interventions.

PERCEIVED PHYSICAL FITNESS

The telerehabilitation programme did not have an impact on the perceived physical fitness of family caregivers, despite their active participation. Their vigilance and physical activity were evident as they supervised and supported older adults in performing exercises and activities at home, occasionally even providing live demonstrations of the exercises. Family caregivers played an essential role in ensuring programme security and proper execution, collaborating with healthcare providers from a distance to guarantee efficacy. The lack of a discernible association between physical fitness and rehabilitation might be attributed to the absence of specific content and training tailored for family caregivers supporting older adults in the telerehabilitation programme. Our results pose a challenge in terms of comparison as, to the best of our knowledge, this is the inaugural study considering the perceived fitness of family caregivers. Nevertheless, a previous study (83) highlighted caregivers' physical issues and their impact on caregiving within the initial six months following hip fracture. Another study that brings together different types of non-pharmacological interventions in caregivers of people with dementia does not find an improvement in general health after physical exercise (159). Thus, physical fitness should be studied in the future as a possible factor influencing the general health status and the caregiver burden, in addition to the mental health status which has been further studied in the literature (145).

This observation suggests the need for a more comprehensive approach in future telerehabilitation programmes, one that not only addresses the needs of the patients but also considers the physical well-being of the family caregivers. The physical demands placed on caregivers, especially in a home setting, can be significant, often involving assisting with mobility, exercise demonstrations, and daily care tasks. While these activities do indicate a level of physical involvement, they may not necessarily translate to improved physical fitness or health outcomes for the caregiver. This gap in the telerehabilitation programme underscores the importance of developing targeted strategies and resources that support the physical health of caregivers. Incorporating caregiver-specific physical training and wellness components into telerehabilitation programmes could potentially offer dual benefits: enhancing the caregiver's ability to provide effective care and improving their own physical health. Moreover, recognizing and addressing the physical strain on caregivers is crucial in designing holistic healthcare solutions that cater to the overall well-being of both patients and their caregivers, thereby creating a more sustainable and effective care environment.

INCLUSION AND TRAINING OF FAMILY CAREGIVERS DURING THE RECOVERY PROCESS

The inclusion of family caregivers during the decision-making process about the transition to home (95,160), as well as the active role that they took during the recovery process (161), are demands stated by caregivers around the world, and we included them in our study. This may explain the lack of association between family caregivers who

used the @*ctivehip* telerehabilitation programme and an increase in their caregiver burden, compared to those who received face-to-face rehabilitation at home. This is despite the fact that caregivers using the @*ctivehip* telerehabilitation programme had to dedicate more time to supporting their relatives without receiving any specific intervention for themselves.

In relation to current interventions, caregivers have been the focus of study when it comes to pathologies such as dementia, frail older people, cancer or stroke (162). In the treatment of caregiver symptoms, non-pharmacological treatments have been recommended as the first option (163). A systematic review about different interventions in caregivers of older adults with dementia show that music therapy ah physical exercise interventions had not effects on symptoms related to carrying and burden while psychoeducation and multicomponent intervention showed good results (159). Related to cancer, a recent systematic review shows no benefits for cancer patients caregiver in intervention about skills and education either face-to-face, by telephone or via web (164). Mindfulness strategies have been used with caregivers of patients with cirrhosis, with only very short-term results in relation to mental health (165). As far as caregivers of stroke patients are concerned, interventions that combine skill building with psychoeducation should be chosen, and that those interventions delivered by web and telephone can be useful in relation to caregivers' outcomes (166).

A recent review highlighted that digitally enhanced health interventions, that combine various strategies, can improve caregivers' outcomes, such as psychological health, burden, self-efficacy, and quality of life, across different medical illnesses (167). However, the absence of studies focusing on musculoskeletal conditions, like hip fractures, underscores the need for further research in this area. Given the positive impact of caregiver involvement seen in our study, exploring similar digitally enhanced

interventions for musculoskeletal pathologies could yield valuable insights and potentially enhance caregiver and patient outcomes in these scenarios.

In summary, there is a clear demand of family caregivers to be included in the recovery process of older adults with hip fracture (161) but there is a lack of interventions designed to response their needs (167). Family caregivers can be a key factor to introduce telerehabilitation programmes but specific training for them should be designed to improve their overall health and wellbeing. The experiences conducted in caregivers of other type of pathologies could be considered for the design of new interventions for family caregivers of older adults with hip fracture.

RELATED FACTORS

Throughout the discussion of our findings, it has become increasingly clear that several factors beyond the immediate scope of the *@ctivehip* program significantly impact the experience of family caregivers. The number of rehabilitation sessions, for instance, likely affects the duration and intensity of the caregivers' involvement, potentially influencing their perceived burden and well-being. Moreover, the pre-intervention depression status of family caregivers is a crucial variable, as existing mental health conditions can shape their experiences and reactions to the caregiving role. Additionally, the age of the older adults, along with their functional status and physical performance, are pivotal in determining the level of care required, which in turn affects the caregiver's physical and psychological state. These elements collectively suggest that caregiver support needs are multifaceted and influenced by a constellation of factors. Recognizing this complexity is vital for tailoring interventions that holistically address the diverse needs of family caregivers, ultimately leading to our conclusion that these varying

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characteristics notably influence the caregiver burden, psychological factors, and perceived physical fitness of family caregivers

STRENGTHS AND LIMITATIONS

This study is not free of limitations. A choice-based non-randomized controlled trial was conducted, which could influence the results. Family caregivers who participated in the study could be more motivated than those who chose face-to-face rehabilitation at home. However, there were no differences between groups in terms of the caregiver burden, psychological factors and perceived physical fitness. The reasons why family caregivers did not choose the @ctivehip programme were previously reported (82): the perception that older adults would not complete the exercise at home, the barriers that could be posed by the use of technology or caregivers' lack of time to support their relative with technology (82). Concerning the lack of time, it is surprising that this was one of the reasons for not carrying out the programme when there was a greater number of family caregivers employed in the telerehabilitation group, as described above, who finally were not more burdened by the @tivehip telerehabilitation programme. The second limitation is the profile of the older adults and caregivers who participated in our study. We included family caregivers of older adults with a high pre-fracture functional level and no cognitive impairment because the programme would be supervised by the family caregivers at home. We considered that it could be more feasible to test an online intervention with this profile of older adults. Thus, our results cannot be extended to all older adults with hip fracture and their family caregivers. However, to our knowledge, this is the first study to test a telerehabilitation programme for older adults with hip fracture with the support of their family caregivers. Our results support the feasibility to use the telerehabilitation programme without overburdening or having negative effects on family caregivers.

Regarding strengths, we have the existence of a comparison group. Despite the nonrandomized design, a group that continued with the usual face-to-face system was implemented for comparison with those who utilized @*ctivehip* telerehabilitation
programme. Another strength to highlight is the real-life implementation of the telerehabilitation programme. The ability to choose whether to participate in the programme or not provides us with a real-world context regarding the motivation and learning needs of family caregivers and older adults.

Our greatest strength lies in enhancing understanding about family caregivers in the recovery process of older patients with hip fractures. This opens the possibility of creating new interventions focused on caregivers.

CONCLUSIONS

The results obtained of this International Doctoral Thesis show that the use of the telerehabilitation programme @*ctivehip*, carried out with the support of family caregivers of older people with hip fracture had no negative effects on caregiver's overall health.

Related to the specific objectives of this International Doctoral Thesis, we can conclude:

Caregiver burden: the use of the *@ctivehip* telerehabilitation programme do not increase caregiver burden of family caregiver of older people with hip fracture compared with those who follow face-to-face rehabilitation.

Physiological factors: the use of the *@ctivehip* telerehabilitation programme reduce anxiety and depression levels of family caregiver of older people with hip fracture compared with those who follow face-to-face rehabilitation.

Fitness level: there is no association in relation to perceived physical fitness on caregiver's who follow the *@ctivehip* telerehabilitation programme versus those who follow face-to-face rehabilitation.

Influence of other characteristics: The total number of rehabilitation sessions, the initial depression status of the caregivers prior to the intervention, the age of the older adults, and their functional and physical capabilities influence the caregivers' burden. These elements also had a notable influence on the psychological factors and the self-perceived physical fitness of the caregivers. This highlights the multifaceted nature of caregiver experiences and the need for tailored support that considers these diverse influencing factors.

CONCLUSIONES

Los resultados obtenidos en esta Tesis Doctoral Internacional muestran que el uso del programa de tele-rehabilitación @*ctivehip*, llevado a cabo con el apoyo de los cuidadores informales de pacientes mayores con fractura de cadera, no tiene efectos negativos en la salud general de los cuidadores.

En relación con los objetivos específicos de esta Tesis Doctoral Internacional, podemos concluir que:

Sobrecarga del cuidador: el uso del programa de tele-rehabilitación *@ctivehip* no aumenta la sobrecarga en los cuidadores informales de pacientes mayores con fractura de cadera en comparación con aquellos que siguen el sistema de rehabilitación cara a cara.

Factores psicológicos: el uso del programa de tele-rehabilitación @*ctivehip* reduce los niveles de ansiedad y depresión de los cuidadores informales de pacientes mayores con fractura de cadera frente a los que siguieron la rehabilitación cara a cara.

Nivel de forma física: no existe una asociación en relación con el nivel auto percibido de forma física en los cuidadores informales que siguieron el programa de telerehabilitación @*ctivehip* frente a aquellos que siguiente la rehabilitación cara a cara.

Influencia de otras características: El número total de sesiones de rehabilitación, el estado de depresión inicial de los cuidadores antes de la intervención, la edad de los adultos mayores y sus capacidades funcionales y físicas influyen en la sobrecarga de los cuidadores. Estos elementos también influyeron notablemente en los factores psicológicos y el nivel de forma física auto percibida de los cuidadores. Esto pone de relieve la naturaleza polifacética de las experiencias de los cuidadores y la necesidad de un apoyo adaptado que tenga en cuenta estos diversos factores de influencia.

CLINICAL IMPLICATIONS

Our results have clinical implications and support the literature's recommendations to: i) including family caregivers during the decision-making process (160), the transition care (95), and the functional recovery process (82); (ii) improving communication and information sharing with older adults with hip fracture and their family caregivers (168); and iii) increasing family caregivers' knowledge and skills for them to feel more confident during the provision of care (116).

We could say that the clinical implications for practice found are:

- The absence of increased burden on caregivers reinforces the inclusion of family caregivers to support the use of telerehabilitation programmes for older adults with hip fractures.
- The improvements of psychological factors of those family caregivers who supported the use of the @*ctivehip* programme hold up the need to give them an active role during the recovery process.
- The implication of family caregivers as a key factor to use the @*ctivehip* programme, and the effects on their overall health-suggest the need to consider specific interventions for family caregivers that should be studied in deep.

FUTURE LINES OF RESEARCH

Based on the results obtained in this International Doctoral Thesis, a series of research lines are proposed aimed at expanding knowledge about family caregivers of older people with hip fractures.

Firstly, there is a proposal to conduct an in-depth analysis of the need of family caregivers. A qualitative study could be carried out on the use of the telerehabilitation programme *@ctivehip*. This way, potential improvements or strengths perceived by caregivers at the user level could be explored. Similarly, a qualitative analysis could be carried out to identify the current needs of caregivers after addressing previous deficiencies. Moreover, aiming to delve into the burden of family caregivers of older adults with hip fracture, a longitudinal study at the Andalusian level could reveal new challenges.

On the other hand, it would be highly valuable to develop specific programmes focused on family caregivers. These programmes would aim to alleviate caregiver burden and enhance aspects related to their overall health, including mental and physical well-being. It is crucial that these programmes are designed with consideration of support caregivers needs, both in the acute phase of the hip fracture process and during the functional recovery process. Linked to this potential research direction is the possibility of creating resources for caregivers. These resources could include information about hip fractures and the associated processes. Additionally, specific information for caregivers on handling the situation and developing skills to cope with it could be incorporated.

As another potential avenue of research, we encounter formal caregivers. There is limited scientific evidence regarding formal caregivers, their characteristics, and needs. This study could lead us to develop specific tools for both family caregivers and formal caregivers, as some aspects may be similar. It is crucial to provide support to professionals responsible for caregiving. Therefore, similar variables to those studied here, such as burden, mental health, and physical health, could be analyzed.

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