Universidade de Évora - Escola de Saúde e Desenvolvimento Humano

Mestrado em Exercício e Saúde

Dissertação

Developing a Digital Health Solution: The Knee Care at Home Programme

Daniela Carmelo Pina

Orientador(es) | João Paulo Brites de Sousa

Jose Alberto Parraca

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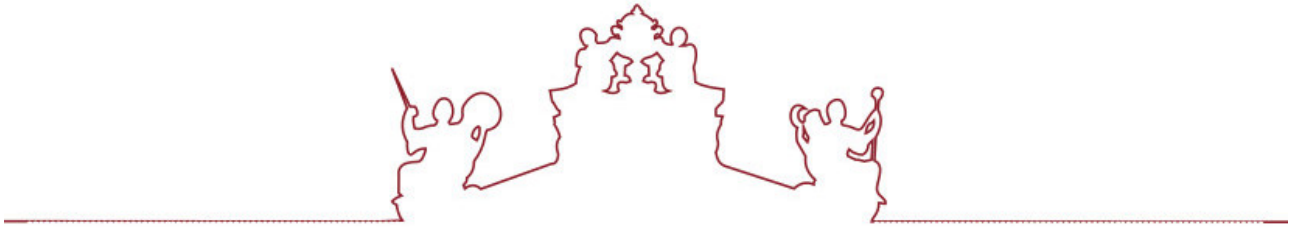

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Évora 2025

CONFLICT OF INTEREST

The author declares no conflicts of interest exist with respect to the research, authorship, and/or publication of this thesis.

Daniela Carmelo Pina

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I began my journey at the Universidade de Évora in 2018 and it has been a very positive experience from the start. While my passion for Sports Sciences has evolved over the years, I have come to realize that my true calling is in helping others through research and provide evidence-based practice. I am very grateful to the Departamento de Desporto e Saúde for their guidance and continuous support along the way, especially in the person of Professor Nuno Batalha and Professor José Parraça.

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To Lili, I want to express my gratitude for your presence in my life. I understand that I can be challenging to be around when I am stressed and anxious, but you have consistently been there for me. Whether it was during the ups and downs of my master's degree or when I had good news to share, you have always been by my side. Words cannot fully convey my appreciation, so I will simply say this: You hold great significance in my life, and I cherish our bond. I love you!

A special thank you to my parents. From a young age, you encouraged me to participate in sports, excel in school, and be a kind person. Your guidance has shaped me into the person I am today and has enabled me to achieve my goals. It hasn't always been easy, but through our heartfelt conversations and your wise advice, I have reached the end of this chapter. I am grateful for your unwavering support through my successes and failures. Thank you for being amazing parents and individuals.

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DISSEMINATION STRATEGY

Poster Presentations

1) **Pina, D.**, Alegrete, J., Batalha, N., Fernandes, O., Parraca, J., Rodrigues, A.M., Londral, A.R., Sousa, J.P. (2023). "*Implementation of the Knee Care @Home Programme for Patients Recovering from Anterior Cruciate Ligament Reconstruction: Protocol for a Randomised Feasibility Trial*". 4th Comprehensive Health Research Centre Annual Summit. Universidade de Évora. 25 e 26 de maio de 2023. Évora, Portugal. Handle: http://hdl.handle.net/10174/35451

Expected Publications

1) **Pina, D.**, Alegrete, J., Batalha, N., Fernandes, O., Parraca, J., Rodrigues, A.M., Londral, A.R., Sousa, J.P. (first semester of 2025). "Utilization of *Digital Health Tools in the Recovery Process of Patients Following Anterior Cruciate Ligament Reconstruction: A Scoping Review*" [Peer Reviewed Scientific Article]

2) **Pina, D.**, Alegrete, J., Batalha, N., Fernandes, O., Parraca, J., Rodrigues, A.M., Londral, A.R., Sousa, J.P. (first semester of 2025). "*The Knee Care at Home Programme for Patients Recovering from Anterior Cruciate Ligament Reconstruction: Protocol for a Feasibility Study*" [Peer Reviewed Scientific Article]

3) Sousa, J.P., Alegrete, J., **Pina, D.**, De Luca, T. (first semester of 2025). "*Knee Care at Home: A Digital Health Solution to Assist in the Recovery Process of Patients Following Anterior Cruciate Ligament Reconstruction. Comprehensive Manual*". First Edition. Imprensa da Universidade de Évora. [English Version]

4) Sousa, J.P., Alegrete, J., **Pina, D.**, De Luca, T. (first semester of 2025). "*Knee Care at Home: Uma Solução de Saúde Digital para Auxílio do Processo de Recuperação de Pacientes Submetidos à Reconstrução Cirúrgica do Ligamento Cruzado Anterior. Manual Geral*". First Edition. Imprensa da Universidade de Évora. [Portuguese Version]

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ABSTRACT

The adoption of digital health tools for consultations (telemedicine) and rehabilitation (telerehabilitation) is gaining popularity due to enhanced accessibility and the mitigation of travel and time restrictions. The implementation of digital health solutions to complement conventional healthcare is somewhat recent, particularly with respect to telerehabilitation after orthopaedic injury or surgery.

A scoping review was undertaken to identify scientific papers reporting on the use of digital health solutions in patient care during the postoperative period following anterior cruciate ligament reconstruction. This review discloses all the predominant digital health solutions and alerts to possible development and implementation difficulties.

The findings from the later review enabled the development of evidence-based recommendations that assist in the development and implementation planning of a new digital health solution, the Knee Care at Home Programme, and highlighted the challenges to be overcome in implementing a digital health solution to support patients in their recovery process after anterior cruciate ligament reconstruction surgery.

Finaly, a protocol was developed for assessing the feasibility of the Knee Care at Home Programme. The expected outputs of the feasibility protocol include facilitating streamlining of planning, enhancing overall quality, and simplifying implementation processes related to digital health solutions.

KEYWORDS: Anterior Cruciate Ligament; Reconstruction; Surgery; Feasibility; Digital Health; Telerehabilitation; eHealth; Mobile Health; Recovery; Wearable Sensors; Telehealth; Review; Exercise Progression; Exercise Regression; Exercise Manual; Knee Care at Home; Patient-reported

Outcomes; Clinician-reported Outcome; Functional Performance; Acceptability; Satisfaction; Motivation; Home-based Exercise Programme; Supervision; Monitoring

Desenvolvimento De Uma Solução De Saúde Digital: O Programa Knee Care at Home

RESUMO

A adoção de ferramentas digitais de saúde para consultas (telemedicina) e reabilitação (telerehabilitação) está a ganhar popularidade devido à maior acessibilidade e à mitigação das restrições de viagens e de tempo. A implementação de soluções digitais de saúde para complementar os cuidados de saúde convencionais é algo recente, particularmente no que diz respeito à telerreabilitação após lesão ou cirurgia ortopédica.

Uma revisão da literatura foi realizada para identificar artigos científicos que relatassem o uso de soluções digitais de saúde no atendimento ao paciente durante o pós-operatório da reconstrução do ligamento cruzado anterior. Esta revisão divulga todas as soluções digitais de saúde predominantes e alerta para possíveis dificuldades de desenvolvimento e implementação.

As conclusões da revisão permitiram o desenvolvimento de recomendações baseadas em evidências que auxiliam no desenvolvimento e no planeamento da implementação de uma nova solução digital de saúde, o Programa Knee Care at Home, e destacaram os desafios a serem superados na implementação de uma solução digital de saúde para apoiar os pacientes no seu processo de recuperação após a cirurgia de reconstrução do ligamento cruzado anterior.

Por fim, foi desenvolvido um protocolo para avaliar a viabilidade do Programa Knee Care at Home. Os resultados esperados do protocolo de viabilidade incluem a facilitação da racionalização do planeamento, a melhoria da qualidade geral e a simplificação dos processos de implementação relacionados com soluções digitais de saúde.

PALAVRAS-CHAVE: Ligamento Cruzado Anterior; Reconstrução; Cirurgia; Viabilidade; Saúde Digital; Telereabilitação; Saúde Eletrónica; Saúde Móvel; Recuperação; Sensores Wearable; Telesaúde; Revisão; Progressão do exercício; Regressão do Exercício; Manual de exercícios; Knee Care at Home; Resultados Relatados pelo Paciente; Resultados Relatados pelo Médico; Desempenho Funcional; Aceitabilidade; Satisfação; Motivação; Programa de Exercícios em Casa; Supervisão; Monitorização

ABBREVIATIONS

ACL – Anterior Cruciate Ligament

ACLR – Anterior Cruciate Ligament Reconstruction

CBRE – Clinic-based Rehabilitation

CHRC – Comprehensive Health Research Centre

CoLAB – Value for Health CoLAB

CONSORT – Consolidated Standards of Reporting Trials

CR – Conventional Rehabilitation

CR10 – Borg Category Ratio Scale

DH – Digital Health

DHT – DH Technologies

eHealth – Electronic Health

EHC – Exercise and Health Coaches

EUROSTAT – European Statistical Office

EU – European Union

FABQ – Fear Avoidance Belief Questionnaire

FCT - Foundation for Science and Technology

HBE – Home-based Exercise

HBEP – Home-based Exercise Programme

HME – Hospital da Misericórdia de Évora

HR – Health Researchers

IKDC – International Knee Documentation Committee

IKDC-SKF – IKDC Subjective Knee Form

IPAQ – International Physical Activity Questionnaire

KC@H – Knee Care at Home

KOOS – Knee injury and Osteoarthritis Outcome Score

KOOS-QoL – KOOS Quality of life

KOS-ADLS – Knee Outcome Survey Activities of Daily Living

K-SES – Knee-Self Efficacy Scale

MCTES – Ministry of Science, Technology, and Higher Education

mHealth – Mobile Health

NMS – Nova Medical School

OS – Orthopaedic Surgeon

PI – Principal Investigator

PT – Physiotherapists

RCT – Randomised Controlled Trial

ROM – Range of Motion

R&D – Research and Development

SMS – Short Message Service

SPIRIT – Standard Protocol Items: Recommendations for Interventional Trials

TAS – Tegner Activity Scale

TSK – Tampa Scale of Kinesiophobia

UE – Universidade de Évora

VAS – Visual Analog Scale

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PRELIMINARY STATEMENT

This dissertation was inspired by our involvement in the project "Knee Care @Home: Home exercise-based rehabilitation program following surgical reconstruction of the anterior cruciate ligament," which received a research grant from the Comprehensive Health Research Centre – CHRC in November 2021. We were tasked with assisting in the development of the above-mentioned programme and evaluating the feasibility of the intervention.

As such, our research aimed to: (a) investigate the use of digital health tools in the recovery process of patient that underwent anterior cruciate ligament reconstruction surgery; (b) assist in the development of an digital health solution – Knee Care at Home – informed by the previous task and the feedback from patients and healthcare professionals; (c) develop strategies to implement the digital health programme; and (d) design a protocol to assess the feasibility of the digital health programme.

This thesis is organised into four chapters, purely for the sake of readability. The first three chapters include a dedicated references and appendices heading. Chapter I provides a scoping review on the use of digital health tools during the recovery pathway after anterior cruciate ligament reconstruction surgery. Chapter II describes the design of a new digital health solution – the Knee Care at Home programme – and discusses some challenges to successful implementation. Chapter III outlines the protocol of examining the feasibility of the Knee Care at Home programme. Chapter IV concludes the dissertation and proposes further research directions.

CHAPTER I – DIGITAL HEALTH AND RECOVERY FROM ACLR

A. WORKING TITLE

Use of Digital Health Tools in the Recovery Pathway of Patients Following Anterior Cruciate Ligament Reconstruction: A Scoping Review

B. ABSTRACT

Background: Anterior cruciate ligament reconstruction is one of the most common orthopaedic surgeries aimed at restoring stability and functionality to the knee following injury. The postoperative recovery period is crucial for achieving optimal results, and the utilisation of digital health tools may improve patient care and recovery outcomes.

Objective: To conduct a scoping review to identify and synthesise existing evidence on the use of digital health tools in assisting patients recovering from an anterior cruciate ligament reconstruction.

Design: A scoping review method was used to systematically search and review literature on the use of digital health tools in the recovery pathway of patients following anterior cruciate ligament reconstruction. Relevant studies from 2014 to 2024 were identified through scientific databases such as PubMed, Scopus, and Web of Science. Studies were included if they specifically focused on the use of digital health tools, including mobile apps, wearables, telehealth, telemedicine, and other online platforms. Data were extracted and synthesised into key topics and findings regarding the use of digital health tools in anterior cruciate ligament reconstruction recovery.

Results: A total of 14 studies that met the inclusion criteria were identified, involving patients who were rehabilitated from anterior cruciate ligament reconstruction using various digital health tools like mobile apps, which guide the exercises; wearable devices, which monitor the progress; telemedicine, allowing the consultation with experts remotely; and online portals used for

education and support. Digital tools can be used to increase engagement in recovery, improve protocol adherence, and enhance communication with health providers.

Conclusions: Digital health tools may improve the recovery of patients following anterior cruciate ligament reconstruction. Mobile apps, wearables, telemedicine, and online platforms are helpful for improving patient care, patient outcomes, and communication with healthcare providers. Further research will help us understand the long-term implications of these tools for patient recovery. In healthcare studies, it is important to consider innovative recovery pathways to improve patient adherence and healthcare quality when healthcare professionals use digital tools.

Review Registration Number: Open Science Framework 10.17605/OSF.IO/2WQRM.

Keywords: anterior cruciate ligament reconstruction; digital health; recovery; wearable sensors; mobile health; telehealth; telemedicine; review

C. INTRODUCTION

Orthopaedics is the most in-demand medical specialty for appointments and the second most common for surgeries in Portugal.**[1]** Since most orthopaedic conditions require physiotherapy, it is essential to have sufficient postoperative healthcare resources and facilities to accommodate all patients.

In 2023, the European Statistical Office (EUROSTAT) **[2]** stated that the European Union (EU) 611,00 physiotherapists, equating to a ratio of 137 professionals per 100.000 inhabitants. Portugal has 1,456 physiotherapists, representing 14 professionals per 100,000 residents. However, this data only covers the public sector. The Ordem dos Fisioterapeutas **[3]** reports that there are 11,000 registered physiotherapists in Portugal, equating to 110 professionals per 100,000 inhabitants. This accounts for fewer than three physiotherapists per thousand individuals aged over 16. Also, 76% of physiotherapists are employed in the private sector. **[4]**

The data indicates a clear need for additional human resources to support rehabilitation services, particularly for clinical cases lasting over 6 months. **[5]** Patients seeking extended rehabilitation face financial challenges that exacerbate this shortage of rehabilitation professionals. **[6]**

The rise of digital health (DH) has been significant, especially during the Covid-19 pandemic, and has played a vital role in offering rehabilitation services and medical consultations. **[7]** This experience and knowledge are essential for designing and implementing new DH solutions that support patients recovering from anterior cruciate ligament reconstruction (ACLR) surgery.

Developing and integrating DH solutions for patients recovering from ACLR is crucial for enhancing rehabilitation outcomes. **[8]** This shift from conventional clinic-based rehabilitation (CBRE) to DH

interventions offers benefits such as enhanced patient engagement, **[9]** real-time monitoring, **[10]** personalised care, **[11]** and a significant advancement in orthopaedic rehabilitation.

1. Objectives

The main aim is to conduct a scoping review to identify and synthesise existing evidence on the use of DH tools in assisting patients recovering from ACLR. Additionally, our conclusions are intended to help refine future DH research priorities and intervention studies.

2. Review Question

The underlying questions for this review were:

- What are the current DH tools being applied in assisting patients recovering from an ACLR?
- Should patients recovering from an ALCR use DH tools as a complement or a replacement for healthcare interventions?
- What are the main barriers and facilitators to use DH tools in conventional healthcare interventions to help patients who have had an ACLR?

D. METHODS

1. Research Design and Protocol Registration

We conducted a scoping review was conducted using the recommendations from the "Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist". **[12]** The review protocol was prospectively registered in Open Science Framework https://doi.org/10.17605/OSF.IO/2WQRM.

2. Eligibility Criteria

To be included in this scoping review, scientific articles should: (a) be written in English; (b) be published between January 2014 to December 2024; and (c) include patients from primary, secondary, and tertiary care settings at healthcare facilities. The following points (focus, type of participants, type of studies, type of outcome measures) describe additional eligibility criteria.

2.1. Focus

The primary focus of this review is DH. The World Health Organisation (WHO) defines DH as"…*the field of knowledge and practice associated with the development and use of digital technologies to improve health*." **[13]**

With this concept in mind, DH tools may include mobile health (mHealth) apps, wearable devices or sensors, telehealth or telemedicine platforms, artificial intelligence, augmented reality, patient portals, digital therapeutics, and electronic health records.

2.2. Type of Participants

The review only considered studies on patients recovering postoperatively from an ACLR with or without concomitant injuries (i.e. meniscus, cartilage injuries) repair.

2.3. Type of Studies

We included published protocols (trials and feasibility), feasibility studies, and clinical studies that followed an experimental or observational design in peer-reviewed scientific journals.

We searched each study reference list to find additional references not classified in scientific databases. We also consulted the grey literature to identify additional references that were not categorised in scientific databases.

2.4. Type of Outcome Measures

We placed no restrictions on the reported outcome measures. We included all outcomes reported by the patient and/or the clinician.

3. Information sources

Three electronic databases (PubMed, Scopus, and Web of Science) were searched thoroughly to find relevant papers. Bibliographic references were also read, and two ACL research experts (RO and JS) were consulted. Two reviewers (DP and JS) independently searched each database from January 2014 to December 2024.

4. Search Strategy

The main search terms used in the three databases were "anterior cruciate ligament reconstruction" combined with "digital health," "telerehabilitation", "telemedicine", "wearable

devices", “wearable sensors”, “augmented reality”, “virtual reality”, “gamified” and “gamification” (appendix 1).

5. Study Selection

After the search, identified articles were collated and uploaded into Rayyan.ai review software, and duplicates were removed. Inclusion decisions were made by two reviewers, RO and JS, with expertise in anterior cruciate ligament reconstruction rehabilitation and research methods, respectively, through planning the search strategy and selecting records related to the study. Disagreements were resolved by consensus.

6. Data Collection

One reviewer (DP) pilot-tested a data extraction form (appendix 2) on two randomly selected papers to summarise evidence. A second reviewer (JS) verified the data extraction, resolving any discrepancies through discussion. This approach improved accuracy and identified additional items to collect. Complete study characteristics were considered in data extraction to avoid inconsistencies and limitations, even when matched with other papers.

7. Data Items

We did not assume incomplete information from the papers. The reviewing team attempted to contact authors for clarification, but no response has been received. Our goal was to present easily accessible data to end users.

E. RESULTS

1. Study Selection

The selection process followed the guidelines of PRISMA 2020 for systematic reviews, which included three basic steps: identification, screening and inclusion. Figure 1 shows the flow chart of articles selection process.

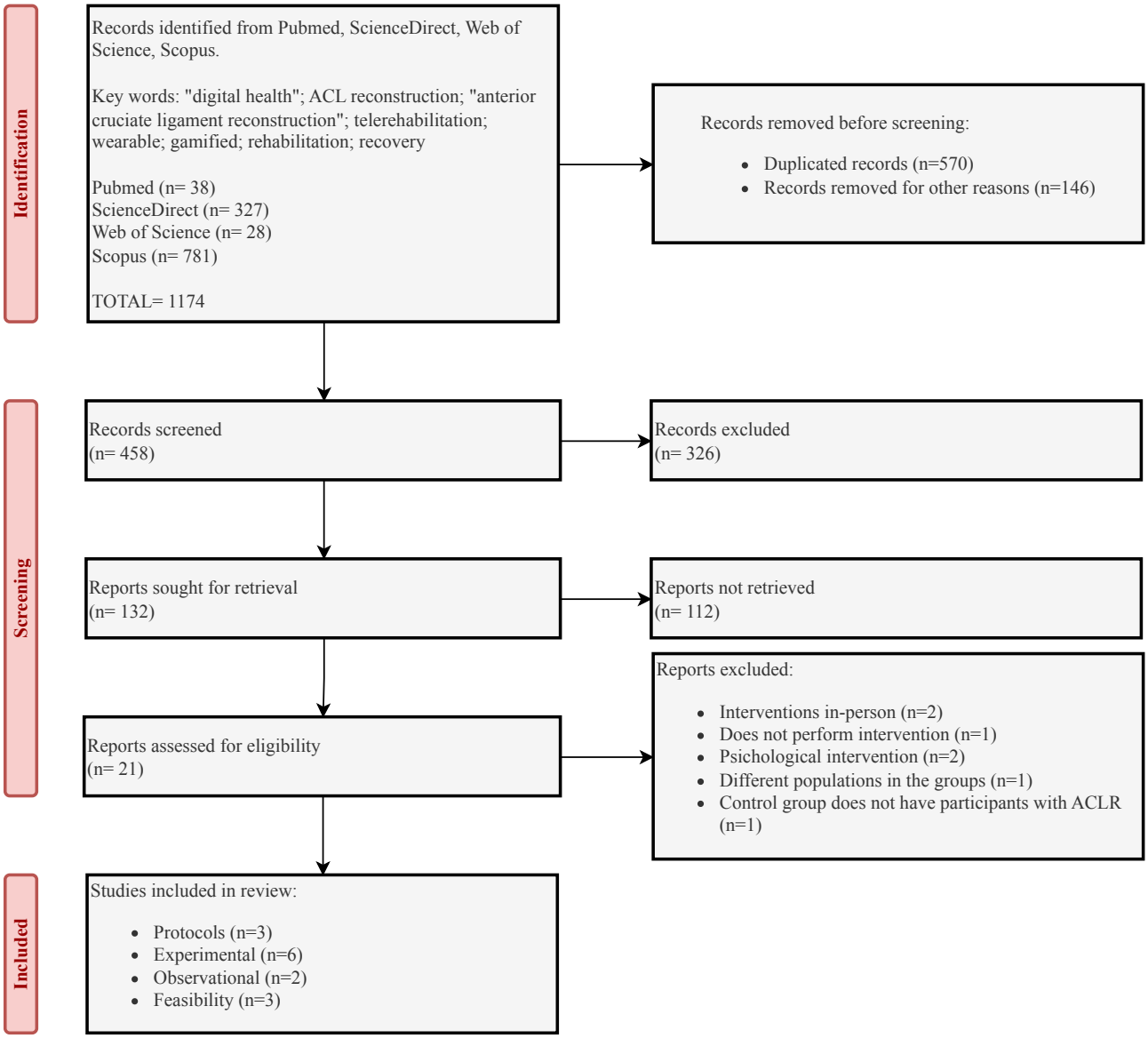


Figure 1. Flow Chart

In the initial step, 1174 records were found in four databases. After removing 570 duplicates and excluding 146 records for various reasons, 458 records remained for further review. We excluded 326 papers while reading the title and abstract. On the remaining 132 papers, after full paper screening, only 21 papers were deemed eligible. Two of the eligible papers were excluded due to the referral of exclusively face-to-face interventions, one paper due to lack of DH intervention, two papers due to the use of an exclusive psychological intervention, one paper due to the use of a different target population, and one paper due to not have included ACLR participants in the control group.

Ultimately, 14 papers were included in the analysis, comprising 3 protocols, 6 experimental studies, 2 observational studies, and 3 feasibility studies (Table 1).

Table 1. Included Papers in Scoping Review

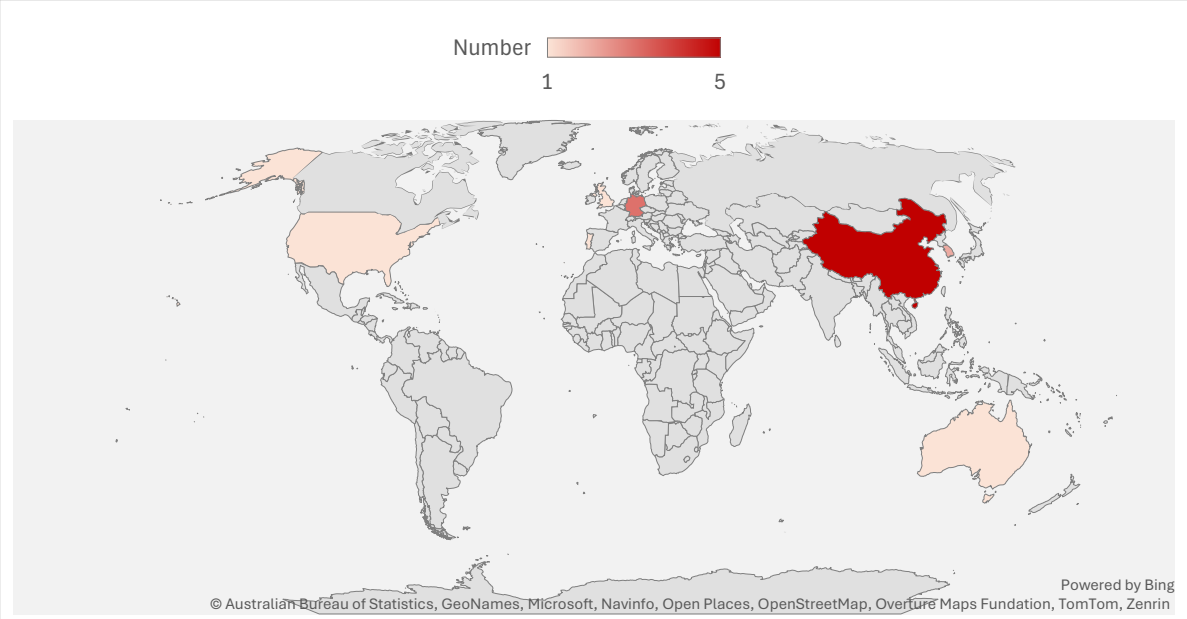
Code	First Author	Year of Publication
#01	Levinger [14]	2017
#02	Clausen [15]	2020
#03	Kim [16]	2020
#04	Dunphy [8]	2021
#05	Kuenze [17]	2021
#06	Hong [18]	2022
#07	Guo [19]	2023
#08	Lee [20]	2023
#09	Liao [21]	2023
#10	Mengis [22]	2024
#11	Lim [23]	2024
#12	Schmidt [24]	2024
#13	Wang [25]	2024
#14	Alegrete [26]	2024

2. Study Design

We included eleven randomised controlled trials (RCTs), three of which are protocols, three are feasibility, and six are experimental. Besides, we also included one case series study and one cohort study, both observational (appendix 3 – Table 2).

3. Source of Information

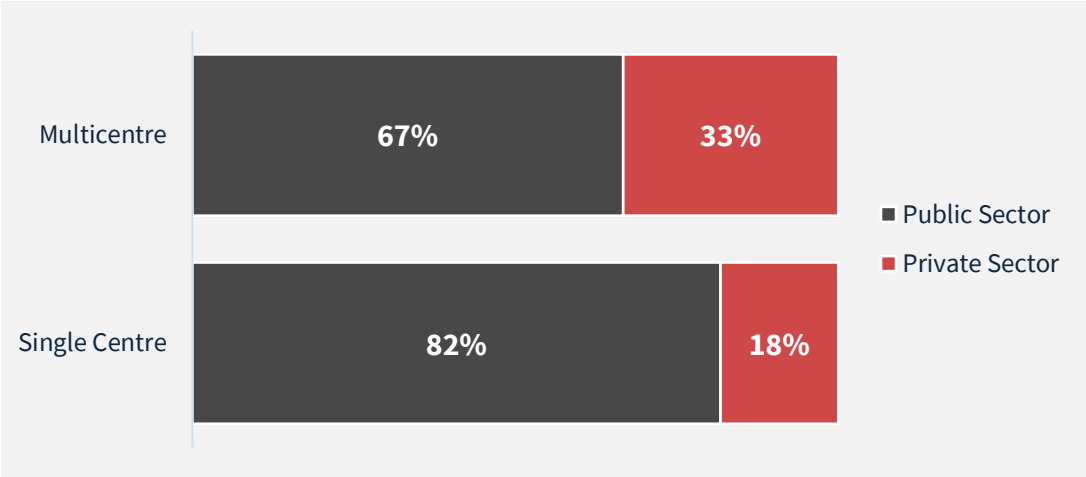
Our sample included studies from various regions (Graph 1). Seven from Asia (South Korea and China), five from Europe (Germany, United Kingdom, and Portugal), one from Australia, and one from North America (United States).



Graph 1. Distribution of Studies per Country

Most of the papers reviewed reported that ACLR surgeries were conducted in single centres, such as public hospitals, private hospitals, university hospitals, and medical centres (appendix 4 – Table 3). Upon further analysis of the relationship between the sector (public or private) and the type of study

source (single-centre or multi-centre), a higher percentage of private institutions were involved in multicentric studies (Graph 2).

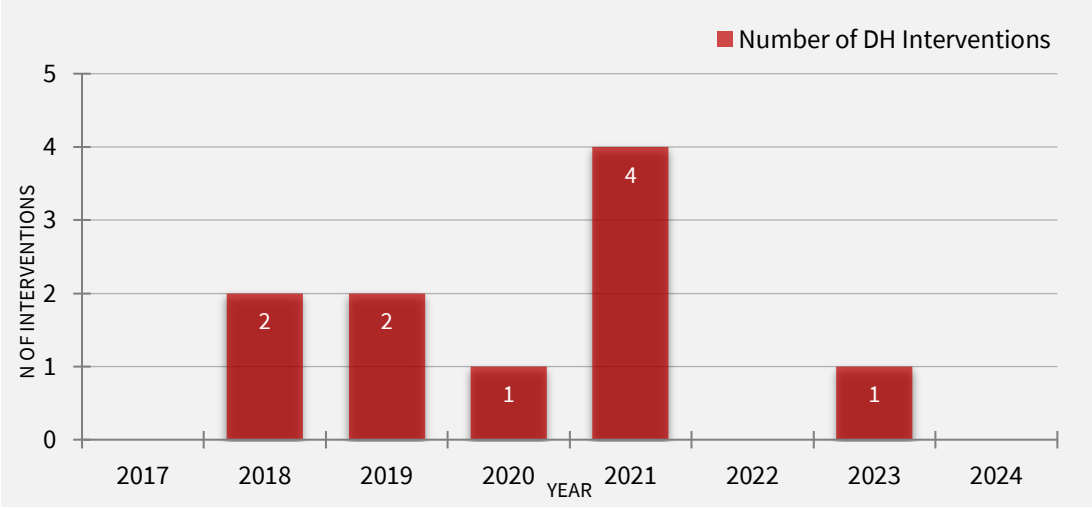


Graph 2. Relationship Between the Number of Institutions and Sector

4. Synthesis of results

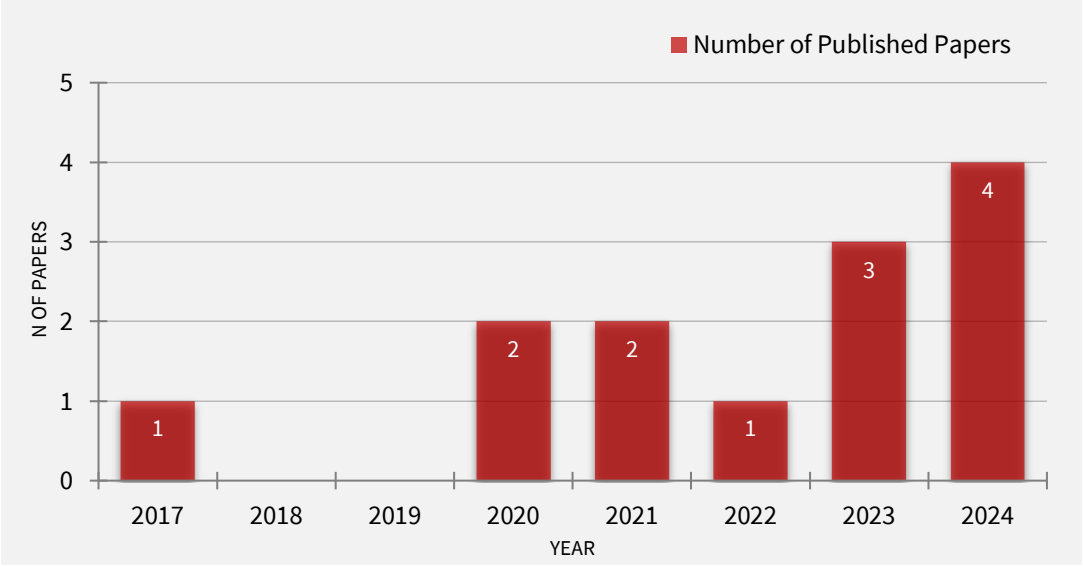
4.1. Included Papers

This scoping review includes fourteen papers published between 2017 and 2024, with 2023 and 2024 being the peak years for publications (Graph 3 and Graph 4). Among the papers reviewed, eleven were already implemented at the time of publication, while there were still in development (appendix 3 – Table 2). Graph 3 shows that DH interventions started to be implemented before the COVID-19 pandemic, indicating that the pandemic may have accelerated the growth of these interventions rather that the emergence of DH solutions.



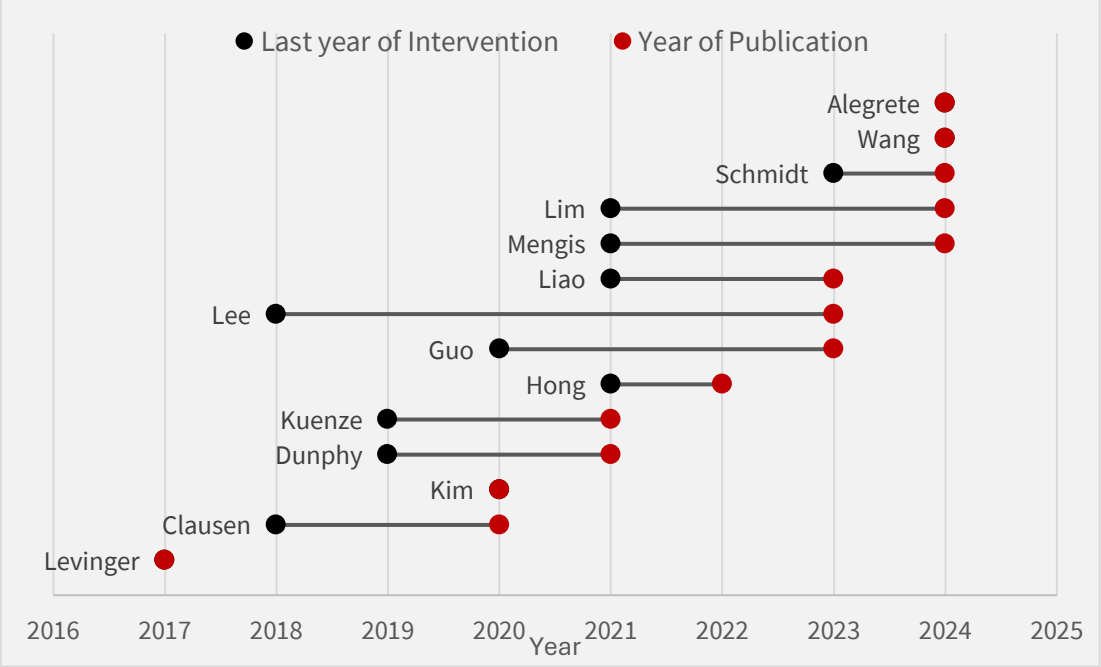
Graph 3. Number of DH Interventions per Year

These results receive additional confirmation by the analysing the data reported on the number of published papers per year (Graph 4). Published papers on DH increased after the COVID-19 pandemic.



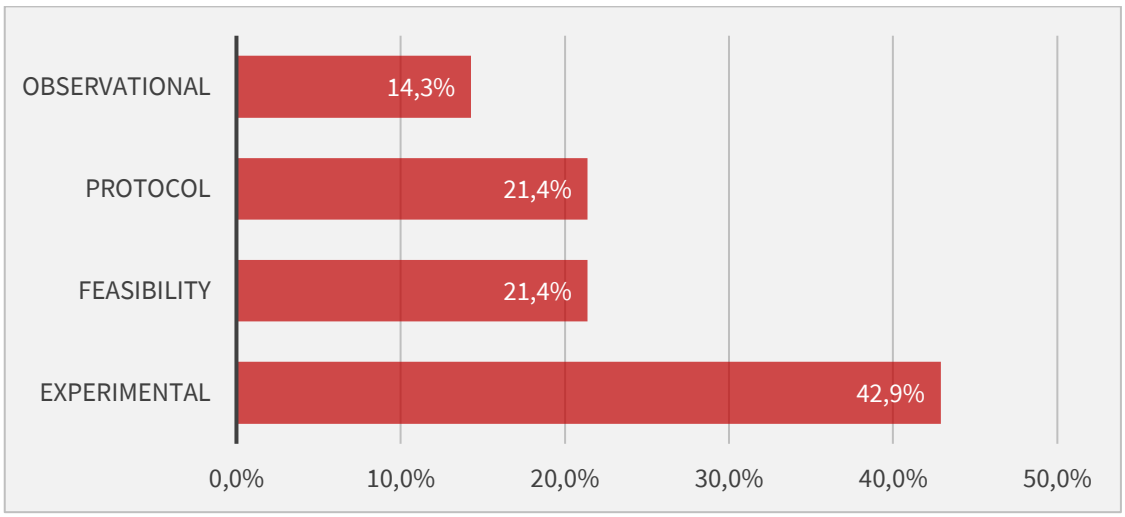
Graph 4. Number of Published Papers per Year

To better understand the relationship between the last year of intervention and the effective year of publication we produced the Graph 5.



Graph 5. Relationship Between Intervention and Publication

We identified four types and three subtypes of papers. Out of the total, six papers were experimental studies, three were feasibility studies, and the remaining four comprised two observational studies and three protocols (appendix 3 – Table 2). The overall percentual distribution in 14 papers is depicted in Graph 6.

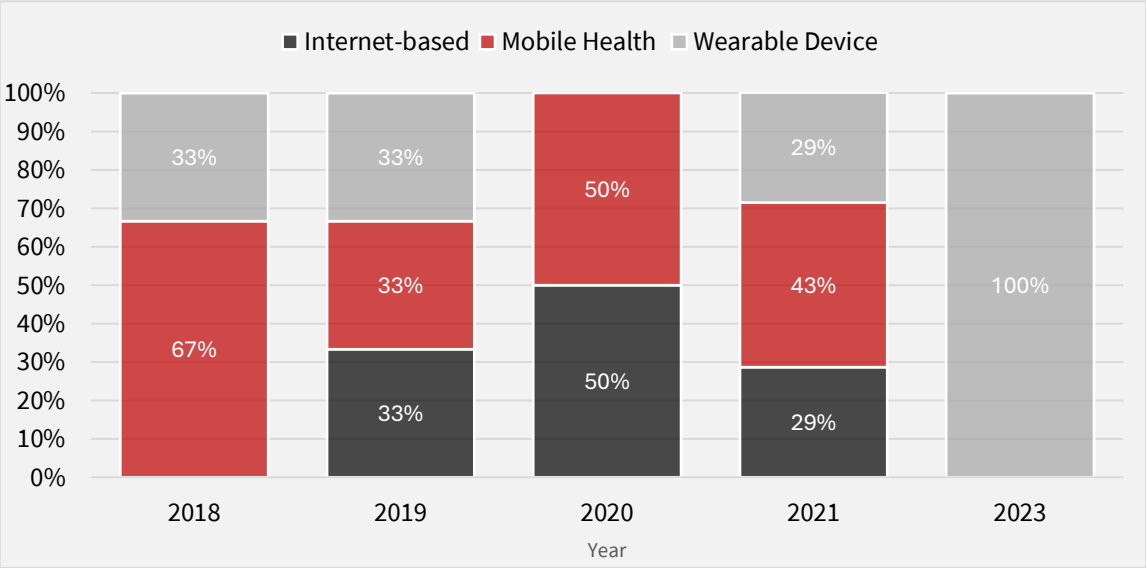


Graph 6. Distribution of Study Type (14 papers)

Most of the studies subtypes were randomised controlled trials (RCTs), with only two being observational studies – one was a case series and the other a cohort study. Among the RCTs, we have found typical experimental designs, one validation study, protocols and feasibility studies. Only one observational study was found to have used a retrospective (historical) data collection window (appendix 3 – Table 2).

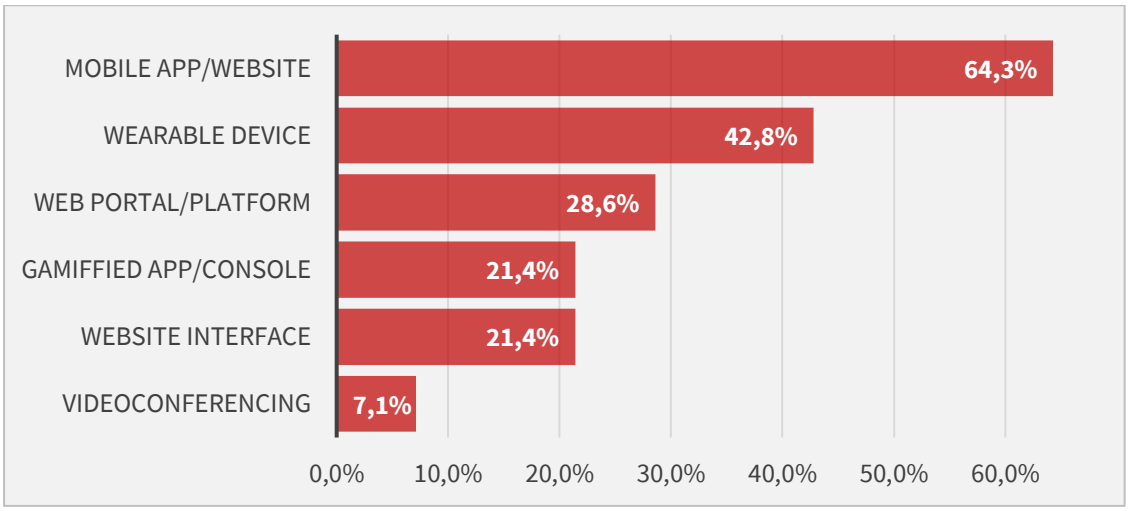
4.2. Digital Health Technologies

We have categorised DH solutions into three main groups: internet-based; mobile health (mHealth); and wearable devices. Independent of the scientific technology employed, except for two papers, **[8, 26]** 85.7% of studies used mHealth. Within this category, three papers incorporated a gamified intervention. **[15, 16, 23]** Wearable devices were featured in five out of fourteen studies, with a notable preference for movement sensors (appendix 5 – Table 4). We analysed the relationship between the type of DH category used and the corresponding year of implementation (Graph 7). Except for the COVID-19 pandemic year, the use of a wearable device or some type of mHealth device is expressive.



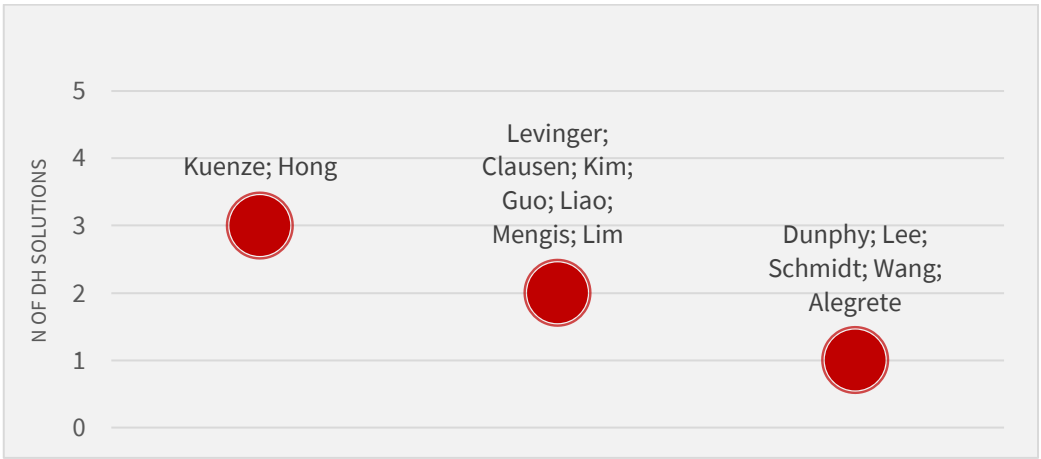
Graph 7. Type of Digital Health Solution Implemented per Year (14 papers)

When analysing the applied specific type of DH solution, we confirmed the above-mentioned trend of mobile applications and wearable devices (Graph 8).



Graph 8. Specific DH Solution Used (14 papers)

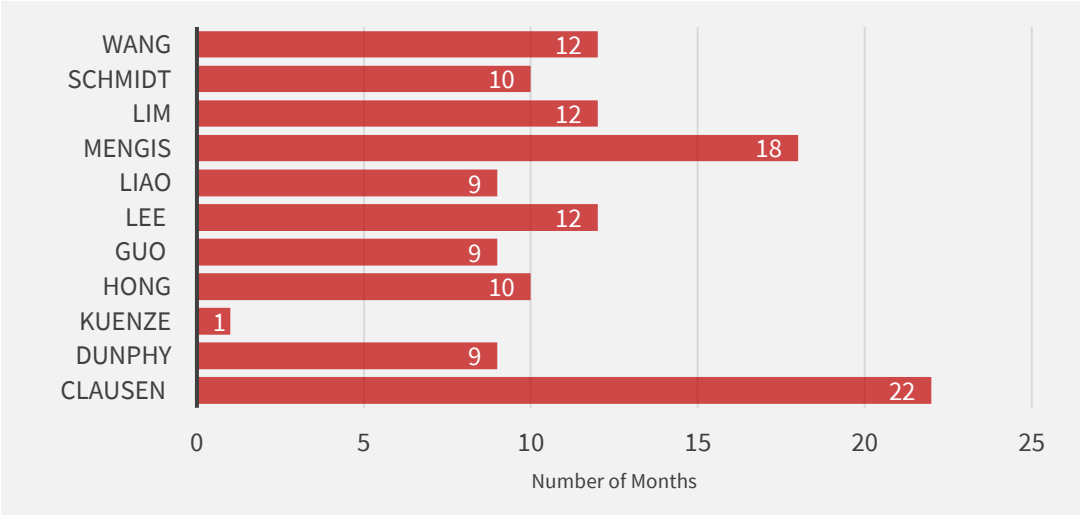
With respect of the number of DH solution applied in 14 papers in our review sample, only two papers used a combination of three solutions (Graph 9).



Graph 9. Number of DH Solutions Used and Reported (14 papers)

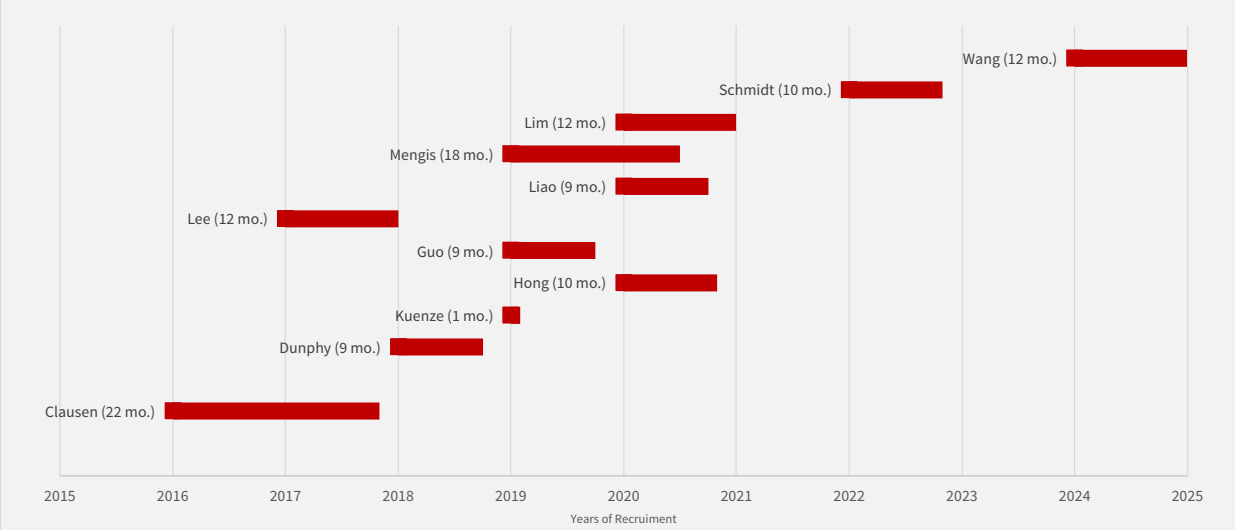
4.3. Recruitment

On average, excluding three papers **[14, 16, 26]** that did not report data about the duration of recruitment, the recruitment procedure took 11,3 months to complete (appendix 4 – Table 3). The lowest reported period was one month and the highest 22 months (Graph 10).



Graph 10. Number of Months Lasting the Recruitment Procedure (11 papers)

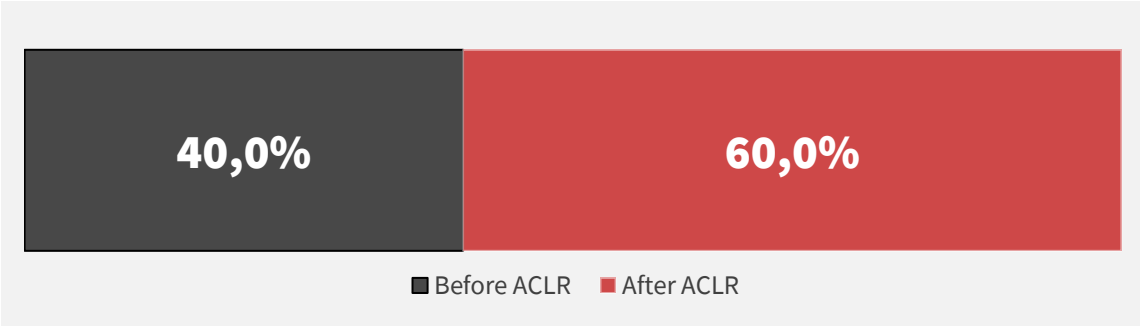
Graph 11 display the analysis of the relationship between the recruitment time frame in months and the years of recruitment.



Graph 11. Relationship Between the Time Frame and the Years of Recruitment (11 papers)

4.4. Randomisation

Four **[17, 18, 21, 22]** of the fourteen studies did not provide information on the randomisation process (appendix 6 – Table 5). Upon further analysis of the remaining papers, it was observed that most of them opted to conduct randomisation after the ACLR surgery (Graph 12).

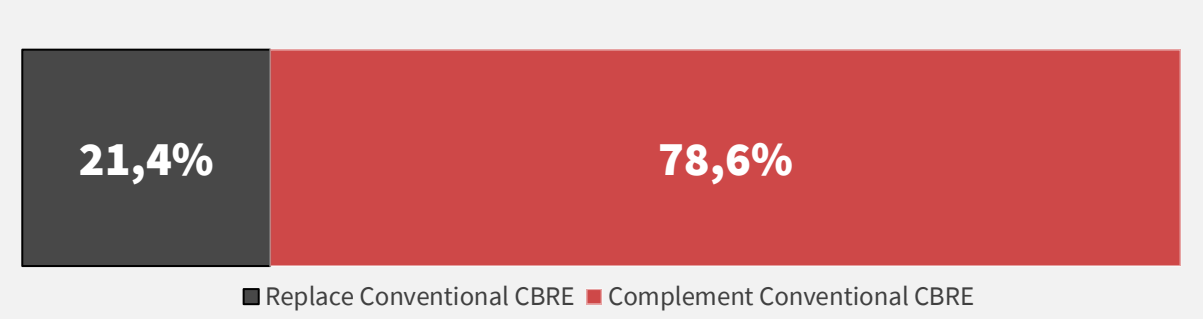


Graph 12. Moment of Participant Allocation/Randomisation (10 papers)

Four **[15, 16, 23, 25]** of these ten studies opted to use secure envelopes to inform participants of the randomisation results, and blinding was often reported on behalf of the outcome assessor and patient (appendix 7 – Table 6). During the randomisation 75% of patients and outcome assessors were blinded to the procedure. The outcome assessor was also blinded in three studies. **[8, 23, 26]** With respect to the collected data analysis, the researcher was also blinded in four studies. **[16, 17, 25, 26]**

4.5. Purpose of Intervention

With respect to the purpose of intervention, a marked tendency was found to complement rather than replace conventional CBRE (Graph 13).

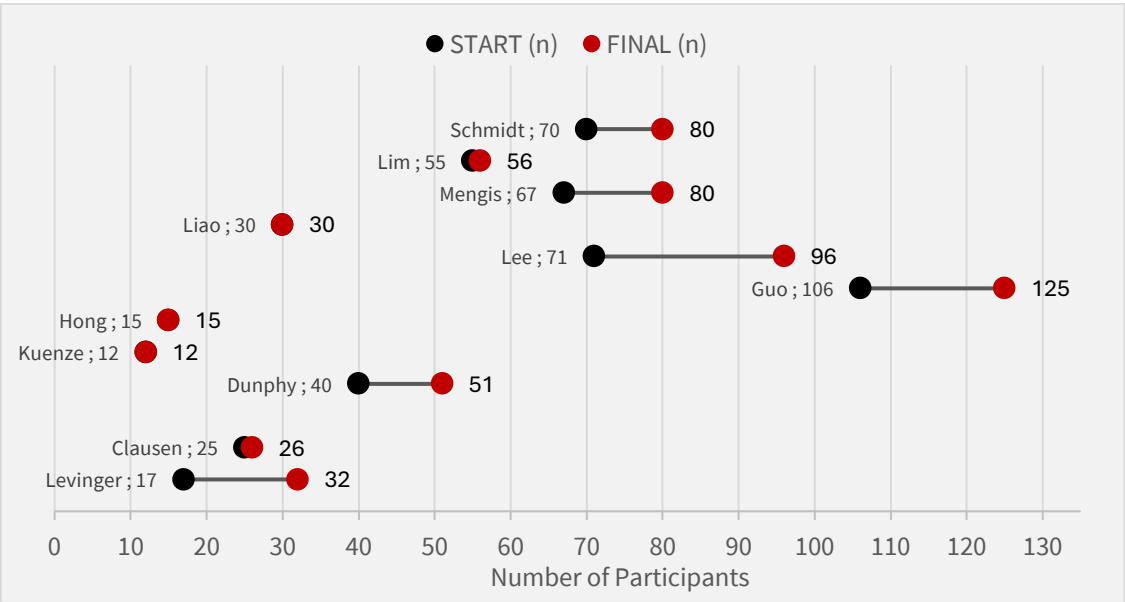


Graph 13. Purpose of DH Solution

As regards the experimental group, 57.14% of intervention strategies opted for combined clinical-based rehabilitation (CBRE) and home-based rehabilitation, while 42.86% preferred to use only home-based rehabilitation (appendix 8 – Table 7).

4.6. Demographic Details

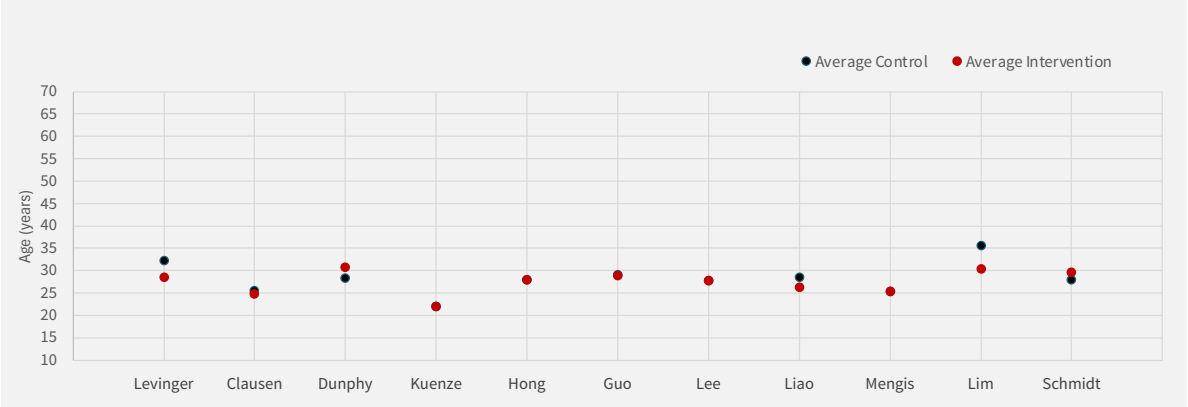
The difference between the type of ACL injury reported shows that the majority opts to use samples with isolated tears (appendix 9 – Table 8). The overall number of participants in the beginning and the end of the study is displayed in Graph 14.



Graph 14. Number of Participants at the Start and End of the Study (11 papers)

4.7. Age

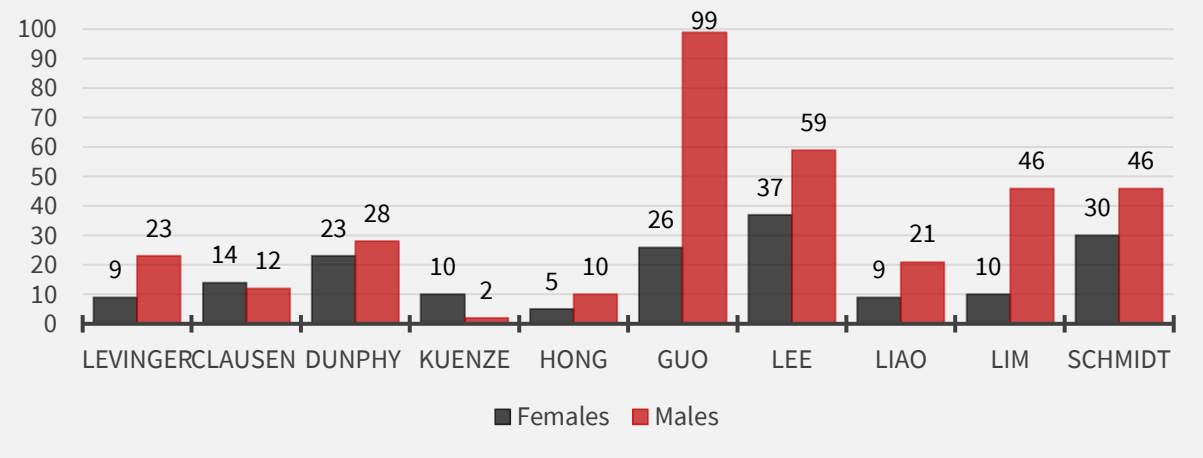
Across the included studies, participant age was reported with different levels of detail (Graph 15). The mean age of participants ranged from 22 to 28 years, with most studies enrolling adults with the range 18-67 years, while a small proportion included younger adults and adolescents (appendix 10 – Table 9). Overall, the reporting of age was consistent in most studies, though a subset did not provide age ranges.



Graph 15. Age Details by Group

4.8. Sex

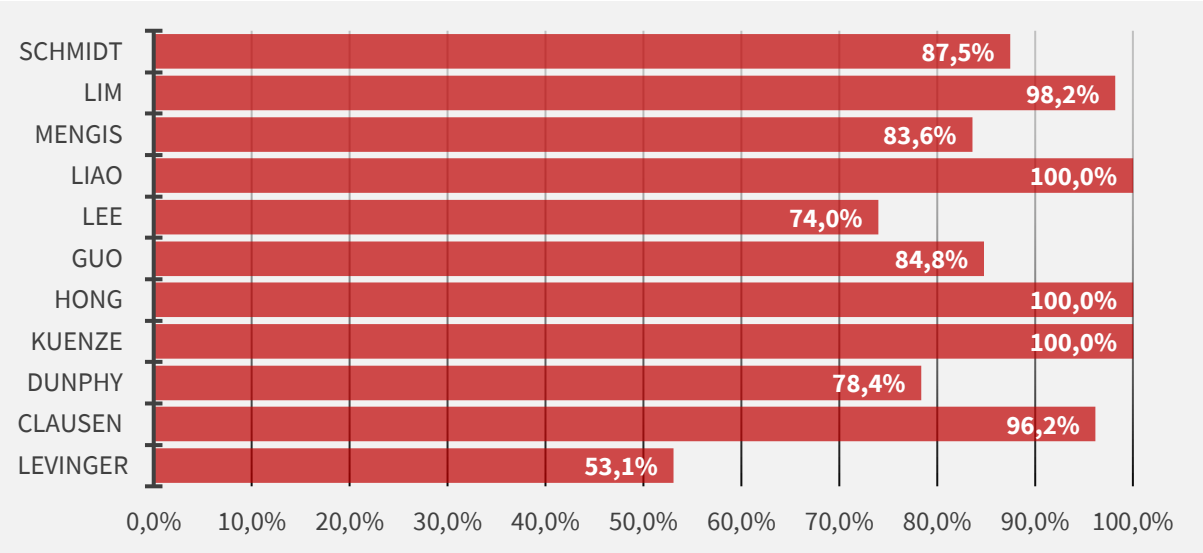
The included studies in this review demonstrated varying representation of female and male participants (appendix 11 – Table 10). Overall studies were skewed toward male samples except for three papers. **[8, 15, 17]** Graph 16 depicts the distribution of sex in samples from 10 papers.



Graph 16. Sex Details (10 papers)

4.9. Retention

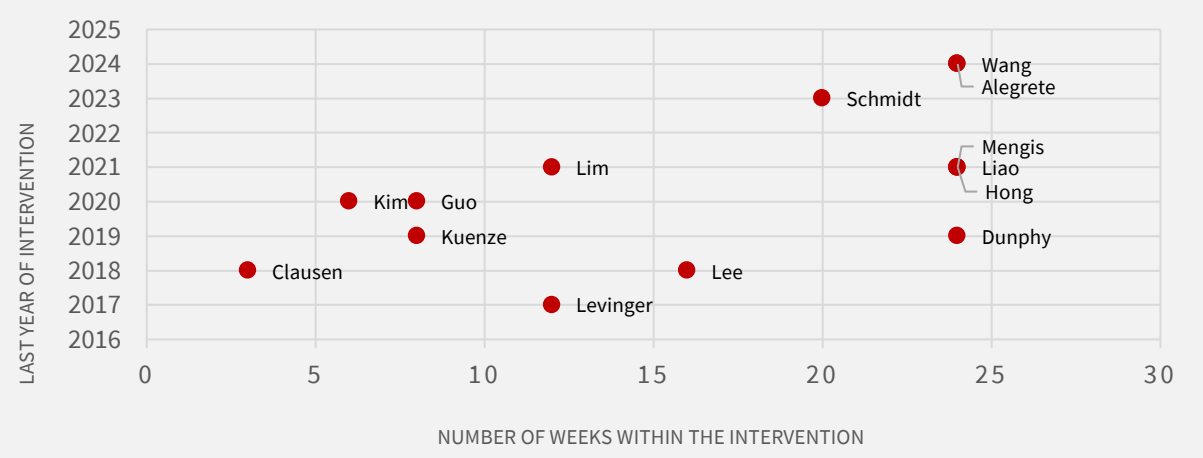
Excep with one study, **[26]** the retention of participants was reported by the remaining studies, which shows concern in enduring the robustness and reliability of study outcomes. Notably, the retention rate differed between studies. Only three studies reported a retention rate inferior to 80% (Graph 17).



Graph 17. Retention Rates (11 papers)

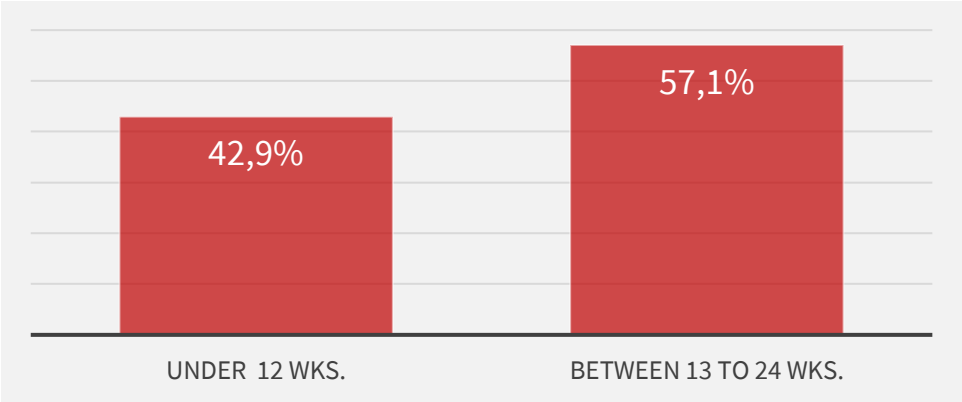
4.10. Intervention Details

Most of the papers (92,3%) reported that the intervention started after surgery (appendix 12 – Table 11). However, only **[22]** specifies the concrete time. Relative to the length of intervention, only six papers reported using the recommended length for ACL rehabilitation protocol, which is of 6 months. **[8, 18, 21, 22, 25, 26]** Graph 18 explores the relationship between the last year of intervention and the reported number of weeks included within the intervention



Graph 18. Relationship Between Intervention and Number of Weeks

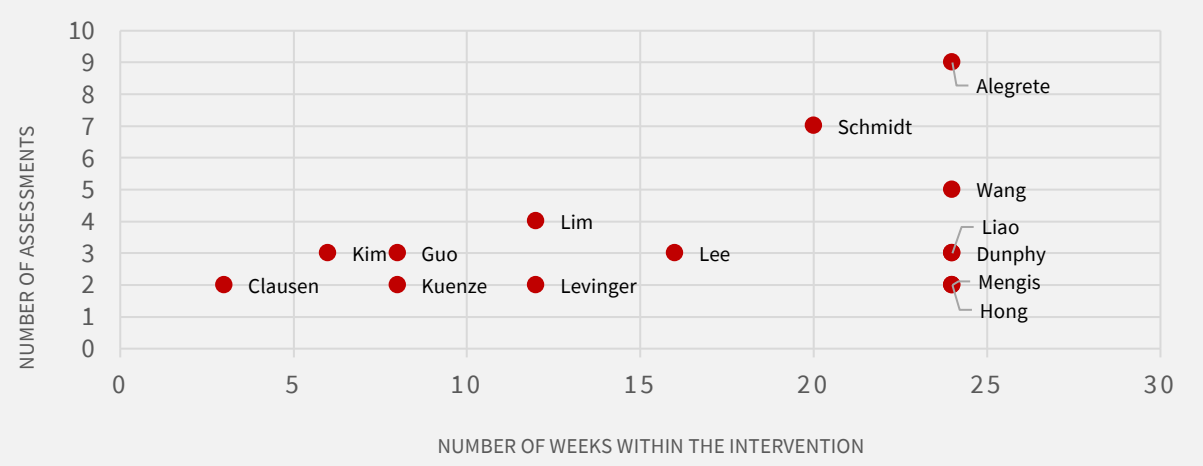
In addition, we also provide a global analysis of the duration of the intervention were most studies (57,1%) applied intervention periods ranging from the 13th to the 24th week (Graph 19)



Graph 19. Common Length of Interventions

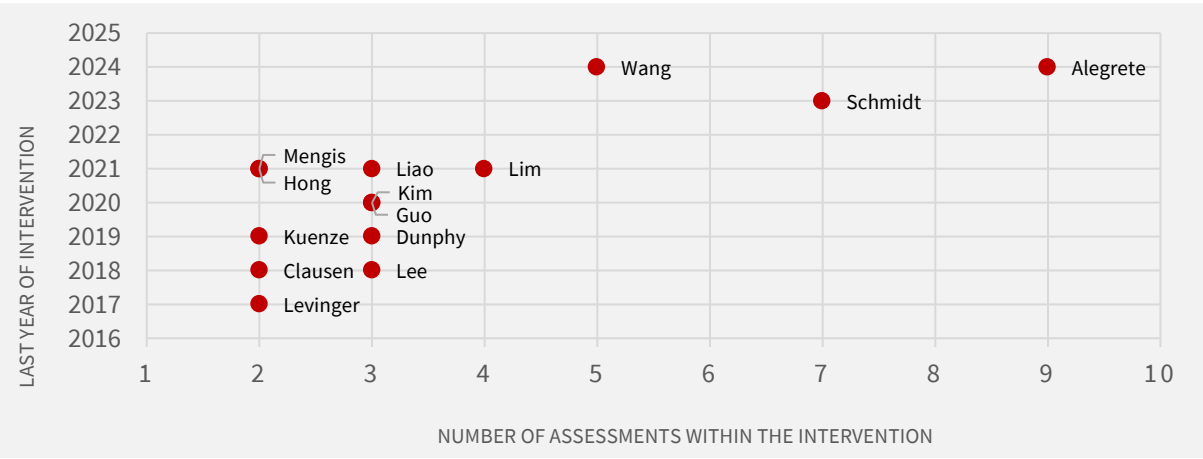
4.11. Moments and Number of Assessments

The timing and number of outcome assessments varied across the included studies. All studies conducted baseline and post-intervention assessments (appendix 13 – Table 12). The total number of assessment points per study ranged from 2 to 9 (Graph 20), with only one trial incorporating a one long-term follow-up. **[26]**



Graph 20. Relationship Between the Number of Assessments and Intervention Weeks

We also considered the analysis of the last year of intervention and the number of assessments to observe if the number increased over the years.



Graph 21. Relationship Between the Number of Assessments and Last Week of Intervention

4.12. Outcomes and Location of Assessments

All interventions implemented questionnaires to understand the evolution of participants, with the International Knee Documentation Committee (IKDC), Knee injury and Osteorthritis Outcome Score (KOOS), Tegner Lysholm Score (LKS), and Tegner Activity Scale (TAS) being the most used. In 85.7% of interventions, questionnaires were administered in person (appendix 14 – Table 13).

4.13. Surgical Information

With respect to the ACLR surgery, seven studies **[15, 17–19, 21, 22, 26]** mentioned the type of graph used and the donor site, with only three **[18, 19, 21]** specifying the number of bundles. Only one study reported to have used the patellar tendon in addition to the hamstring tendon. **[17]** Amongst thirteen studies, only four **[19, 22, 25, 26]** considered the interval between injury and surgery as being relevant (appendix 15 – Table 14).

4.14. Eligibility Criteria

Eligibility criteria were reported in all or most of the included studies, though the level of detail and consistency varied (appendix 16 – Table 15, Table 16, Table 17). Commonly used inclusion criteria included factors such as age range, ACLR surgery confirmation, and given informed consent. Exclusion criteria frequently addressed comorbid conditions, or contraindications to the intervention. Only three studies **[8, 20, 22]** did not mention exclusion criteria. A subset of trials employed more inclusive criteria, allowing for greater external validity.

4.15. Adherence Reminders

Eight of the included studies received reminders to complete the prescribed training (appendix 17 – Table 18). For this submission, four different methods were used: short message service (SMS), **[14, 17, 20]** web portal messages, **[18, 21]** cloud platform messages, **[19]** and a specified application. **[24]**

4.16. Procedures of Ethical Research

Reporting the ethical research procedures varied across the included clinical trials. Most studies explicitly stated that they received approval from an institutional ethics committee or review board. Additionally, informed consent procedures were documented in all studies. Few studies did not mention funding trial registry (appendix 18 – Table 19).

F. DISCUSSION

This scoping review aimed to assess the existing research on DH solutions to aid the recovery of patients following ACLR. We selected fourteen studies based on our eligibility criteria, including three protocols without evidence of intervention implementation. Only one study reported the definition of a prior protocol publication, highlighting that a need for better quality control still exists. Protocols are essential for guiding the repetition of procedures, especially in unfamiliar interventions, and are crucial in healthcare research.**[27]**

DH is a concept encompassing both eHealth and mHealth, which aim to improve health outcomes and increase the accessibility to healthcare services. Electronic health includes remote monitoring and web-based intervention, while mHealth focus on healthcare support through mobile devices and wireless monitoring equipment (wearable devices). Both approaches also intend to promote patient independence.**[28]** In addition, DH may also compromise AR or artificial intelligence (AI) to complete the available solutions.

Contrary to popular belief, DH has been around since the 1990s in Europe. **[29]** Our results demonstrate that an increase of specific interventions to aid the recovery of patients following ACLR exist and were implemented very closely to the COVID-19 pandemic, more specifically before the emergence of the obligatory confinement.

Our review identified four main DH solutions, with most studies opting for a combination of these strategies. This suggests a focus on improving the quality of measures and services. The use of wearable devices has increased in conjunction with mHealth, providing precise data in a non-invasive manner. Besides that, with the technological advances, these devices can be affordable. **[30]** Technological advances have made these devices more affordable and easily integrated into the patient daily life.

We found some recruitment difficulties, with 80% of studies reporting the use of a single centre, which may indicate sample size constrictions and reduce the ability to determine the effectiveness of the intervention. However, research has shown that 76% of discontinued RCTs are related to recruitment difficulties. **[31]**

The DH procedures used to aid patients to recover were mostly consistent across all studies. Six studies focused solely on home-based rehabilitation, while the other eight studies incorporated both conventional and home-based rehabilitation methods.

Most physical and musculoskeletal issues typically require convention CBRE. However, in cases where treatment is required for longer periods, patients may face challenges such as financial constraints, transportation costs, and time constraints. Home-based rehabilitation appears to offer a solution to these issues by providing convenient and cost-effective options that are easily accessible. By incorporating HBEP programs alongside conventional CBRE, it is possible to bridge the gap in rehabilitation services and maintain the quality of physical assessments. **[32]**

Some papers reported surgical information but did not discuss graft selection, which is a critical aspect for the recovery after ACLR. The selection of the appropriate graft in ACLR is integral to successful surgical outcomes, affecting both the integration and maturation timing of the graft, as well as the long-term stability of the knee. **[33]** Several studies emphasize that the graft type and donor site are critical determinants in mitigating risks such as re-rupture and the subsequent need for revision surgery.**[34]** The selection of graft type and donor site is crucial in ACL surgery. Commonly used autografts include hamstring tendon, bone-patellar-tendon-bone, and quadriceps tendon, with hamstring tendon being the most frequently utilized. **[35]** These findings are consistent with existing literature, which also emphasizes the importance of hamstring tendon in ACLR. **[34–36]**

Most identified studies reported on patient populations that underwent ACLR with autographs, meaning that the graft is tissue from the patient's own body that is transplanted to a new location. **[37]** This method is preferred due to its potential for better integration and healing, leveraging the biological properties inherent in one's own tissues. **[38]** A significant portion of studies analysing post-operative outcomes shows that interventions lasting 12 months or longer are common, aligning with the anticipated ligamentization time, which is the period during which the graft transitions to full functional capacity, enabling a safe return to high-demand activities such as pivoting sports. **[39–41]**

Although digital interventions have been implemented, all studies that required complex physical evaluations were conducted face-to-face. This highlights the need for further research and investment in digital health technologies to enable medical teams to perform physical evaluations remotely without the patient needing to be physically present.

Regarding the number of evaluations conducted during the intervention period, it depends on the duration of the intervention itself and the type of assessments the authors intended to use. However, it is important to consider that the evaluation is intended to assess the patient's progress and assist the physiotherapist or exercise coach in determining if the patient is ready to advance to the next level. The literature shows us that interventions after ACLR have four or sometimes five phases of rehabilitation, all of them with physical and psychological goals. **[42]** This means that four or five evaluations must be done. In the papers we collected, the number of evaluations ranged from two to eight. Addressing only the studies with six or more months of intervention, two studies did less than four evaluations.

G. CONCLUSION

This study explores various solutions of using DH for the recovery of patients following ACLR surgery. Based on our findings, the primary goal of DH is not to replace conventional CBRE but rather to complement it. However, as technology continues to advance, we might anticipate that DH solutions will become the predominant method for the recovery pathway due to its accessibility and cost-effectiveness.

Our results also raise questions about conducting physical assessment remotely. Some studies have used wearable devices on their interventions, but none of the devices was able to be used for complex physical assessments, such as muscle strength and thigh circumference measurements, which typically require face-to-face evaluation. However, it is anticipated that future advancements will enable these devices to perform such actions.

In addition, more robust recruitment strategies are needed to enhance the intervention's impact, as most of the final sample fall short of achieving statistical power. Our study has identified potential gaps in the existing literature surrounding ACLR information and postoperative interventions, such as the graft used in surgery, the time between injury and ACLR, the follow-up duration, and the injury mechanism.

In conclusion, further research in DH for patients recovering from ACLR is needed to enhance the effectiveness and safety of recovery protocols. This approach represents the future of exercise active participation in the rehabilitation of specific orthopaedic patient populations. In addition, we feel that building studies based on appropriate protocols that also assess feasibility of the intervention is a gold standard to support this advancement.

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I. APPENDICES

1. Terms Used in the Search Strategy by Source of Information

PubMed Search Strategy/Scopus Search Strategy/Web of Science Search Strategy/B-ON Search Strategy (EBSCO, MEDLINE, CINAHL, DOAJ)

"anterior cruciate ligament reconstruction" AND "digital health"

"anterior cruciate ligament reconstruction" AND "telehealth"

"anterior cruciate ligament reconstruction" AND "telemedicine"

"anterior cruciate ligament reconstruction" AND “telerehabilitation”

"anterior cruciate ligament reconstruction" AND “wearable sensors”

"anterior cruciate ligament reconstruction" AND “wearable devices”

"anterior cruciate ligament reconstruction" AND “augmented reality”

"anterior cruciate ligament reconstruction" AND “virtual reality”

"anterior cruciate ligament reconstruction" AND “gamified”

"anterior cruciate ligament reconstruction" AND “gamification”

2. List of Data Elements for Data Extraction

DATA ELEMENTS
Code
Included Studies
First Author
Year of Publication
Last year of Intervention
Study Design
Subtype
Timeframe
Status (concluded, ongoing)
Implementation
Internet-based
Mobile Health
Wearable Device
Recruitment
Country
Source (single-centre, multi-centre)
Nature (public, private)
Type
Time Frame
Duration (months)
Randomisation
Moment of Aplication (before surgery, after surgery)
Type of Allocation (computer-generated, paper, other)
Delivery (hand, envelope)
Blinding
Randomisation (assessor, physician, patient, coach)
Intervention (assessor, physician, patient, coach)
Analysis (researcher)
Purpose of Intervention
Purpose (complement, replace)
Control Group
Intervention Group
Sample Details
ACL Injury (concomitant, isolated)
Starting (n, groups n)
Dropouts (n)
Final (n, groups n)
Retention (%)
Power

DATA ELEMENTS
Sex Details
Initial (n, females, males)
Final (n, females, males)
Retention (%, females, males)
Age Details
Median
Average and Standard Deviation
Range
Group (average and standard deviation)
Intervention Details
Start
Length
Moment and Number of Assessments
Assessments (number and moment)
Outcomes and Location of Assessment
Outcomes (interface and tools)
Surgical Information
Type of Repair Graph
Donor Site
Time Since Injury
Eligibility Criteria
Inclusion Criteria
Exclusion Criteria
Adherence Reminders
Source
Procedure
Ethical Research Principals
Registry
Ethical Approval
Informed Consent
Funded

3. Details of Included Studies

Table 2. Details of Included Studies

Code	First Author	Year of Publication	Last year of Intervention	Study Design	Subtype	Timeframe	Status
#01	Levinger [14]	2017	-	Feasibility	Randomised Controlled Trial	Prospective	Concluded
#02	Clausen [15]	2020	2018	Experimental	Randomised Controlled Trial	Prospective	Concluded
#03	Kim [16]	2020	-	Protocol	Randomised Controlled Trial	Prospective	-
#04	Dunphy [8]	2021	2019	Feasibility	Randomised Controlled Trial	Prospective	Concluded
#05	Kuenze [17]	2021	2019	Feasibility	Single Group Study	Prospective	Concluded
#06	Hong [18]	2022	2021	Observational	Case Series	Prospective	Concluded
#07	Guo [19]	2023	2020	Experimental	Randomised Controlled Trial	Prospective	Concluded
#08	Lee [20]	2023	2018	Experimental	Randomised Controlled Trial	Prospective	Concluded
#09	Liao [21]	2023	2021	Observational	Cohort	Retrospective	Concluded
#10	Mengis [22]	2024	2021	Experimental*	Randomised Controlled Trial	Prospective	Concluded
#11	Lim [23]	2024	2021	Experimental	Randomised Controlled Trial	Prospective	Concluded
#12	Schmidt [24]	2024	2023	Experimental*	Randomised Controlled Trial	Prospective	Concluded
#13	Wang [25]	2024	-	Protocol	Randomised Controlled Trial	Prospective	Ongoing
#14	Alegrete [26]	2024	-	Protocol	Randomised Controlled Trial	Prospective	Ongoing

* Identified as a clinical validation study, within an experimental study

4. Recruitment Details

Table 3. Recruitment Details

Code	First Author	Country	Source	Nature	Type	Time Frame	Duration
#01	Levinger [14]	AU	Multi-Centre (n=2)	Private	Hospital	-	-
#02	Clausen [15]	DE	Single-Centre	Public	Clinic (Health Care Centre)	Apr 2016 to Feb 2018	22 mo.
#03	Kim [16]	KR	Single-Centre	Public	Hospital (University)	-	-
#04	Dunphy [8]	UK	Multi-Centre (n=2)*	Public	Hospital and Health Board	Jul 2018 to Mar 2019	9 mo.
#05	Kuenze [17]	US	Single-Centre	Public	Community (University)	Oct 2019	1 mo.
#06	Hong [18]	CN	Single-Centre	Public	Hospital (University)	May 2020 to Apr 2021	10 mo.
#07	Guo [19]	CN	Single-Centre	Public	Hospital (University)	Apr 2019 to Dec 2019	9 mo.
#08	Lee [20]	CN	Single-Centre	Public	Clinic (Hospital)	Aug 2017 to Aug 2018	12 mo.
#09	Liao [21]	CN	Single-Centre	Public	Clinic (Medical Centre)	Jan 2020 to Sep 2020	9 mo.
#10	Mengis [22]	DE	Single-Centre	Private	Clinic (Medical Centre)	Jul 2019 to Dec 2020	18 mo.
#11	Lim [23]	KR	Multi-Centre (n=2)	Public	Clinic (Medical Centre) and Hospital (University)	April 2020 to May 2021	12 mo.
#12	Schmidt [24]	DE	Single-Centre	Public	Clinic (Medical Centre)	Feb 2022 to Dec 2022	10 mo.
#13	Wang [25]	CN	Single-Centre	Public	Hospital (University)	Jul 2024 to Jul 2025	12 mo.
#14	Alegrete [26]	PT	Single-Centre	Private	Hospital	-	-

*Initially 3 sites were considered; however, no subjects were recruited in one site, therefore one site was excluded by the authors.

5. Implemented Digital Health Solutions

Table 4. Implemented Digital Health Solutions

Code	First Author	Last year of Intervention	Internet-based	Mobile Health	Wearable Device
#01	Levinger [14]	-	Website Interface	Mobile Website	-
#02	Clausen [15]	2018	-	Gamified App	Strength Monitor (popliteal)
#03	Kim [16]	-	-	Gamified App	Electric Stimulator, Muscular Activity, Knee Angle
#04	Dunphy [8]	2019	Website Interface	-	-
#05	Kuenze [17]	2019	Website Interface	Mobile App	Smartwatch
#06	Hong [18]	2021	Web Portal*	Mobile App	Motion Tracker (knee brace)
#07	Guo [19]	2020	Web Cloud Platform	Mobile App	-
#08	Lee [20]	2018	-	Mobile App	-
#09	Liao [21]	2021	Web Portal*	Mobile App	Motion Tracker (knee brace)
#10	Mengis [22]	2021		Mobile App	Motion Tracker (leg strap)
#11	Lim [23]	2021	Web Portal*	Videogame Console (AR Webcam)	-
#12	Schmidt [24]	2023	-	Mobile App	-
#13	Wang [25]	-	-	Mobile App	-
#14	Alegrete [26]	-	Synchronous Videoconferencing	-	-

*For healthcare professionals

6. Randomisation Procedures, reported in 10 studies

Table 5. Randomisation Procedures, Reported in 10 Studies

Code	First Author	Moment of Aplication	Type of Allocation	Delivery
#01	Levinger [14]	Day of discharge	Computer-generated (simple)	-
#02	Clausen [15]	Before surgery	Computer-generated	Secure envelope
#03	Kim [16]	After discharge	Computer-generated (block)	Secure envelope
#04	Dunphy [8]	After discharge	Computer-generated (sequential)	-
#07	Guo [19]	Before surgery	Statistician-generated (simple)	-
#08	Lee [20]	First postoperative appointment	Computer-generated	-
#11	Lim [23]	After discharge	Block	Secure envelope
#12	Schmidt [24]	Preoperative appointment	Computer-generated	-
#13	Wang [25]	Before surgery	Computer-generated	Secure envelope
#14	Alegrete [26]	First postoperative appointment	Computer-generated (covariate adaptive)	-

7. Blinding of Research Participants, reported in 8 studies

Table 6. Blinding of Research Participants, Reported in 8 Studies

Code	First Author	Randomisation				Intervention				Analysis
		Assessor	Physician	Patient	Coach	Assessor	Physician	Patient	Coach	Researcher
#02	Clausen [15]	-	-	Yes	-	-	No	-	-	-
#03	Kim [16]	Yes	-	Yes	-	-	-	-	-	Yes
#04	Dunphy [8]	Yes	-	-	-	Yes	-	No	No	-
#05	Kuenze [17]	-	-	-	-	-	-	-	-	Yes
#07	Guo [19]	Yes	-	Yes	Yes	-	-	-	-	-
#11	Lim [23]	Yes	-	Yes	-	Yes	-	-	-	-
#13	Wang [25]	Yes	Yes	Yes	-	-	-	No	-	Yes
#14	Alegrete [26]	Yes	-	Yes	-	Yes	No	No	No	Yes

8. Purpose of Intervention

Table 7. Purpose of Intervention

Code	First Author	Purpose	Control Group	Intervention Group
#01	Levinger [14]	Complement	Conventional physiotherapy	
#02	Clausen [15]	Complement	Conventional physiotherapy	
#03	Kim [16]	Complement	Home-based self-exercise program	Home-based exercise program with wearable device
#04	Dunphy [8]	Complement	Conventional physiotherapy	Conventional physiotherapy plus TRAK-ACL website
#05	Kuenze [17]	Replace	-	-
#06	Hong [18]	Replace	-	-
#07	Guo [19]	Complement	Conventional rehabilitation	Conventional physiotherapy plus mHealth intervention
#08	Lee [20]	Complement	Conventional physiotherapy	Conventional physiotherapy plus smartphone app
#09	Liao [21]	Replace	Face to face rehabilitation	Telerehabilitation with artificial Intelligence
#10	Mengis [22]	Complement	-	Home-based rehabilitation with wearable device
#11	Lim [23]	Complement	Conventional rehabilitation	Conventional rehabilitation plus AR based telerehabilitation
#12	Schmidt [24]	Complement	Conventional physiotherapy	Conventional physiotherapy plus smartphone app
#13	Wang [25]	Complement	Home-base self-rehabilitation	Multicomponent supervised telerehabilitation
#14	Alegrete [26]	Complement	Conventional rehabilitation	Conventional rehabilitation plus home-based exercise programme

9. Sample Details

Table 8. Sample Details

Code	First Author	ACL Injury	Starting		Dropouts	Final		Retention (%)	Power
			n	Groups (n)	n	n	Groups (n)		
#01	Levinger [14]	Isolated	32	C = 16; I = 16	15	17	C = 7; I = 100	53,1	Yes (n=40)
#02	Clausen [15]	Isolated	26	C = 12; I = 14	1	25	C = 11; I = 14	96,2	-
#04	Dunphy [8]	Isolated	51	C = 25; I = 26	C = 8; I = 3	40	C = 17; I = 23	78,4	Yes (n=50)
#05	Kuenze [17]	Concomitant	12	-	-	12	-	100	-
#06	Hong [18]	Concomitant	15	-	-	15	-	100	-
#07	Guo [19]	Isolated	125	C = 63; I = 62	C = 19; I = 15	106	C = 52; I = 54	84,8	-
#08	Lee [20]	Concomitant	96	C = 55; I = 41	C = 16; I = 9	71	C = 39; I = 32	74,0	-
#09	Liao [21]	Isolated	30	C = 15; I = 15	-	30	C = 15; I = 15	100	-
#10	Mengis [22]	-	80	-	13	67	-	83,6	-
#11	Lim [23]	Concomitant	56	C = 28; I = 28	C = 1	55	C = 27; I = 28	98,2	Yes (n=56)
#12	Schmidt [24]	-	80	C = 38; I = 42	C = 5; I =5	70	C = 33; I = 37	87,5	Yes (n=40)
#14	Alegrete [26]	Isolated	-	-	-	-	-	-	Yes (n=56)

C – Control; I - Intervention

10. Age Details

Table 9. Age Details

Code	First Author	Median	Average ± SD	Range	Group (average ± SD)
#01	Levinger [14]	-	-	-	Control (32,2 ± 10,2); Intervention (28,5 ± 9,1)
#02	Clausen [15]	-	25,19 ± 8,2	13 to 46	Control (25,6 ± 6,4); Intervention (24,9 ± 9,71)
#04	Dunphy [8]	-	-	-	Control (28,4 ± 8,2); Intervention (30,8 ± 11,4)
#05	Kuenze [17]	-	22,0 ± 3,0	19 to 28	-
#06	Hong [18]	-	28,0 ± 7,0	21 to 42	-
#07	Guo [19]	-	-	-	Control (29,1 ± 6,8); Intervention (28,9 ± 7,1)
#08	Lee [20]	-	27,82 ± 8,73	18 to 53	-
#09	Liao [21]	-	-	-	Control (28,6 ± 9,3); Intervention (26,3 ± 8,59)
#10	Mengis [22]	25,3	-	-	-
#11	Lim [23]	-	-	-	Control (35,7 ± 9,6); Intervention (30,5 ± 11,0)
#12	Schmidt [24]	-	-	Control (18 to 67); Intervention (18 to 57)	Control (28,0 ± 11,0); Intervention (29,6 ± 10,1)

11. Sex Details

Table 10. Sex Details

Code	First Author	Initial			Final			Retention		
		n	F	M	n	F	M	%	F	M
#01	Levinger [14]	32	9	23	17	8	11	53,1	88,8	47,8
#02	Clausen [15]	26	14	12	25	-	-	96,2	-	-
#04	Dunphy [8]	51	23	28	40	-	-	78,4	-	-
#05	Kuenze [17]	12	10	2	12	10	2	100	100	100
#06	Hong [18]	15	5	10	15	5	10	100	100	100
#07	Guo [19]	125	26	99	106	-	-	84,8	-	-
#08	Lee [20]	96	37	59	71	-	-	74,0	-	-
#09	Liao [21]	30	9	21	30	-	-	100	-	-
#10	Mengis [22]	80	-	-	67	20	47	83,6	-	-
#11	Lim [23]	56	10	46	55	-	-	98,2	-	-
#12	Schmidt [24]	80*	30	46	70	-	-	87,5	-	-

*4 participants were identified as “divers”, 2 on each group

F – Females; M - Males

12. Intervention Details

Table 11. Intervention Details

Code	First Author	Start	Length
#01	Levinger [14]	After surgery	3 months
#02	Clausen [15]	Day of surgery	3 weeks
#03	Kim [16]	After discharge	6 weeks
#04	Dunphy [8]	-	6 months
#05	Kuenze [17]	After surgery	2 months
#06	Hong [18]	Day of surgery	6 months
#07	Guo [19]	After discharge	2 months (42 days)
#08	Lee [20]	After surgery	4 months
#09	Liao [21]	Day of surgery	6 months
#10	Mengis [22]	After surgery (3 days)	6 months
#11	Lim [23]	After discharge	3 months
#12	Schmidt [24]	Before surgery (2 to 6 weeks)	14 to 20 weeks
#13	Wang [25]	After surgery	6 months
#14	Alegrete [26]	After surgery (first postoperative appointment)	6 months

13. Moment and Number of Assessments

Table 12. Moment and Number of Assessments

Code	First Author	Assessments
#01	Levinger [14]	(1) 2-3 days after surgery (baseline); (2) 3 months after surgery
#02	Clausen [15]	(1) 6 wks. before surgery (baseline); (2) 6 wks. after surgery
#03	Kim [16]	(1) Not reported (baseline); (2) 2 wks. after surgery; (3) 12 wks. after intervention
#04	Dunphy [8]	(1) Not reported (baseline); (2) 3 months after surgery; (3) 6 months after surgery
#05	Kuenze [17]	(1) 28 days after observation period (baseline); (2) 28 days after intervention period
#06	Hong [18]	(1) 6 months before surgery (baseline); (2) 6 months after surgery
#07	Guo [19]	(1) Before surgery (baseline); (2) 2 weeks after surgery; (3) 6 weeks after surgery
#08	Lee [20]	(1) Before surgery (baseline); (2) 2 months after surgery; (3) 4 months after surgery
#09	Liao [21]	(1) 1 month after surgery (baseline); (2) 3 months after surgery; (3) 6 months after surgery; (4) 12 months after surgery
#10	Mengis [22]	(1) 3 months after surgery; (2) 6 months after surgery
#11	Lim [23]	(1) 2 weeks after surgery (baseline); (2) 6 weeks after surgery; (3) 12 weeks after surgery; (4) 24 weeks after surgery
#12	Schmidt [24]	(1) 6 weeks before surgery (baseline); (2) 3 weeks before surgery; (3) before surgery; (4) 3 weeks after surgery; (5) 6 weeks after surgery; (6) 9 weeks after surgery; (7) 14 weeks after surgery
#13	Wang [25]	(1) Preoperative appointment (baseline); (2) 2 weeks after surgery; (3) 4 weeks after surgery; (4) 8 weeks after surgery; (5) 24 weeks after surgery
#14	Alegrete [26]	(1) Preoperative appointment (preliminary evaluation); (2) 2 weeks after surgery (baseline); (3) 4 weeks after surgery; (4) 8 weeks after surgery; (5) 12 weeks after surgery; (6) 16 weeks after surgery; (7) 20 weeks after surgery; (8) 24 weeks after surgery; (9) 36 weeks after surgery. Every remote session (VAS for pain and CR10 for physical exertion) from 2nd week until 24th week after surgery

14. Outcomes and Location of Assessments

Table 13. Outcomes and Location of Assessments

Code	First Author	Outcomes
#01	Levinger [14]	Website interface (participant logs, KOOS, K-SES, FAB-Q, TSK, IPAQ); Phone interviews (perceptions)
#02	Clausen [15]	Wearable device (strength monitor); face-to-face (IKDC, LKS, TAS, KOOS, VAS, thigh measuring tape)
#03	Kim [16]	Wearable device (sEMG, ROM sensor); face-to-face (isokinetic dynamometer, IKDC, LKS, KOS-ALDS, EQ-5D, VAS, satisfaction, exercise logbook)
#04	Dunphy [8]	Face-to-face (feasibility questionnaires, KOOS, S-SEQ, EQ-5D, CSRI, hand-held dynamometer)
#05	Kuenze [17]	Website interface (step count log); wearable device (step count sensor); face-to-face (KOOS)
#06	Hong [18]	Wearable device (ROM sensor); face-to-face (MRI; arthrometer; isokinetic dynamometer, IKDC)
#07	Guo [19]	Web cloud platform (ROM sensor, thigh measuring tape; VAS, IKDC, compliance questionnaires)
#08	Lee [20]	Face-to-face (arthrometer; isokinetic dynamometer, IKDC, SCIRAS, TSRQ, TPB)
#09	Liao [21]	Face-to-face (TAS; KOOS, IKDC)
#10	Mengis [22]	Wearable device (ROM sensor, coordination test, jump performance test); face-to-face (IKDC, TAS, LKS)
#11	Lim [23]	Face-to-face (hand-held goniometer; hop performance test, NRS, EQ-5D, isokinetic dynamometer)
#12	Schmidt [24]	Face-to-face (KOOS, NRS, hand-held, rehab dose, app usage)
#13	Wang [25]	Face-to-face (hand-held; VAS, isokinetic dynamometer, IKDC, KOOS, TAS, LKS, functional outcomes tests)
#14	Alegrete [26]	Remote sessions (VAS, CR10); face-to-face (KOOS, PCS, DASS-21, VAS, patellar tap test, hand-held goniometry and dynamometer, functional performance tests, PASS, SCB, MCID)

KOOS – Knee injury and Osteoarthritis Outcome Score; **K-SES** – Knee Self-Efficacy Scale; **FAB-Q** – Fear-Avoidance Beliefs Questionnaire; **TSK** – Tampa Scale for Kinesiophobia; **IPAQ** – Short-form International Physical Activity Questionnaires; **IKDC** – International Knee Documentation Committee Subjective Knee; **LKS** – Lysholm Knee Score; **TAS** – Tegner activity scale; **VAS** – Visual Analog Scale; s**EMG** – Surface Electromyography; **ROM** – range of motion; **KOS-ALDS** – Knee Outcome Survey Activities of Daily Living Scale; **EQ-5D** – European Quality of Life-5 Dimensions; **S-SEQ** – Stanford Self-Efficacy Questionnaire; **CSRI** – Client Services Receipt Inventory, **MRI** – Magnetic Resonance Imaging; **SIRAS** – Sport Injury Rehabilitation Adherence Scale; **TSRQ** – Treatment Self-Regulation Questionnaire; **TPB** – Theory of Planned Behaviour; **NRS** – Numeric Rating Scale; **KOOS-PS** – Knee injury and Osteoarthritis Outcome Score Physical Function Shortform; **PCS** – Pain Catastrophizing Scale; **DASS-21** – Depression Anxiety Stress Scales; **PASS** – Patient Acceptable Symptomatic Scale; **SCB** – Substantial Clinical Benefit; **MCID** – Minimal Clinically Important Difference

15. Surgical Information

Table 14. Surgical Information

Code	First Author	Type of Repair Graph	Donor Site	Time Since Injury
#02	Clausen [15]		Hamstring tendon	-
#05	Kuenze [17]	Autograph	Hamstring tendon (n=9) and patellar tendon (n=2)	-
#06	Hong [18]	Autograph (single bundle)	Hamstring tendon	-
#07	Guo [19]	Autograph (single bundle)	Hamstring tendon	Under 10 months
#09	Liao [21]	Autograph (quadruple bundle)	Hamstring tendon	
#10	Mengis [22]		Hamstring tendon	Under 6 months
#11	Lim [23]	Autograph and allograph		
#12	Schmidt [24]	Autograph		
#13	Wang [25]	Autograph		Under 3 months
#14	Alegrete [26]	Autograph	Hamstring tendon, rectus femoris tendon	Under 12 months

16. Eligibility Criteria

Table 15. Eligibility Criteria

Code	First Author	Inclusion	Exclusion
#01	Levinger [14]	(1) been aged 18e45 years at the time of surgery; (2) been able to speak English and give informed consent; and (3) had internet access on a daily basis via smartphone or a computer.	(1) had ACL surgery where there was additional surgical intervention or findings that changed routine post-operative physiotherapy care (eg. meniscal repair); and (2) unable to understand basic English.
#02	Clausen [15]	(1) between 13 and 46 years of age.	(1) additional knee injuries that altered the postoperative treatment protocol (such as meniscal suturing, collateral ligament repair, or regenerative cartilage treatment); and (2) unwillingness to participate in the study.
#03	Kim [16]	(1) subjects who underwent ACL reconstruction surgery; (2) nineteen years of age or older; and (3) ability to provide their own consent.	(1) history of surgery or traumatic injury to the uninvolved lower extremity; (2) complication after ACL reconstruction surgery; and (3) dermatological conditions affecting the thigh.
#04	Dunphy [8]	(1) english speaking adults who had undergone ACL reconstruction within the last 12 weeks; (2) had access to the internet; and (3) provided informed consent.	-
#05	Kuenze [17]	(1) age between 18 and 30 years old; (2) had been cleared for unrestricted PA after surgery; and (3) had no history of lower extremity surgery since their ACLR.	(1) history of any health condition that would limit their ability to participate in PA; (2) history of increased risk of adverse events related to participation in recreational PA; and (3) had not been regularly participating in recreational PA before the injury.
#06	Hong [18]	(1) aged 18-50 years with ACL complete ruptures with/without meniscus tears; (2) planned to undergo ACL reconstruction surgeries.	(1) refused the invitation; (2) had concomitant knee ligament injuries; (3) had dermatological problems affecting the thigh and leg; (4) had other unstable lower-extremity orthopedic conditions; and (5) did not have suitable electronic devices for installing apps.
#07	Guo [19]	(1) age between 18 and 60 years; (2) isolated ACL reconstruction for the first time, which can be combined with cartilage injury and partial meniscus resection; (3) a consistent postoperative recovery plan; (4) essential reading and writing skills and no communication problems; and (5) ability to use smartphones with WeChat installed.	(1) previous history of joint infection, joint tuberculosis or osteomyelitis, or lower limb surgery within 6 months; (2) severe heart, brain, kidney, and other organ dysfunctions; (3) combined with other severe knee joint diseases and injuries; (4) patients with mental illness or cognitive impairment; and (5) transfer to other medical institutions after discharge.

Table 16. Eligibility Criteria (cont. 1st part)

Code	First Author	Inclusion	Exclusion
#08	Lee [20]	(1) were adults aged between 18 and 60 years; (2) had received ACL reconstruction surgery in the previous 2 weeks; and (3) were regular smartphone users.	-
#09	Liao [21]	(1) aged between growth plate maturation and epiphyseal fusion to 55 years old; (2) underwent ACLR in our medical center by two experienced surgeons between January and September 2020; (3) a preinjury Tegner Activity Scale (TAS) level of at least level 5; (4) the use of a protective knee brace after ACLR; and (5) the completion of scheduled outpatient department (OPD) follow-up visits (at least 12 months) postoperatively.	(1) underwent revision surgeries; (2) had multiple ligament injuries; (3) had concomitant comorbidities during the study period (e.g., osteochondral lesion (Outerbridge grade 3 or 4) and severe meniscal damage; and (4) those who did not undergo regular follow-up for at least 12 months after their operation.
#10	Mengis [22]	(1) aged between 18 and 65 years; (2) acute period (<6 months between injury and surgery); (3) unilateral ACL tear; and (4) indication for surgical reconstruction.	
#11	Lim [23]	(1) patients who were aged ≥18 years; (2) isolated ACLR surgery; (3) meniscectomy in conjunction with ACLR; and (4) meniscal repair in conjunction with ACLR	(1) patients who had undergone ACLR in the previous 6 months; (2) bilateral ACLR; (3) other knee joint disorders (rheumatoid arthritis, osteoarthritis, etc; (4) neurological deficits; (5) infection in the affected knee joint; and (6) had severe comorbidity that inhibited exercise.
#12	Schmidt [24]	(1) patients older than 18 years; (2) ACL rupture and planned surgical reconstruction with autologous tendons; (3) less than six months between trauma and reconstruction; (4) sufficient skill in using a smartphone; (5) willingness to use the Orthopy app; and (6) adequate Knowledge of the German language.	(1) bucket handle lesion of a meniscus; (2) cartilage damage >International Cartilage Research Society II with an indication for intervention; (3) complete second ligament injury with an indication for intervention; (4) multiligament injury; (5) knee joint dislocation; (6) neurological damage/primary diseases; (7) prior surgeries on the lower extremities; (8) underlying rheumatic disease; and (9) noncompliance or Conformité Européenne (CE) - determined exclusions of app use.

Table 17. Eligibility Criteria (cont. 2nd part)

Code	First Author	Inclusion	Exclusion
#13	Wang [25]	(1) aged between 18 and 50 years at the time of recruit; (2) BMI between 16 and 28 kg/m2; (3) acute unilateral ACL rupture; (4) plan for an ACLR surgery (with autologous hamstrings tendon reconstruction) under arthroscopy; (5) ACL rupture to ACLR within 3 months; and (6) independently use mobile software and HJT software under the guidance of staff	(1) synthetic tendon reconstruction; (2) concomitant meniscus lesion which needs operation; (3) concomitant other ligaments injury which needs operation; (4) concomitant intra-articular knee fracture; (5) concomitant fracture or injury which may affect postoperative exercise; (6) previous history of knee infection, fracture, and surgery; (7) participate in knee exercises and/or rehabilitation programs in the past three months; (8) living outside the city, regular return to the hospital for follow-up cannot be guaranteed; (9) serious cardiopulmonary disease and unable to participate in rehabilitation exercise; and (10) other reasons for exclusion (mental disorders, stroke, pregnancy, etc.)
#14	Alegrete [26]	(1) undergone primary ACLR regardless of surgical method and choice of autograft; (2) aged between 18 and 55 years at the time of ACLR; (3) have a healthy contralateral (opposite) knee; and (4) the time between ACL injury and ACLR should not exceed 12 months.	(1) declined to participate; (2) concomitant osteochondral injuries; (3) undergone multiple reconstructions of the lateral collateral ligament or posterior cruciate ligament; (4) significant lower limb injuries within the 12 months before the ACL injury; (5) medical conditions that may affect recovery; (6) using medication for mental health disorders; (7) severe impairments in communication or balance.

17. Adherence Reminders

Table 18. Adherence Reminders

Code	First Author	Source	Procedure (reminder)
#01	Levinger [14]	SMS	Encourage access to the internet-based resource.
#02	Clausen [15]	-	-
#03	Kim [16]	-	-
#04	Dunphy [8]	-	-
#05	Kuenze [17]	SMS	Daily physical activity goals and charging reminders.
#06	Hong [18]	Web Portal Messages	Completion of daily schedule.
#07	Guo [19]	Cloud Platform Messages	Training and icing reminders.
#08	Lee [20]	SMS	Daily usage reminders.
#09	Liao [21]	Website Messages	Prompts about changes
#10	Mengis [22]	-	-
#11	Lim [23]	-	-
#12	Schmidt [24]	Orthopy App Messages	Daily push notifications of usage.
#13	Wang [25]	-	-
#14	Alegrete [26]	SMS	Weekly reminders on participation in conventional CBRE and scheduled appointments.

SMS – Shorth Messaging Service

18. Procedures of Ethical Research

Table 19. Procedures of Ethical Research

Code	First Author	Registry	Ethical Approval	Informed Consent	Funded
#01	Levinger [14]	ACTRN126160013790404	Yes	Yes	Full
#02	Clausen [15]	Not mentioned	Yes	Yes	Not mentioned
#03	Kim [16]	NCT04079205	Yes (B-1806-475-006)	Yes	Full
#04	Dunphy [8]	ISRCTN55635910	Yes (18/LO/0403)	Yes	Full
#05	Kuenze [17]	Not mentioned	Yes	Yes	Not mentioned
#06	Hong [18]	-	Yes (A-ER-109-121)	Yes	Full
#07	Guo [19]	NCT03890848	Yes	Yes	Full
#08	Lee [20]	HKUCTR-2761	Yes	Yes	Full
#09	Liao [21]	-	Yes (CE21300B)	Yes	No
#10	Mengis [22]	DRKS00024359	Yes (F-2019-048)	Yes	Partial
#11	Lim [23]	NCT04513327	Yes	Yes	Full
#12	Schmidt [24]	DRKS00028028	Yes	Yes	Full
#13	Wang [25]	NCT06232824	Yes	Yes	Full
#14	Alegrete [26]	NCT05828355	Yes	Yes	Partial

CHAPTER II – DEVELOPING A DIGITAL HEALTH SOLUTION

A. WORKING TITLE

Developing the Knee Care at Home Programme to Assist in the Recovery of Patients Following Anterior Cruciate Ligament Reconstruction

B. ABSTRACT

This chapter describes the development of the Knee Care at Home Programme, which is an innovative, patient-centred, home-based digital health solution designed to enhance recovery outcomes following anterior cruciate ligament reconstruction. Specific and personalized home-based exercises are based on pre-specified recovery criteria while also integrating remote exercise supervision and monitoring across the whole of the recovery pathway. The Knee Care at Home programme was devised with a multidisciplinary panel comprising exercise and healthcare professionals. This approach provided evidence-based support to the intervention and adaptation of patient individual needs, while ensuring adherence to recovery milestones and reducing the need for frequent hospital visits. Key components of the programme, include online synchronous supervision and monitoring of home-based exercises, real-time feedback, direct communication with exercise and healthcare coaches, and a comprehensive programme manual with explanation and demonstration of exercises (pictures and video). Usual follow-up hospital appointments enable patients clinical and physical evaluation to provide feedback during the recovery progress.

Keywords: digital health; anterior cruciate ligament reconstruction; recovery; exercise progression; exercise regression: exercise manual; knee care at home; patient-reported outcomes; clinician-reported outcome; functional performance.

C. INTRODUCTION

The anterior cruciate ligament (ACL) plays a crucial role in maintaining the stability of the knee joint, and its reconstruction is a common surgical procedure aimed at restoring knee function following injury. The recovery pathway following anterior cruciate ligament reconstruction (ACLR) is extensive, often lasting up to 12 months, and requires a multifaceted approach to ensure optimal recovery and return to pre-injury activities.**[1]**

Recovery is generally represented through conventional clinic-based rehabilitation (CBRE) sessions. Still, whenever attending a facility or facing some barrier problem hampers treatment for the patients, the idea of telerehabilitation or videoconferencing supports and solves issues related to their health remotely.

Digital health (DH) solutions, such as those utilizing videoconferencing tools, have shown promise in complementing conventional CBRE practices. For instance, Dunphy et al. **[1]** highlighted the acceptability of a DH solution that supports patients' recovery following ACLR by providing tailored exercise programmes, instructional videos, and direct communication with physiotherapists.

Some DH solutions that complement CBRE practices can facilitate real-time feedback and guidance, which are essential for ensuring that patients perform exercises correctly and safely, thereby reducing the risk of complications such as re-injury or improper healing. The integration of these technologies into the recovery pathway can enhance patient engagement and adherence, which are critical factors for successful recovery.**[1]**

Further, videoconferencing tools also help to make rehabilitation more individualized. Patients can have tailored exercise routines based on the unique requirements for recovery, which is particularly relevant due to the variation in recovery pathways following ACLR. In fact, early joint exercises were

shown not to impede graft healing and, therefore, also to reduce pain, thereby helping to recover faster.**[2]** Thus, healthcare professionals monitor the progress of the patients and may change the programmes in real-time using digital media. In such a way, patients not only follow their recovery protocols but also achieve their milestones in time.

In addition to improving the recovery experience for patients, DH solutions can also alleviate some of the burdens on healthcare systems. The temporal utilization of CBRE face-to-face visits following ACLR has been shown to be concentrated in the early stages of recovery, with patients often requiring less frequent visits as they progress.**[3]**

By incorporating DH solutions, healthcare providers can optimize resource allocation, ensuring that patients receive the necessary support while minimizing the need for CBRE face-to-face visits. This not only enhances patient satisfaction but also contributes to more efficient healthcare delivery systems.

Furthermore, the integration of DH solutions into recovery pathways aligns with the growing emphasis on patient-centred care. As highlighted by Ninković et al.**[4]** the goal of ACLR is to restore knee biomechanics and optimize the quality of life for patients. Overall, DH solutions facilitate greater patient involvement in their recovery, allowing them to take an active role in self-management. This empowerment can lead to improved motivation and adherence to rehabilitation protocols, which are essential for achieving successful outcomes.

D. CONVENTIONAL RECOVERY PATHWAY FOLLOWING ACLR

The recovery pathway for patients following ACLR is a structured process that emphasizes gradual conventional CBRE protocols to restore knee function, strength, and stability. This recovery pathway typically spans several months and is characterized by distinct phases, each with specific goals and interventions aimed at optimizing recovery outcomes.

Initially, the postoperative phase focuses on protecting the surgical site and managing pain and swelling. This phase generally lasts from the day of surgery up to two weeks postoperatively. During this time, patients are often advised to use crutches to limit weight-bearing on the affected leg, and they may be prescribed ice and elevation to reduce swelling.**[5]** Early recovery interventions include passive range of motion (ROM) exercises to prevent stiffness and promote joint mobility. Studies indicate that maintaining knee ROM is critical during this phase, as it significantly influences overall recovery.**[6]**

As patients progress to the early recovery phase, typically occurring from two to six weeks following ACLR, the focus shifts towards regaining strength and stability. This period often involves supervised physical therapy sessions that include exercises focused on the quadriceps and hamstring muscles, which are relevant for stability in the knee joint.**[7]** Studies have revealed that early and intense hamstring training may even reduce strain on the growing ACL graft, thus aiding recovery.**[8]** Furthermore, they are advised to do exercises at home to complement their treatment sessions, which has been associated with enhanced compliance and results.**[9]**

During the intermediate recovery stage, which lasts from six weeks up to three months following surgery, strengthening and stabilization of functional strength are prioritized. Patients are gradually introduced to more dynamic exercises, including closed kinetic chain activities that simulate daily movements and sports-related tasks.**[10]** This phase is crucial for restoring muscle strength, as

deficits in knee extensor strength are common following ACLR.**[11]** The use of objective measures, such as limb symmetry index, helps monitor progress and ensure that strength in the reconstructed limb approaches that of the non-injured limb.**[7]**

As patients transition into the late recovery phase, typically occurring from three to six months following ACLR, the focus shifts towards sport-specific training and preparing for a return to physical activities. This stage may incorporate plyometric exercises, agility drills, and sport-specific movements to improve functional performance.**[12]** Studies show that compliance with a structured recovery pathway at this stage is important for achieving acceptable results and preventing the risk of re-injury.**[9]**

Throughout the recovery pathway, periodic monitoring is performed to assess improvement and modification appropriately. Preoperative knee function, psychological readiness, and adherence to recovery exercises are also crucial predictors of postoperative outcome.**[6, 11]** In addition, the inclusion of patient education and self-management has been identified as a key aspect in enhancing adherence and recovery.**[13]**

Conclusive, the established recovery pathway of ACLR patients, in the clinical setting, consists of a full and staged procedure that focuses on early intervention, strength training, and functional recovery. Following this evidence-based guidelines and including education for the patients, healthcare providers can optimize outcomes of recovery as well as assure a successful return to pre-injury activities.

E. DIGITAL HEALTH SOLUTIONS AND ACLR RECOVERY

Some DH solutions have gained significant traction in recent years, particularly in the context of recovery following ACLR. These solutions leverage technology to enhance patient care, improve access to recovery services, and facilitate ongoing monitoring of patient progress. Current DH solutions encompass the following: telehealth, videoconferencing, remote patient monitoring, and mobile health applications-all approaches to providing care through a healthcare service delivery remotely.

Telehealth, defined as the use of electronic information and telecommunications technologies to support long-distance CBRE, has become a cornerstone of modern healthcare delivery.**[14]** This approach includes various modalities such as videoconferencing, which allows healthcare providers to conduct consultations and follow-ups with patients in real-time, thereby overcoming geographical barriers.**[15]**

The COVID-19 pandemic accelerated the adoption of telehealth, demonstrating its effectiveness in maintaining continuity of care while adhering to social distancing measures. For instance, the implementation of teleconsultation services in orthopaedic settings has proven to be an effective method of healthcare delivery, ensuring that patients receive timely care without the need for in-person visits.**[15]**

Videoconferencing platforms specifically have emerged as vital tools in the realm of DH. They facilitate direct communication between patients and healthcare providers, enabling real-time feedback and guidance during recovery exercises.**[16]** Research indicates that these platforms can enhance patient engagement and adherence to recovery pathway protocols, which are critical for achieving successful outcomes.**[17]** Besides, the ease of use of the videoconferencing software will

facilitate patients, including those who are not technologically savvy, in effectively participating in their care.**[16]**

Remote patient monitoring is another significant aspect of DH, allowing healthcare providers to track patient progress and health metrics from afar. This method is particularly beneficial for patients recovering from ACLR, as it enables physiotherapists to monitor adherence to exercise regimens and make necessary adjustments based on real-time data.**[14]** The integration of wearable devices that collect health data further enhances the remote patient monitoring approach, providing healthcare professionals with valuable insights into patient recovery pathways.**[18]**

The DH solutions have been increasingly emphasized as a significant aspect of recovery pathways. The importance of integrating these DH solutions cannot be understated. A review has shown that DH interventions may improve clinical outcomes and patient satisfaction.**[19]**

Some home-based recovery pathways that are supervised and monitored through videoconferencing have been shown to be less costly than the conventional CBRE.**[19]** Additionally, this type of DH solution empowers patients to take an active role in their recovery pathway, fostering self-management and promoting adherence to recovery procedures.**[17]**

However, for a DH solution to be effectively implemented, healthcare professionals need to have appropriate DH competencies. Studies have shown that familiarity with technology and DH systems is an important factor in the effective delivery of patient-centred care through DH channels.**[20]** Educational frameworks that focus on integrating DH into clinical practice are thus critical in graduating health professionals who can use these technologies effectively.**[5]**

In this regard, the current DH solutions vary with a set of technologies that make possible the provision of healthcare, especially the recovery following ACLR. These include telehealth, videoconferencing, and remote patient monitoring to ensure greater patient engagement and better clinical outcomes. As the sector continues evolving, there is a need for continued education and training of the healthcare professional in maximizing these DH solutions.

F. DEVELOPING A DIGITAL HEALTH SOLUTION FOR ACLR RECOVERY

The design of a DH solution for monitoring a home-based exercise programme (HBEP) in patients recovering from ACLR, with videoconferencing software, presents challenges that may affect the effectiveness and adherence to recovery protocols. These challenges can be broadly categorized into technological, psychological, and logistical factors, all of which must be addressed to optimize patient outcomes.

1. Technological Challenges

The major barrier to videoconferencing in HBEP is the use of reliable equipment for both the patients and the healthcare providers. On the patient side, this includes access to a smartphone or computer; technical issues on their end, including poor internet connectivity or unfamiliarity with videoconferencing platforms, impede effective communication and education during the rehabilitation sessions.**[21]**

Technical glitches in the software may daunt the patients and annoy them, which would reduce their interest in their recovery programme altogether.**[9, 22]** Inequality in care provided can be witnessed in the differences in technical literacies of patients where some would require more assistance than others in using the DH platform.**[23]**

2. Psychological Challenges

A major challenge is patient adherence. Studies have indicated that adherence rates for these DH programmes can vary widely, usually between 50% and 70%.**[24]** Adherence to HBEP is often influenced by psychological factors including motivation, confidence, anxiety, depression, fear of re-injury, complexity of the exercise routine, perceived effectiveness, and the burden of the exercises.

It has been identified through research that psychological readiness acts as a factor in a patient's compliance and participation HBEP.**[25]** During the postoperative recovery stages following ACLR, patients may develop kinesiophobia,-a fear of movement that interferes with a person's participation in prescribed exercises.**[26]**

This might be exacerbated in a HBEP where the patients may feel isolated and not receive immediate support from healthcare and exercise professionals. A lack of supervision and monitoring reduces their confidence in exercise execution, hence reducing overall adherence and outcomes.**[27]** Furthermore, the absence of supervision may lead to poor execution of exercises, increasing the chances of either injury or poor recovery.**[28]**

Social support is essential for patient adherence to HBEP. Research indicates that perceived support from family and friends can greatly improve enhance adherence to HBEP.**[22]** Patients without a strong support system may struggle to stay motivated and accountable, leading to poorer recovery outcomes.**[29]** Besides, it is difficult for patients to maintain their motivation, especially when exercises become repetitive, or the benefits are not directly apparent.**[9, 30]**

3. Logistical Challenges

Logistical challenges are more serious hindrances to the establishment of HBEP. These include difficulties on the part of patients to replicate a suitable environment for exercises, including space and safety equipment for performing exercises.**[28]** In this regard, there is mention that lack of structured time for HBEP can ultimately affect participation in exercises because of poor prioritization of exercises due to other daily activities.**[31]**

This may further hinder the process of monitoring progress or making necessary adjustments to the recovery pathway by the healthcare provider due to a lack of regular face-to-face evaluations, which often results in poorer-than-expected patient outcomes.**[13]** Effective recovery requires continuous monitoring and feedback to ensure patients are doing exercises correctly and progressing as expected. In a home-based setting, lack of direct supervision can make it hard to monitor progress and give feedback promptly.**[28]** Remote monitoring tools like wearable devices or mobile apps can help, but they may bring added complexity and technical challenges.**[32]**

4. Other Challenges

Additional challenges include that there is a need for exercise programmes based on the recovery needs and capabilities of each patient, which is very important because it enhances the effectiveness of HBEP if the exercises are specific to the present functional status and the recovery goals of the patient.**[21]** However, such personalization is hardly achieved in a distance setting when a healthcare provider cannot see immediately how the patient performs certain exercises.**[33]** In addition, without personal adaptation, the exercises given to a patient might prove either too light or too complicated for his specific case, thus becoming discouraging for him, which already seriously impairs the expected outcome of his efforts.**[34]**

Patients recovering from ACLR show a wide range of recovery paths, influenced by factors such as age, pre-existing conditions, and the extent of the injury.**[35]** This variability requires a personalized rehabilitation approach, which can be difficult to incorporate into a standardized HBEP. The success of a HBEP for ACLR patients hinges on its ability to meet individual needs.**[21]** Designing and delivering tailored exercises to meet individual needs while maintaining a cohesive programme can be challenging.**[32]** Patients vary in strength, mobility, and functional capacity, requiring a personalized approach to exercise planning.**[21]** A generic programme may not address differences effectively, resulting in less-than-ideal recovery outcomes.

5. Addressing Challenges

Beyond the identified barriers, the intervention should also outline ways through which patients can be supported and educated. For example, advanced training in the use of videoconferencing can reduce technology-use anxiety in patients and make them more comfortable with their recovery pathway.**[36]** Also, frequent contacts and motivational support from health and exercise providers will go a long way in reducing psychological barriers and increasing adherence to exercises.**[37]** Educational resources explaining the purpose of recovery and self-management strategies may enable patients and reinforce their dedication to the HBEP.**[38]**

G. KNEE CARE AT HOME PROGRAMME – A DIGITAL HEALTH SOLUTION

The integration of remote supervision and monitoring of HBEP sessions for patients recovering from ACLR can be partially justified by borrowing from the various insights in related literature. In this regard, the Knee Care at Home (KC@H) programme is set to provide a wide range of exercises, which can be guided and supported by an appropriate exercise and healthcare coach. The programme will complement CBRE and help patients recover from ACLR. It will start two weeks following hospital discharge and continue until the 24th postoperative week (6 months).

The KC@H programme assesses patient self-reported outcomes that include pain intensity, symptoms, function, and quality of life; and clinician-reported measures on height, weight, and joint function. Physical performance will be assessed using such tests as the single leg hop and stair ascend/descend. Improvements in these measures will be clinically significant.

1. Expected Benefits of the KC@H Programme

The advantages that could be accumulated with the implementation of the KC@H programme include increased accessibility, patient autonomy, enhanced functional outcomes and psychological well-being, continuous monitoring and feedback, the ability to address barriers, and cost-effectiveness. In return, healthcare providers will also benefit by utilizing these advantages as patients may have improved recovery outcomes and experience a better recovery pathway.

Although a reduction in healthcare costs and transportation issues is discussed in the literature, these are mainly related to the substitution of conventional CBRE following ACLR. It is not our aim to replace conventional CBRE but to complement it with a HBEP while increasing exposure to recovery-oriented interventions.

1.1. Accessibility and Flexibility

The KC@H Programme can allow patients to manage their recovery exercises at their own pace. This convenience can result in increased adherence because a patient can easily fit in exercises into their daily routine without frequent visits to the clinic.**[39]** A home-based recovery exercise programme can be particularly effective for highly motivated patients since they allow them to take an active role in their recovery pathway without relying on appointment schedules.**[40]**

1.2. Autonomy and Empowerment

Participating in the KC@H programme may help patients feel empowered and in control of their recovery. This sense of autonomy can boost motivation and commitment to the recovery pathway.**[41]** Research indicates that patients who feel empowered are more likely to stick to their prescribed exercise routines.**[42]**

1.3. Functional Outcomes

Research has shown that HBEP could significantly improve functional outcomes following ACLR.**[25]** Patients in such programmes also usually have a better recovery than those receiving conventional CBRE in the aspects of knee ROM and muscle strength.**[43]** Another good thing about the HBEP is that it they can be specific for every individual depending on their requirements and deficiencies.**[44]** However, further study is required to determine how such options compare with more conventionalist, CBRE according to clinician and patient assessments, though there is the suggestion that these may be equally beneficial.**[45]**

1.4. Psychological Advantages

Participating in the KC@H programme may also create psychological benefits. Generally, more active involvement in patients usually results in greater confidence and less anxiety with respect to the recovery pathway.**[46]** Such psychological component plays a significant role because fear of

re-injury is one factor that can compromise recovery and eventual return to sport.**[47]** The KC@H programme can facilitate a more positive outlook while enhancing self-efficacy, ultimately enhancing the whole recovery pathway.

1.5. Continuous Monitoring and Feedback

The current state of technological evolution enables the implementation of the KC@H programme and its remote supervision and monitoring capabilities. Patients can easily monitor their progress and be provided with real-time feedback, which is available from exercise and healthcare professionals.**[48]** It is this constant monitoring that assists patients in their quest to execute the prescribed exercises well, making progress accordingly for better recovery.**[49]** Research shows that synchronous sessions could also improve exposure and recovery control, hence improving treatment adherence.**[50–52]** Other advantages are immediate feedback and modification of the recovery plan according to the progress of the patients.

Currently, physiotherapists cannot offer standardized care due to the ongoing debate about rehabilitation protocols.**[53]** Even when protocols exist, full recovery cannot be ensured.**[54]** For this reason, orthopaedic surgeons need to closely monitor CBRE and frequently evaluate the effectiveness of recovery protocols.**[55]**

1.6. Addressing Barriers

The KC@H programme may eliminate major barriers to access CBRE, like transportation difficulties, conflicts in scheduling, and some patients' anxiety with clinical environments.**[56]** By offering a comfortable and familiar setting for rehabilitation practices, these can enhance engagement in and compliance with recovery pathways, particularly for those who might be challenged in other environments.**[57]**

1.7. Cost-Effectiveness

While not intended to replace CBRE, the KC@H programme may help reduce some healthcare costs of rehabilitation by limiting the number of CBRE sessions. With convenience and reduction in travel time, the advantages of this programme may improve adherence, thus being cost-effective, especially in underserved areas.**[45, 50, 58–60]** This approach also saves costs to the patients in form of transportation and time wasted from work or other commitments.**[61]** Literature also shows that HBEP can be equally effective as supervised treatments, thus making HBEP relatively inexpensive for attaining recovery outcomes.**[44]**

A questionnaire suggested a gap between the end of rehabilitation programmes and the resumption of daily activities; some patients did not access appointments because of financial challenges during this stage.**[51]** This means that healthcare professionals need to advocate for longer periods of supervision that will suit the patient's needs and schedules for optimum clinical and functional outcomes.**[53, 62]**

Government agencies often overlook orthopaedic services in DH integration efforts, hindering access to rehabilitation services.**[59]** Healthcare professionals must develop innovative strategies to enhance rehabilitation services availability in underserved areas for equitable distribution of services ensuring all individuals have access.

2. The KC@H Recovery Pathway

Recovery following ACLR is important for restoring knee function and helping the patient return to previous activity levels. Due to continued variability in specific content and duration of recovery protocols following ACLR, some healthcare professionals have developed criterion-based guidelines to guide clinical decision-making that complement earlier time-based protocols. A criterion-based approach focuses on the patient's attainment of specific milestones prior to

progression to more difficult exercises.**[53, 63, 64]** This can be smoothly incorporated into the KC@H programme, where patients recover at home and are still making progress.

2.1. Recovery Stages

Patients in the KC@H programme will participate in supervised and monitored HBEP sessions designed for postoperative recovery stages following ACLR.**[65–67]** The KC@H programme includes a personalized recovery pathway based on individual progress (Table 20).

Table 20. Postoperative Recovery Stages following ACLR

Recovery Stages	Timeframe (wks.)
Early	3rd and 4th
Intermediate	5th and 6th 7th and 8th 9th to 12th
Late	13th to 16th
Final	17th to 24th

2.1.1. Patient Progression

A recovery pathway following ACLR may follow various forms and stages depending on the nature of the injury sustained, type of surgery performed, and patient-specific requirements. Several recovery protocols have focused on early range and strength exercises, while others emphasize neuromuscular training aimed at enhancing balance and proprioception.**[68, 69]**

Such protocols can differ in both aim and method, thereby influencing patients' rates of recovery. The intensity and duration of HBEP can be progressively changed based on the patient's progress, and time-based and criterion-based assessments can be combined to guide progression.**[63, 70]**

2.1.1.1. Time-based Approach

There are no adjustments to the timeframes for each postoperative recovery stage following ACLR.**[69]** Table 21 outlines the expected timeframes for each stage following ACLR.

Table 21. Time-based Approach Parameters

Timeframe (wks.)	Duration (wks.)	Recovery Stages
3rd and 4th	2	Early
5th to 12th	8	Intermediate
13th to 16th	4	Late
17th to 24th	8	Final

2.1.1.2. Criterion-Based Approach

The recovery pathway following ACLR using criterion-based progression is systematic, basing itself on specific criteria and functional milestones. Such a recovery method thus provides for personalized treatment plans that maximize recovery and minimize complications.

For instance, Brown et al.**[71]** reported that quadriceps strength in ACLR limbs was lower; thus, the importance of monitoring and improving muscle strength for progress was pointed out. Dewi et al.**[72]** discussed the correlation between muscle strength, knee function, and quality of life following ACLR; therefore, muscle strength and functional outcomes should be used as criteria for progression.

By applying the criteria of muscle strength, joint stability, and functional performance, the healthcare professionals will be able to establish an individualized and structured recovery plan. It will also help the patient reach well-defined functional goals in each phase of recovery, optimize the outcome, minimize complications, and successfully return to pre-injury activity levels.

2.1.2. Restrictions in Patient Progression

The patients, therefore, should adhere to the surgeon's advice and instruction and should not alter prescribed HBEP without the surgeon's consent. Also, some exercises may be limited by the type of graft used in ACLR. Progression within the exercises will be monitored by the exercise and healthcare coach to avoid complications.

2.2. Exercise Components

Key components for each postoperative recovery phase following ACLR are important to enhance the healing process and to improve the strength of the knee joint. Table 22 outlines exercise components and their relationship with postoperative recovery stages and timelines.**[63, 73–76]**

These components include knee ROM, lower limb muscle strength, gait, balance, core strength, agility, and plyometrics exercises. Exercises will support the graft ligament to heal biologically and ensure the knee progresses appropriately through improved load-bearing capacity.**[76–79]**

Table 22. Exercise Components within Recovery Stages

Stage	Timeframe	Components						
	(wks.)	Gait	Core	Strength	Agility	Plyometrics	Balance	Range of Motion
Early	3rd and 4th	✓	✓	✓			✓	✓
Intermediate	5th and 6th	✓	✓	✓			✓	✓
	7th and 8th	✓	✓	✓			✓	✓
	9th to 12th	✓	✓	✓	✓	✓	✓	✓
Late	13th to 16th	✓	✓	✓	✓	✓	✓	✓
Final	17th to 24th	✓	✓	✓	✓	✓	✓	✓

2.2.1. Gait

Following ACLR, the focus for the patients should shift toward the advancement of gait technique, cadence, stride length, swing, and stance patterns. Gait mechanics and endurance can also be enhanced by incorporating walking or running exercises into recovery.**[80–82]** Restoration of a normal gait pattern is very important for functional recovery and prevention of reinjury and osteoarthritis.**[83, 84]** Early weight-bearing and backward walking training may accelerate the recovery of gait kinematics and prepare for a return to sport.**[84]**(Lewek et al., 2002)

2.2.2. Core

The core muscles in the trunk and hips play a very important role in flexion, extension, rotation, and in stabilizing the body. Poor core stability increases the incidence of lower limbs injuries, but the establishment of core muscle control, strength, and stability can prevent injuries.**[78, 85, 86]** Increasing the difficulty in core exercises, patients can add limb movements and add resistance with weights.**[78]**

2.2.3. Strength

Muscle strength of the lower limbs should be increased following ACLR to avoid reinjury.**[87–89]** Specific exercises regarding the ACLR and graft type should be discussed with the patient by the orthopaedic surgeon. Early initiation of strengthening exercises improves outcomes, daily activities, and return to sport. Exercises should be progressively overloaded to avoid reinjury and surgical revision.**[87, 90–92]** It is recommended that general exercises like static contractions should be advanced to strength and power-improving exercises.**[93–96]** The muscular imbalances must be treated, and hip and ankle muscles should be strengthened for maintaining appropriate alignment of the knee.**[97–99]**

2.2.4. Agility

Agility training increases neuromuscular muscle efficiency, reducing fatigue and the risk of ACL reinjury by enhancing hamstring activation with lateral movements.**[100, 101]** Agility training can be initiated as early as the 9th postoperative week. The footwork can be progressed from basic to advanced.**[102, 103]** Varied training drills enhance skill development and minimize training load.

2.2.5. Plyometrics

Plyometric exercises consist of rapid, forceful movements such as jumping and hopping to condition the lower limb muscles for a reduced risk of ACL reinjury.**[103]** Exercises focus on enhancing muscular strength, speed, flexibility, and coordination, with improved mechanics in landing to protect the knee joint while performing various activities such as jumping and cutting.**[73, 104]** When incorporating plyometrics into recovery, start with light, low-impact activities, and progress gradually. Focus on safe, pain-free movements and adjust intensity based on progress.**[73, 76, 104]** Wear proper footwear with good shock absorption and stability, and land with slightly bent knees to avoid excessive stress on the knee.**[76, 77, 102, 105]**

2.2.6. Balance

Improving balance is essential for stability in daily activities and sports and can help prevent ACL reinjury.**[100, 106]** Following ACLR, patients should begin with single and double leg stance training to address changes in proprioception and neuromuscular control.**[102, 107]** Progressively increasing the number and intensity of exercises can challenge balance and coordination without overloading the graft.**[70, 108]** Balance exercises should be incorporated into the recovery pathway from simple to challenging exercises.**[107, 109]**

2.2.7. Range of Motion

Following ACLR, patients have a limited knee ROM, particularly in extension.**[102]** Stretching and ROM exercises can improve knee flexion and extension, reduce pain, and prevent scar tissue.**[53,**

110] Starting these exercises early and maintaining consistency is crucial. Aiming for at least 90 degrees of knee flexion within the first week is an important goal.**[76, 102]**

2.3. Remote Sessions

Patients in the KC@H programme can complement their CBRE with remote monitored and supervised HBEP for 22 weeks following ACLR (Figure 2).

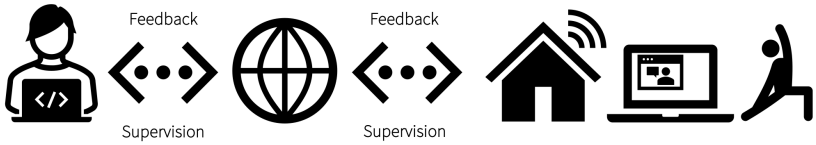

Figure 2. Schematics of Remote Sessions Within Recovery Stages

The KC@H programme remote sessions begin two weeks following ACLR, at the first postoperative visit with the orthopaedic surgeon. Patients will also need to come to the hospital for eight follow-up visits (Figure 3), which should be scheduled on the same day as the first postoperative visit.

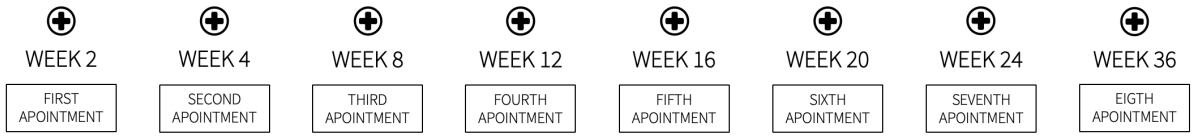

Figure 3. Scheduled Hospital Appointments following ACLR

2.3.1. Structure

Each session of remote exercise lasts 60 minutes, out of which 40 minutes are used for exercising. The sessions are monitored and supervised by an exercise and healthcare coach, conducted three times a week. The sessions are divided into a warm-up phase, conditioning, and cool-down.

2.3.2. Software

Google Meet is a web-based videoconferencing software and requires no special software installation to make the experience of remote monitored and supervised KC@H sessions easier for the patient. The patients need only a web browser and a Gmail account. Google Meet can also be accessed free of charge through the App Store or Google Play. Those who do not have a Google account will be instructed in its creation at their first postoperative appointment by utilizing a provided patient identification number. Patients must have a functioning microphone and camera and are encouraged to test their equipment prior to the session.

2.3.3. Scheduling

The KC@H programme team will request the email of patients who have a Google account to create remote sessions. Then, these remote sessions will be added to Google Calendar, specifying the date and time. Scheduling of remote sessions occurs during each orthopaedic surgeon appointment. Remote sessions are set three times a week for 22 weeks following ACLR. See Figure 4 for the connection between remote sessions and orthopaedic surgeon appointments.

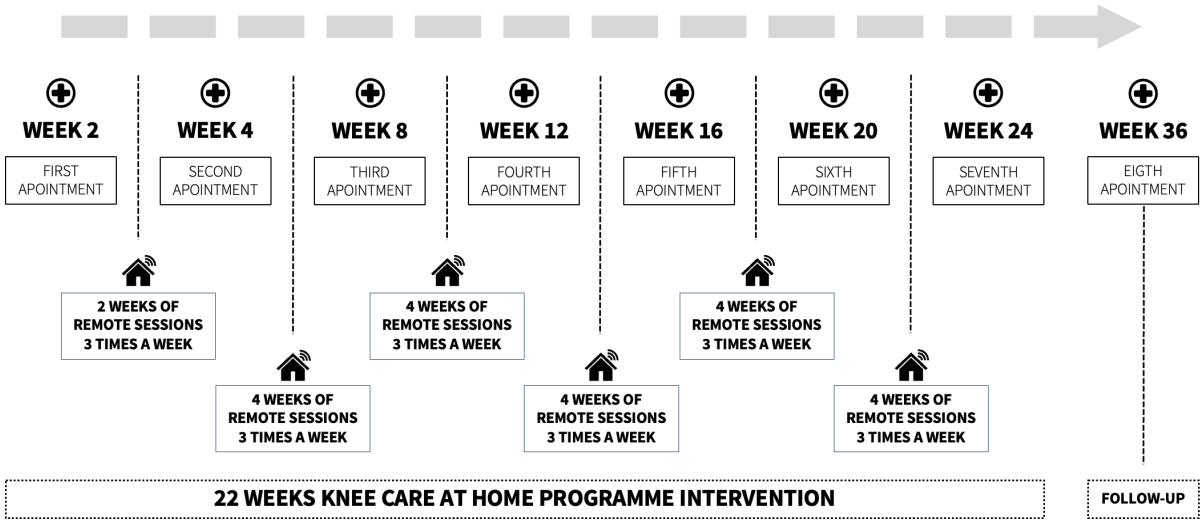

Figure 4. Remote Sessions versus Hospital Appointments

2.3.4. Patient Evaluation

During the KC@H programme remote sessions, the patient will report knee pain intensity, perceived exertion, and adverse events; technical issues also will be captured. The exercise and healthcare coach will capture exercise completion and patients' adherence, adverse events, and technical issues during exercise execution. Refer to Table 23 for evaluation criteria during remote sessions.

Table 23. Evaluation within Remote Sessions

Source	Collected Information
Patient (self-report by SMS)	▪ Pain intensity ▪ Perceived physical exertion ▪ Exercise completeness ▪ Adherence to remote sessions ▪ Adverse events and safety ▪ Technological issues

2.3.4.1. Pain intensity

It is relevant to control both the load of exercise and the perceived pain level during any type of physical activity. Pain during exercise may be indicative of specific adaptations and quality of execution. If exercises are painful continuously, they may not be appropriate. The intensity of perceived pain can be measured using a numeric rating scale - NRS ranging from 0 (no pain) to 10 (worst pain imaginable).**[111]**

Each exercise in the KC@H programme has a maximum pain level threshold that should not be exceeded. If pain surpasses this level, the patient should reduce the exercise load. If pain persists, the exercise should be stopped immediately. Patients should follow the instructions of their exercise and healthcare coach and adhere to self-care recommendations.

2.3.4.2. Perceived Physical Exertion

The perceived physical exertion during the KC@H programme will be measured using the Borg Category Ratio Scale (CR10).**[112]** It consists of a 10-point numerical rating to assess how hard the patient perceives their body is working during exercise. The scale addresses perceptual responses such as fatigue, pulse rate, respiratory rate, and pain. Each exercise in the KC@H programme has an associated CR10 value, which should be kept during performance by changing either speed or load.

2.3.4.3. Exercise Completeness

The exercise and healthcare coach will categorize each patient's exercise by recording their identifier and rating the level of completion (complete, incomplete, unable to perform). This information will be accessible to the orthopaedic surgeon during scheduled hospital appointments.

2.3.4.4. Adherence

Patient adherence of KC@H remote sessions is crucial for recovery. It is evaluated through attendance, cancellations, delays, registration, and completion of sessions.

2.3.4.5. Adverse Events and Safety

During KC@H remote sessions, patients may experience adverse events such as knee infection, deep vein thrombosis, and psychological distress. Patients should report these events to the orthopaedic surgeon or exercise and healthcare coach. The exercise and healthcare coach will monitor symptoms, improvement, and exercise workload. Serious events will be reported to the Ethics Committee if they are life-threatening, cause disability, or require hospitalization.

2.3.4.6. Technological Issues

Evaluation of implementation and technical issues involves assessing the cost and time needed to address technical problems, determining the necessary resources for monitoring patients, and collecting feedback from patients and coaches on any technical difficulties during KC@H remote sessions.

2.4. Comprehensive Programme Manual

The KC@H programme manual (appendix 1) provides a set of exercises for all ACLR postoperative recovery stages. We took part of a panel of experts of the Universidade de Évora and the Hospital da Misericórdia de Évora to develop the manual, which describes exercises in detail supported by pictures and video demonstrations.

It was intended for exercise and healthcare professionals to provide remote support. A patient should consult with the orthopaedic surgeon before entering the KC@H programme and follow the prescribed exercises under the control of an exercise and healthcare coach. Proper exercise can, therefore, assist in recovery, but one should be careful and aware of the risks involved.

2.5. Electronic Data Collection

We developed a website to facilitate data collection (appendix 2), which may be essential for several reasons, primarily centred around enhancing data management efficiency,**[113]** improving participants engagement,**[114]** real-time data visibility and monitoring,**[115]** facilitating recruitment and retention,**[116]** and cost effectiveness.**[117]**

H. CONCLUSION

We developed KC@H programme that takes advantage of a videoconferencing platform for supervising and monitoring HBEP for patients recovering from ACLR, representing the future of rehabilitation services. The combination of conventional CBRE and the KC@H Programme, exercise and healthcare providers can offer a more comprehensive and personalized approach to patient care.

Supervision and monitoring of HBEP enhance recovery pathways protocols and assist patients in reaching their goals. Future studies should focus on optimizing these interventions for outcome improvement in ACLR patients as the DH field continues to evolve.

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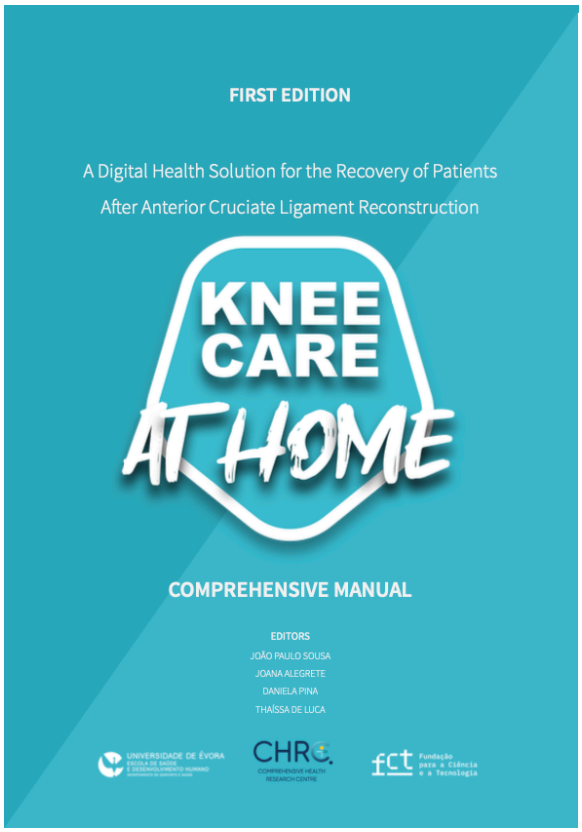
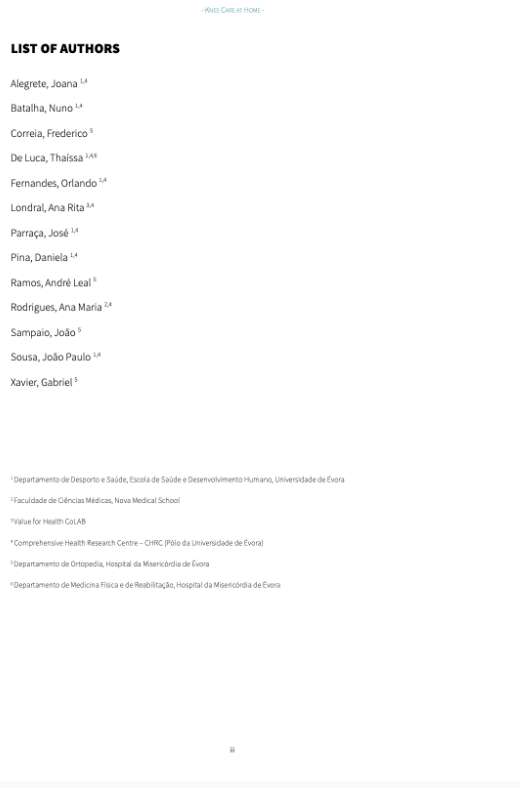
J. APPENDICES

1. Knee Care at Home Programme Manual (English and Portuguese)

Due to copyrights can be consulted, on demand, but not available as an appendix.





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2. Data Collection Website

https://kneecareathome.notion.site/KNEE-CARE-AT-HOME-dda93632a8a5499dbcce9271a174983c

Add icon Add comment

KNEE CARE AT HOME

> INTERVENÇÃO DE EXERCÍCIO SUPERVISIONADO REMOTAMENTE EM CASA PARA MAXIMIZAR A RECUPERAÇÃO APÓS A RECONSTRUÇÃO DO LIGAMENTO CRUZADO ANTERIOR

ANTES DA CIRURGIA

CONSULTA

APÓS A CIRURGIA

EM CASA

Primeiros 15 dias

CHAPTER III – FEASIBILITY OF THE KC@H PROGRAMME

A. WORKING TITLE

Using the Knee Care at Home Programme to Complement the Conventional Rehabilitation of Patients Who Have Had Anterior Cruciate Ligament Reconstruction: Protocol for a Feasibility Study

B. ABSTRACT

Background: The Knee Care at Home programme incorporates supervision and monitoring of home-based exercises via videoconferencing software, which can be a valuable complement to conventional clinic-based rehabilitation, for patients recovering from anterior cruciate ligament reconstruction. This type of digital health solution will further improve access to orthopaedic care and reduce the burden associated with conventional clinic-based rehabilitation.

Objective: The aim of this study is to assess the feasibility, rather than the effectiveness, of a randomised controlled trial on the Knee Care at Home programme for patients recovering from anterior cruciate ligament reconstruction. There were two key objectives: (a) to assess the feasibility of conducting a trial to evaluate the effectiveness of the Knee Care at Home programme, including its acceptability outcome measures; (b) to assign a qualitative evaluation within the trial to identify challenges with the implementation and delivery of the Knee Care at Home programme.

Methods: This protocol is for a randomised feasibility study concurrent to a superiority clinical trial. Patients with anterior cruciate ligament reconstruction will be allocated to a conventional clinic-based rehabilitation group or the Knee Care at Home group. As a complement to conventional clinic-based rehabilitation in an outpatient setting, the Knee Care at Home group will receive synchronous supervision and monitoring, via videoconferencing software, of a home-based exercise program.

Ethics and Dissemination: This feasibility study protocol was approved by the Ethics Committee of the Universidade de Évora (Appendix CIII.01) and complies with the Code of Ethics of the World Medical Association. All recordings will be stored on a secure server with limited access and deleted as soon as they are no longer needed.

Discussion: The Knee Care at Home programme is simple to implement as a complement to conventional clinic-based rehabilitation and is likely to be highly acceptable to patients following anterior cruciate ligament reconstruction, particularly in the early stages of recovery. It has the potential to extend the duration of recovery practices, widen access, and increase supervision and monitoring. For these reasons, the intervention is likely to optimize patient recovery on multiple outcome measures.

Trial Registration: ClinicalTrials.gov NCT06152380

Keywords: Anterior Cruciate Ligament Reconstruction, Feasibility, Acceptability, Satisfaction, Motivation, Home-based Exercise Programme, Telehealth, Supervision, Monitoring

C. INTRODUCTION

One of the main ligaments that stabilises the knee joint via passive restraint is the anterior cruciate ligament (ACL)**[1, 2]** and its rupture is one of the most frequent ligament injuries in sports activities,**[3, 4]** which may cause significant functional restrictions.

Engaging in rehabilitation practices following anterior cruciate ligament reconstruction (ACLR) is an important step towards a quicker restoration of knee function and quality of life, as well as the prevention of an ACL re-injury. However, conventional clinic-based rehabilitation (CBRE) still faces issues related to accessibility, cost, and the patient's adherence to sessions. Digital health (DH) solutions have recently gained increasing interest as they can support technology-enabled improvements in rehabilitation outcomes. Due to technological advances, DH solutions may be more cost-effective and sustainable than conventional CBRE sessions, and they are expected to improve the effectiveness of rehabilitation practises.**[5]**

This feasibility study protocol is combined with a randomised controlled trial (RCT)**[6]** examining the effectiveness of the Knee Care at Home (KC@H) programme, a DH solution using a videoconferencing platform, often called telehealth, to deliver synchronous remote supervision and monitoring of home-based exercises (HBE) as a complement to conventional CBRE. Employing the KC@H programme to complement conventional CBRE may enhance patient access to rehabilitation.

Research using telehealth can introduce innovative strategies to enhance user participation in rehabilitation programmes. However, due to an ongoing scarcity in examining this topic,**[7]** there is still a clear necessity for more research regarding the acceptability and efficacy of telehealth in ACLR rehabilitation.

It has been established that HBE are very successful in many populations enhancing adherence.**[8–13]** That would suggest HBE might be advantageous for patients following ACLR, since personalized supervision and monitoring are important for patient motivation and appropriate execution of exercises.

Transportation barriers and schedule conflicts are major issues that contribute to poor participation in rehabilitation programmes, hence impeding a successful recovery. Supervision of HBE may provide a solution. The remote supervision and monitoring of HBE may offer numerous advantages, such as reduced travel time, expenses, and caregiver burden,**[14]** more satisfaction**[15]** and higher rates of adherence.**[5, 8, 16]** Telehealth may facilitate an enhanced recovery pathway, which includes the use of a variety of exercises that can be supervised and monitored at the convenience of the patients' homes.

Research has supported the feasibility of implementing DH solutions, such as those using telehealth in rehabilitation practice, **[17, 18]** and demonstrates that HBE can lead to significant improvements in physical function and quality of life for different patient populations.**[19, 20]** Overall, findings seem to suggest that using telehealth for ACLR recovery could be both feasible and beneficial for patients. .**[19]** As such, examining the effectiveness and feasibility of the KC@H programme, which includes remote supervision and monitoring of a HBE may represent a timely and innovative approach to ACLR recovery.

Most patients find it difficult to finish six months of conventional CBRE.**[21]** According to estimates, only 30% of patients complete CBRE beyond the first six months following ACLR.**[22]** The KC@H programme is designed to address this gap in the current rehabilitation practise, with the enablement of videoconferencing technology for better engagement and adherence in patients, this trial can immensely add to the recovery pathway following ACLR, potentially leading to better long-term outcomes and lower re-injury rates.**[23]**

1. Objectives

Our study tries to answer the following question: “Is it possible for patients who have had ACLR to use a DH solution, providing HBE, to complement their conventional CBRE?”

As such, the aim of this study is to assess the feasibility, rather than the effectiveness, of a RCT on the KC@H programme for patients recovering from ACLR. There were two key objectives: (a) to assess the feasibility of conducting a trial to evaluate the effectiveness of the KC@H programme, including the acceptability of the intervention and outcome measures; (b) to assign a qualitative evaluation within the trial to identify challenges with the implementation and delivery of the KC@H programme.

Additional objectives include recruitment and retention rates, acceptability and adherence, randomisation, data collection and outcome measures, safety and adverse events, logistical considerations, protocol refinement, sample size determination, assessment of outcome variability, and assessment of study procedures.

D. METHODS

1. Study Design

This protocol describes a feasibility study running in parallel with a single-centre, randomised, two-arm superiority trial.**[6]** The complete protocol is illustrated in Figure 5.

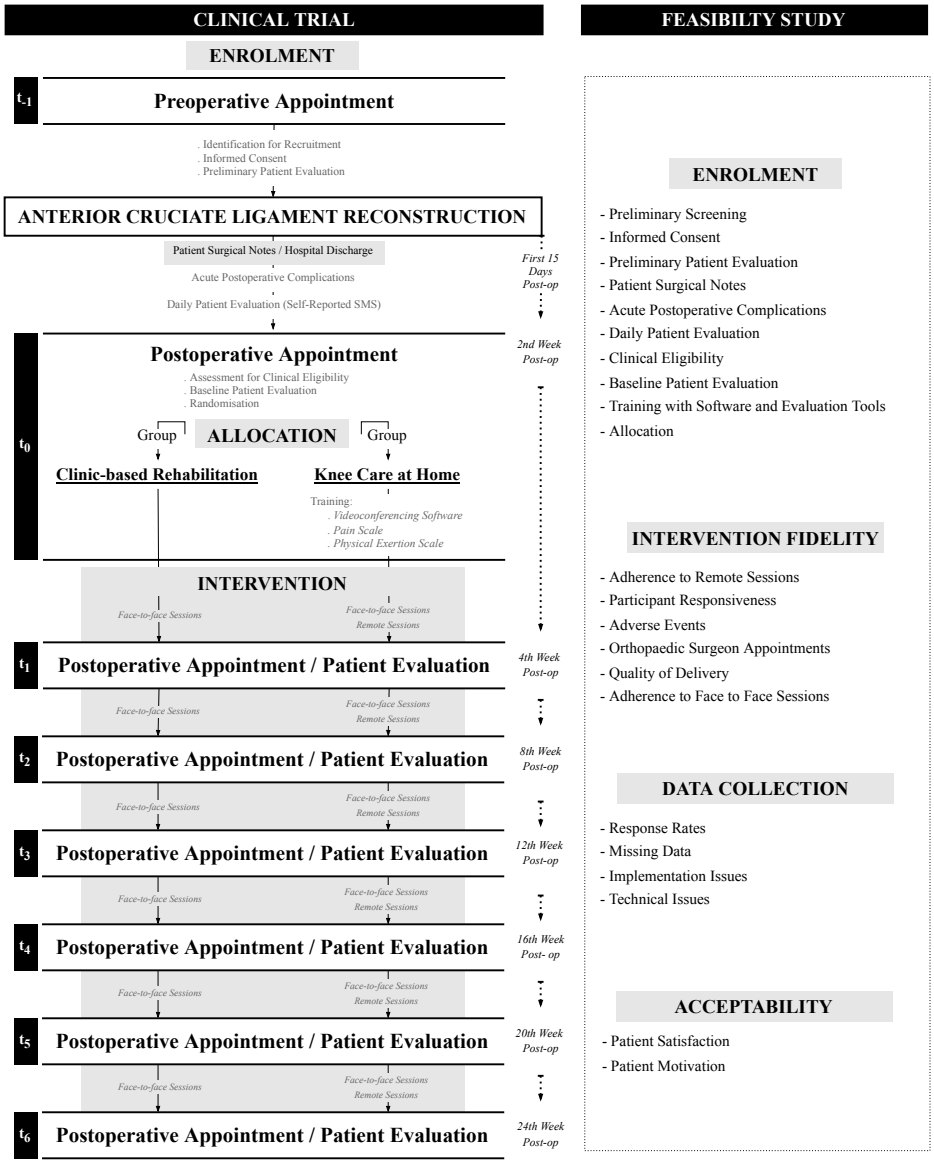

Figure 5. Flow Diagram of Study Protocol

The protocol will follow the Consolidated Standards of Reporting Trials – CONSORT 2010 Statement Extension for Randomised Pilot and Feasibility Trials Recommendations.**[24]**

2. Research Team and Organisation

Our team includes orthopaedic surgeons (OS), physiotherapists (PT), exercise and health coaches (EHC), and health researchers (HR) from four Institutions: (a) Universidade de Évora (UE); (b) Nova Medical School (NMS); (c) Value for Health CoLAB (CoLAB); and (d) Hospital da Misericórdia de Évora (HME). The service providers include the OS, PT, and EHC. The OS has medical and knee surgery training.

The outcome assessor is a PT with orthopaedic rehabilitation training and experience. The EHC has either physiotherapy, sports science, or exercise and health training, or a combination of the three. When necessary, the EHC receives extra instruction from a skilled PT with over twenty years of expertise in ACLR orthopaedic rehabilitation.

The project steering group will consist of the principal investigator (PI) and HR from the UE, NMS, and CoLAB. This group will oversee adherence to the study protocol, data collecting, and data analysis during the study period.

Although the project management is located at the UE, the HME is also responsible for counselling. The PI, OS, PT and EHC will establish the composition of the reference group with the objective to facilitate the interaction with stakeholders that possess diverse expertise and backgrounds.

3. Sample Size

Given that this is feasibility study, a formal sample size estimate is not required.**[25, 26]** However, we aimed to use a sample size determined for the clinical trial,**[6]** based on the results obtained from the Knee Injury and Osteoarthritis Outcome Score (KOOS) for pain.**[27]**

According to the existing data from the HME, about the number of ACLR surgeries over a period of 36 weeks, we would expect three patients per week that could be targeted for recruitment. As such, the sample size for this feasibility study may reach, after adjustment for dropouts, around 56 participants (23 for each group).

4. Feasibility Evaluation

Our study appraises the feasibility of conducting a clinical trial to evaluate the effectiveness of the KC@H programme, including its acceptability. We scheduled the feasibility evaluation into four main periods, which are described in Table 24. A dedicated outcomes assessor, who is blind to the clinical trial, will assist with the feasibility evaluations.

Table 24. Clinical Trial Periods

Periods
1. Enrolment
2. Intervention Fidelity
3. Data Collection
4. Acceptability

4.1. Enrolment

Each of the outcomes that will be examined during the enrolment period are shown in Table 25, in addition to the specific time frame for their evaluation. Our intention is to ensure that the enrolment process is conducted in a way that is both ethical and efficient.

Table 25. Enrolment Outcomes and Time Frame of Evaluation

Outcomes
Preoperative Appointment • Preliminary Screening • Informed Consent • Preliminary Patient Evaluation
At The Time of the ACLR Surgery • Patient Surgical Notes
First 15 Days After ACLR Surgery • Acute Postoperative Complications • Daily Patient Evaluation
First Postoperative Appointment • Clinical Eligibility • Baseline Patient Evaluation • Training with Software and Evaluation Tools • Group Allocation

4.1.1. Preliminary Screening

The preoperative appointment with the OS serves as the opportunity for a preliminary screening for potential participants that are scheduled to ACLR surgery. At this stage, neither age nor gender are considered additional criteria for eligibility since they may limit participation.**[28]** The screening outcomes for the feasibility evaluation are outlined in Table 26.

Table 26. Preliminary Screening Outcomes for the Feasibility Evaluation

Outcomes
Qualitative Data
Screening Resources: Description of the required resources.
Quantitative Data
Participant Availability: Determine the potential number of available participants.
Recruitment Rate: Determine the number of participants screened per week/month.
Participant Screening Time: Monitor the time (min) spent screening.
Screening to Enrolment Rate: Calculate the number of ineligible at screening / total screened × 100

The OS is the only authorized professional to access and consult the patients' electronic health records. This will help identify potential participants more efficiently.**[29]** By analysing the feasibility of screening outcomes, we can ensure they accurately represent the target population.**[28]**

4.1.2. Informed Consent

During the preoperative appointment, potential participants receive with an informed consent document outlining the trial protocol including its purpose, procedures, potential risks, and benefits (appendix CIII.02 and appendix CIII.03). They can ask questions and address any concerns about the KC@H programme or the upcoming ACLR surgery. Participants who consent to participate also receive a KC@H programme manual (appendix CIII.04).

The research team aims to improve the clarity of the informed consent while preserving participants' willingness to engage in the study.**[30]** The form is constructed to be patient-centred, with the objective of enhancing understanding and acceptance of involvement in clinical trials. Table 27 delineates the outcomes of informed consent and the proposed feasibility assessment, encompassing both qualitative and quantitative data.

Table 27. Informed Consent Outcomes for the Feasibility Evaluation

Outcomes
Qualitative Data
Consent Resources: Description of the required resources to obtain face-to-face consent.
Consent Comprehension: Describe if informed consent form is understandable and succinct.
Consent Refusal: Describe the reasons for not agreeing to consent.
Quantitative Data
Consent Rate: Calculate the number of participants who consent / total eligible participants x 100
Withdrawal After Consent Rate: Calculate the number of withdrawals / total number of participants x 100
Time to Obtain Consent: Monitor the time (min) it takes from first contact to obtain consent.

The decision was made to utilise electronic informed consent forms to enhance the recruitment process.**[31]** Electronic informed consent can deliver clear, comprehensible information and promote a more interactive permission procedure, potentially augmenting trust and comprehension amongst prospective participants.**[32]** In accordance with recommendations,**[31, 33]** additional researchers and healthcare experts were approached to provide feedback for the amendment of consent forms.

4.1.3. Preliminary Patient Evaluation

The preliminary patient evaluation takes place during the preoperative appointment with the OS, immediately after the signing of the informed consent form. Upon obtaining agreement, in accordance with data protection regulations,**[34]** sociodemographic information will be directly gathered from the patient utilising a designated code to maintain anonymity (Table 28).

Table 28. Sociodemographic Information

Collected Data
• Date of birth • Biological sex • Upper limb and lower limb dominance • Education level • Occupational status • Smoking habits • Side of ACL injury • Type of ACL injury • Mechanism of ACL injury • Time from ACL injury to ACLR

This preliminary evaluation includes the capture of additional patient-reported and clinician-reported outcomes, which are essential for assessing the recovery pathway (Table 29).**[35]**

Table 29. Patient-reported and Clinician-reported Outcomes

Collected Data
Patient Self-Response • Knee pain intensity and management • Knee function on daily living, sports, and recreational activities • Knee-related symptoms, stiffness, and physical function • Knee-related quality of life • Pain catastrophizing • Anxiety, depression, and stress
Clinical Tests • Height • Weight

Table 30 provides a summary of the outcomes of patient evaluation and the proposed feasibility assessment, encompassing both qualitative and quantitative data.

Table 30. Preliminary Patient Evaluation Outcomes for the Feasibility Evaluation

Outcomes
Qualitative Data
Evaluation Resources: Describe the required resources for patient evaluation and data collection.
Participant Engagement: Describe the participant willingness to engage with the preliminary evaluation.
Protocol Adherence: Monitor how closely the preliminary evaluation follows the protocol.
Evaluation Practicality: Analyse preliminary data for consistency and reliability.
Quantitative Data
Time to Outcome Evaluation: Monitor time (min) spent per outcome evaluation.
Evaluation Budget: Conduct a simple budget analysis.
Collected Data Completeness: Analise data collections forms for completeness.

4.1.4. Patient Surgical Notes

To determine the factors that may influence subsequent patient recovery, data from surgical notes will also be examined (Table 31).**[36, 37]**

Table 31. Collected Data from Surgical Notes

Data
• Timing • Type of surgical approach and graft • Graft diameter • Duration of surgical procedure • Donor site • Anaesthesia and/or nerve block • Additional joint reconstruction

4.1.5. Acute Postoperative Complications

Acute postoperative complications may occur, which can affect the long-term ACLR recovery pathway and related outcomes. The constant communication between the patient and OS is essential for monitoring any signs of infection or other problems. Although ACLR is typically safe, it entails a risk of acute postoperative complications, as illustrated in Table 32.

Table 32. Potential Acute Postoperative Complications

Complications
• Acute knee joint pain and swelling • Severely limited knee range of motion • Sudden increase in pain (pulsating) • Rapidly increased and persistent effusion • Incision drainage • Local erythema • Local warmth • Intermittent fever (usually over 38 degrees Celsius) • Hyperaemia with serous or purulent discharge

4.1.6. Daily Patient Evaluation

The first 15 days following ACLR are decisive for establishing a strong recovery pathway foundation. Throughout this period, the patient receives a daily notification through short message service (SMS) at 9 p.m. containing a link to a questionnaire regarding knee symptoms and knee pain management strategies. This questionnaire contains several categories of information that are described in Table 33.

Table 33. Daily (first 15 days) Patient Evaluation

Collected Information
Patient Self-Response • Frequency of knee pain • Intensity of knee pain • Management of knee pain • Frequency of knee pain • Type of medication • Frequency of medication intake • Frequency of other physical complaints • Intensity of other physical complaints

Clinically, the main goal during this initial postoperative period includes relieving and managing pain, reducing swelling, beginning early mobilisation, initiating the restoration of range of motion and muscle strength in the knee joint, and evenly distributing the body weight across both lower extremities.**[38, 39]** By concentrating on these objectives and adhering to moderate exercise, patient can enhance their recovery and eventually return to pre-injury activity levels.

4.1.7. Clinical Eligibility

Adults of any sex who meet all eligibility criteria and have submitted written consent will be eligible for participation (Table 34).

Table 34. Participant Eligibility

Criteria	
Inclusion	
1)	Received primary ACLR irrespective of surgical technique and autograft selection.
2)	Age must be between 18 and 55 years at the time of ACLR.
3)	Maintain a healthy contralateral (opposite) knee.
4)	The interval between ACL injury and ACLR should not surpass 12 months.
Exclusion	
1)	Declined to participate
2)	Concurrent osteochondral injuries.
3)	Experienced multiple reconstructions of the knee ligaments or meniscus.
4)	Significant lower limb injuries within the 12 months preceding the ACL injury.
5)	Medical conditions that may affect recovery.
6)	Using medications for mental health disorders.
7)	Severe impairments in communications or balance.

Discussion concerning the planned ACLR, including risks, benefits, and expectations, are held to promote informed decision-making. This appointment is essential for ensuring patient safety, informed consent, and ethical standards adherence. Despite being exhaustive and long, the screening of patients and verification of eligibility criteria will be conducted manually due to policy and ethical constraints.**[40]** Table 35 delineates our eligibility outcomes and the corresponding planned feasibility evaluation.

Table 35. Eligibility Outcomes for the Feasibility Evaluation

Outcomes
Qualitative Data
Criteria Strictness: Describe whether the inclusion/exclusion criteria are very restrictive.
Reasons for Ineligibility: Apply questions to OS about the reasons for patient ineligibility.
Reasons for Refusal: Apply questions to participants about the reasons for not participating.
Reasons for Ambiguities: Apply questions to OS about the reasons for enrolment ambiguities.
Quantitative Data
Eligibility Rate: Calculate the number of participants who meet eligibility / total screened participants x 100
Number of Eligible: Calculate the number of patients assessed for eligibility
Number of Included: Calculate the number of patients included.
Time to Eligibility: Monitor the time (min) from screening to eligibility confirmation.

It may be necessary to revise or modify the criteria for eligibility to optimise participation rates.**[41]** We clearly defined the population of participants without excessive restrictions to enhance enrolment and the generalizability of findings.

4.1.8. Baseline Patient Evaluation

In the first appointment with the OS following ACLR, the outcome assessor will collect all data for each patient. Data will be collected by patient self-reporting, as well as clinical and physical performance tests (Table 36).

Table 36. First Evaluation Following ACLR

Collected Information
Patient Self-Response • Knee pain intensity and management • Knee-related symptoms, stiffness, and physical function • Knee function on daily living, sports, and recreational activities • Knee-related quality of life • Pain catastrophizing • Anxiety, depression, and stress
Clinical Tests • Height • Weight • Passive knee flexion and extension (range of motion) • Knee extensors and knee flexors muscle length and strength
Performance Testing • Stair ascending/descending*

**Not possible to evaluate if body weight cannot be evenly distributed on both feet*

4.1.9. Training With Videoconferencing Software and Evaluation Tools

At the first appointment following ACLR, the PI will provide participants with additional training on the use of videoconferencing software – Google Meet or Zoom Workplace – as well as the Visual Analog Scale – VAS**[42]** for pain assessment, and the Borg Category Ratio Scale – CR10**[43]** for measuring physical exertion.

4.1.10. Group Allocation

The final stage of patient recruitment occurs during the first postoperative appointment following ACLR. After establishing patient eligibility and obtaining consent, participants will be randomly assigned (in a 1:1 ratio) to either the CBRE or KC@H group (Figure 6). At this stage, covariate

adjustment will be undertaken to ensure uniformity in age and sex.**[44, 45]** The randomisation sequence will be assessed via the 'ralloc' STATA package, considering the variables.

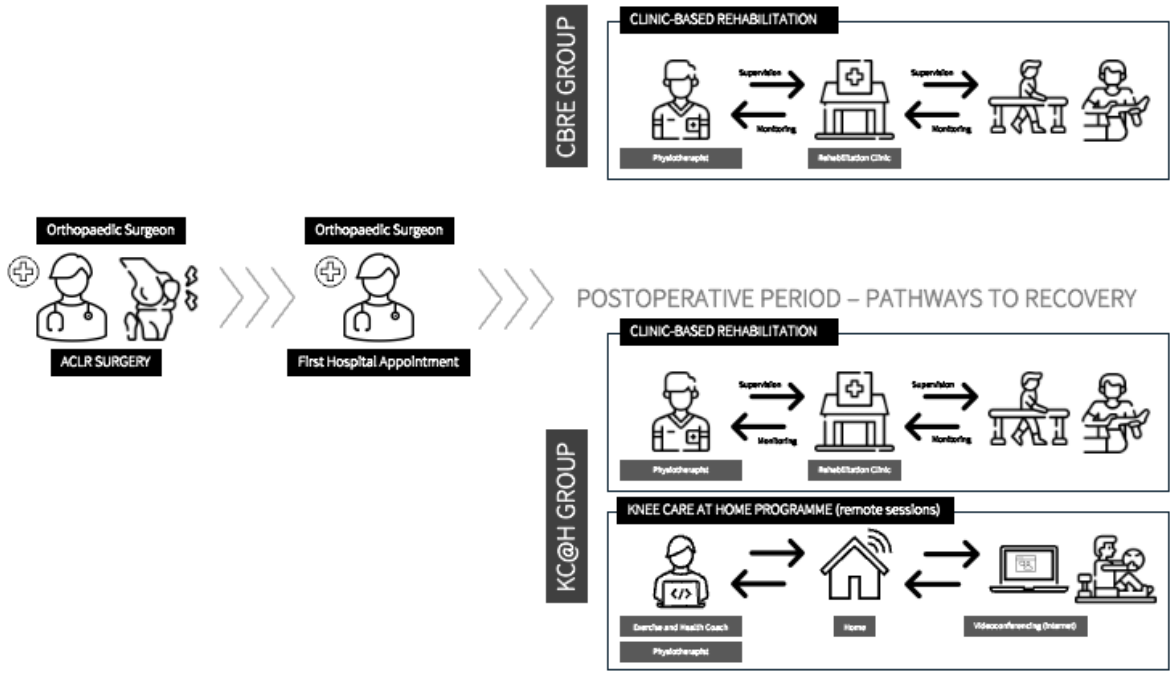

Figure 6. Allocation to Groups and Postoperative Pathways to Recovery

All patients in the KC@H group are invited to complement conventional CBRE sessions with HBE sessions, which are subject to remote supervision and monitoring via videoconferencing. A self-owned computer or tablet with internet access is required for patients assigned to the KC@H group. Members of the CBRE group exclusively engage in conventional CBRE sessions. The clinical trial lasts for a total of thirty-six weeks. Table 37 provides a summary of the outcomes of participant allocation and the proposed feasibility assessment, encompassing both qualitative and quantitative data.

Table 37. Participants Allocation Outcomes for the Feasibility Evaluation

Outcomes
Qualitative Data
Patients Difficulties: Apply questions to patients about any problems they experienced.
Surgeons Difficulties: Apply questions to OS about their reluctance to randomise patients.
Quantitative Data
Allocation Rate: Calculate the number of participants allocated / total eligible participants x 100
Screening to Allocation: Monitor the time (min) spent from screening to randomization.
Participant Acceptance: Calculate the number of patients who agreed to be randomly assigned.
Participant Dropout: Calculate the number of participants who dropped out after randomisation.
Withdrawal After Consent: Calculate the number of participants willing to proceed after randomization.

To enhance participant trust and willingness to enrol, the allocation process is transparent and equitable.**[46]** Several researchers and healthcare professionals were involved in the definition of allocation methods. Throughout the clinical trial, the outcome assessor will uphold blinding.

In addition to the feasibility evaluation, the outcome assessor will abstain from involvement in any other trial components and will be specifically instructed to avoid discussing group allocation with participants. Participants and orthopaedists will be instructed to refrain from discussing group allocation with the assessor.

4.2. Intervention Fidelity

Assessing the fidelity of the KC@H intervention is vital to ensure that it is implemented as planned, that participants follow it, and that all issues are detected early. Table 38 provides details on our intervention fidelity outcomes and time frame of evaluation.

Table 38. Intervention Fidelity Outcomes and Time Frame of Evaluation

Outcomes
Each remote session (n=66) • Adherence Rate to Remote Sessions • Participant Responsiveness • Adverse Events
Each postoperative appointment (n=7) • Orthopaedic Surgeon Appointments • Quality of Delivery • Adherence Rate to Face to Face Sessions

4.2.1. Remote Sessions Containing Home-Based Exercises

The KC@H programme integrates an HBE intervention, supervised and monitored remote sessions as a complement to conventional CBRE, as well as evaluations during OS appointments at the HME and during remote sessions. The HBE intervention was developed using evidence-based practise guidelines**[38, 47–51]** to comply with both time-based and criterion-based requirements.

Consequently, advancement in the recovery process is determined by objective criteria rather than only the elapsed time following ACLR.**[47]** The implementation of time-based and criterion-based conditions facilitates the integration of approaches for ACL injury prevention throughout the programme,**[38, 52–54]** while also generalising the intervention to all clinical settings and individuals.**[47]**

Remote supervision and monitoring of HBE will be undertaken at the patient's home via synchronous online conferencing software, referred to "remote sessions" of the KC@H programme. A total of sixty-six remote sessions, each lasting forty minutes, are scheduled to occur three times a week over a twenty-two-week intervention period.

The remote sessions provide ongoing supervision and monitoring during the postoperative recovery pathway, therefore alleviating accessibility issues. Furthermore, as indicated in the recruitment section, all patients who give consent will also receive the KC@H exercise manual. The OS will suggest patients to attend conventional CBRE sessions with the physiotherapist, termed "face to face sessions", which are expected to occur in public or private rehabilitation facilities according to participant preference and availability. We will evaluate acceptability and feasibility during scheduled OS appointments and throughout each remote session.

4.2.1.1. Adherence Rate to Remote Sessions

The adherence to remote sessions measures how well participants comply with the HBE intervention and the KC@H protocol and how often they attend, engage and complete sessions. Table 39 provides a summary of the outcomes of participant adherence rate to remote sessions and the proposed feasibility assessment, encompassing both qualitative and quantitative data.

Table 39. Adherence Rate to Remote Sessions Outcomes for the Feasibility Evaluation

Outcomes
Qualitative Data
Simplicity of Use: Assess the simplicity of use of remote sessions.
Technical Issues: Identify technical barriers with remote sessions that may affect adherence.
Quantitative Data
Web Monitoring: Calculate the number of participants adhering to the use of web software.
Adherence Rate: Calculate the number of completed interventions / total expected intervention × 100
Activity Diaries: Calculate the number of participants completing activities.
Session Attendance Logs: Calculate log-ins, frequency, and time spent in sessions.
Automated Reminders: Calculate the number of participants responding to automated reminders.

4.2.2. Participant Responsiveness

Evaluating patient responsiveness is crucial in understanding the feasibility of the KC@H clinical trial, especially because we are dealing with a new DH solutions.**[55]** Responsiveness relates to the extent to which patients can engage with the KC@H protocol, follow the HBE program, and provide meaningful feedback regarding their experiences and outcomes.**[56]** This assessment of responsiveness serves as a critical barometer for determining the practicality and effectiveness of the KC@H intervention. Table 40 provides a summary of the outcomes of participant responsiveness and the proposed feasibility assessment, encompassing both qualitative and quantitative data.

Table 40. Participant Responsiveness Outcomes for the Feasibility Evaluation

Outcomes
Qualitative Data
Reasons for Non-Engagement: Apply questions to patients to understand barriers to engagement.
Responsiveness: The health and exercise coach describe on participant responsiveness.
Dropout Analysis: Apply questions for those participants who dropout.
Mixed Data
Self-reported Adherence: Participants self- report on how closely they followed the exercise programme.
Exercise Corrections: Measure the need of exercise adjustments.
Quantitative Data
Session Attendance: Calculate the number of remote sessions completed versus scheduled.
Exercise Completion Rate: Calculate how many prescribed exercises were performed.
System Logs: Collect data on log-ins, duration of sessions, and interactions with the system.
Engagement in Sessions: Measure participant engagement using a scale.
Retention Rates: Calculate the number of participants who completed / total number of enrolled x 100
Dropout Rates: Calculate the number of participants who dropped out / total number of enrolled x 100

4.2.3. Adverse Events

To ensure patient safety and compliance in the KC@H clinical trial involving supervised and monitored HBE following ACLR, the frequency and severity of negative side effects or unintended consequences must be tracked. Table 41 provides a summary of the outcomes of adverse events and the proposed feasibility assessment, encompassing qualitative data.

Table 41. Adverse Events Outcomes for the Feasibility Evaluation

Outcomes
Qualitative Data
Participant Self-Report: A weekly self-report form, displaying any physical complaints or other effects.
Clinician Report: Monitor physical complaints or other type of adverse side effects reported by participants.

We shall analyse two categories of adverse events: moderate or severe. Moderate adverse effects encompass any unexpected physical symptoms such as pain, swelling, discomfort, or even functional decline that arises during recovery but does not require hospitalisation.**[57]** Severe adverse events refer to any occurrence that leads to re-injury of the ACL, fractures from falls or significant trauma, deep vein thrombosis symptoms, or any other cause for hospitalisation.

4.2.4. Orthopaedic Surgeon Appointments

A dedicated assessor will evaluate patient-reported outcomes, clinician-reported outcomes and physical performance outcomes (Table 42), during each scheduled appointment with the OS.

Table 42. Outcomes Collected During Hospital Appointments

Collected Information
Patient Self-Response • Knee pain intensity and management • Knee-related symptoms, stiffness, and physical function • Knee function on daily living, sports, and recreational activities • Knee-related quality of life • Pain catastrophizing • Anxiety, depression, and stress • Motivation and satisfaction with remote sessions • Remote sessions delivery quality • Adherence to clinic-based rehabilitation and remote sessions
Clinical Tests • Height • Weight • Passive knee flexion and extension (range of motion) • Knee extensors and knee flexors muscle length and strength
Performance Testing • Stair ascending/descending • Single leg hops for distance

After the baseline evaluation (t_0), during the first postoperative appointment, follow up appointments with the OS are scheduled to occur after hospital discharge: (t_1) the 4th week; (t_2) the 8th week; (t_3) the 12th week; (t_4) the 16th week; (t_5) the 20th week; (t_6) the 24th week, coinciding with the end of the intervention; and (t_7) the 36th week, coinciding with a follow up 12th weeks without intervention (Table 43).

Table 43. Scheduled Appointments with the OS Following ACLR

Only the outcome assessor is blinded throughout the clinical trial. Patients will also be asked if they have had any adverse events to report between their scheduled appointments with the OS. If patients are required to take additional clinical outcome measured in addition to the intervention, the study team will keep track of it.

4.2.5. Quality of Delivery

Assessing the feasibility of quality delivery is essential to ensure that the KC@H intervention is delivered consistently and according to protocol, ultimately enhancing the patient's recovery process and functional outcomes.**[58]** DH offer a unique opportunity to deliver HBE remotely, which can increase patient accessibility and adherence, especially for individuals who may face geographical or mobility barriers.**[59]** Table 44 provides a summary of the outcomes of quality of delivery and the proposed feasibility assessment, encompassing qualitative data.

Table 44. Quality of Delivery Outcomes for the Feasibility Evaluation

Outcomes
Qualitative Data
Protocol Adherence Form: Describe if coaches, clinicians, and assessors follow the KC@H manual.
Audio/Video Recordings: If authorised, analyse the session recording to compare with KC@H manual.
Exercise and Health Feedback: Describe and identify gaps or barriers to consistent delivery.
Participant Feedback: Describe the clarity and consistency of the intervention.

4.2.6. Face to Face Sessions in Clinic-Based Rehabilitation

Participation in conventional CBRE, face to face, is intended to be maintained for both groups involving face-to-face sessions with PT. Outpatient rehabilitation clinics are available in both public and private environments.

Accessibility concerns to CBRE sessions**[47, 48]** as well as differences in content and exposure**[53]** may have an impact on our study sample. Attendance and coverage may differ. These sessions can range from a daily programme for at least 24 weeks to no rehabilitation at all. This was expected in our methodology, and the random assignment puts both groups in comparable situations.

The KC@H team will have no authority over the content of the CBRE sessions. The attendance and coverage of all participants' CBRE sessions will be tracked weekly via SMS. Furthermore, an attempt will be made to monitor the comparability of material between CBRE sessions and the remote sessions of the KC@H programme.

4.2.6.1. Adherence Rate (General)

The adherence rates observed with clinical trials involving DH technologies have gained high relevance due to their potential for enhanced participant engagement and compliance with procedures. The KC@H intervention objectively monitors adherence, enabling the examination of trends in engagement and association with the trial outcomes.**[60]**

Table 45 provides a summary of the outcomes of general participant adherence rate and the proposed feasibility assessment, encompassing quantitative data. The outcomes are designed to capture data on how well participants comply and follow the intervention protocol.

Table 45. Adherence Rates Outcomes for the Feasibility Evaluation

Outcomes

Quantitative Data Adherence Rate: Calculate the number of completed activities / total expected activities × 100 Self-reports & Diaries: Calculate number of participants that adherence to treatment and complete activities. Session Attendance Logs: Calculate face-to-face and remote sessions participation.

4.2.6.2. Adherence Rate to Face to Face Sessions

Assessing the feasibility of face-to-face sessions is crucial for ensuring that patients receive comprehensive and effective care. While DH interventions, offer convenience and accessibility, the inclusion of face-to-face sessions can significantly enhance patient engagement, understanding, and overall satisfaction with the recovery pathway.**[61]**

Overall, evaluating the feasibility of face-to-face sessions in conjunction with the KC@H intervention not only helps in identifying barriers to implementation but also maximizes the potential benefits of hybrid recovery approaches, ultimately improving clinical outcomes for patients. Table 46 provides a summary of the outcomes of participant adherence rate to face to face sessions and the proposed feasibility assessment, encompassing both qualitative and quantitative data.

Table 46. Adherence Rate to Face to Face Sessions Outcomes for the Feasibility Evaluation

Outcomes
Qualitative Data Session Feedback Forms: Describe participant-reported barriers to attendance. Direct Observations: Describe participant engagement and interaction.
Quantitative Data Missed Appointment Logs: Calculate trends in no-shows and cancellations.

4.3. Data Collection

Assessing the feasibility of data collection is critical for optimizing patient outcomes and ensuring effective intervention delivery.**[62]** A need exists to evaluate if data is obtained efficiently, precisely, and in alignment with research objectives.**[63]** Essential aspects to evaluate encompass response rate, missing data, implementation issues, and technical difficulties (Table 47).

Table 47. Data Collection Outcomes and Time Frame of Evaluation

Outcomes
Preoperative appointment, ACLR surgery, first 15 days after ACLR surgery, postoperative appointments. • Response Rates • Missing Data • Implementation Issues • Technical Difficulties

4.3.1. Response Rates

Assessing the feasibility of response rates is essential for ensuring effective treatment and patient engagement. High response rates are crucial for obtaining reliable data on patient progress, which aids clinicians in tailoring recovery protocols to individual needs.**[64]** High participation rates in HBE correlate with better outcomes, indicating that enhanced motivation from supervised exercises can lead to improved functional scores.**[65]**

Additionally, the KC@H programme can facilitate real-time feedback and interpersonal connectivity, which are pivotal for maintaining patient motivation and adherence to rehabilitation protocols. Therefore, evaluating response rates to the KC@H programme intervention is essential for refining therapeutic strategies and enhancing the quality of care delivered to patients recovering from ACLR.**[64, 65]** Table 48 provides a summary of the outcomes of response rates and the proposed feasibility assessment, encompassing quantitative data.

Table 48. Response Rates Outcomes for the Feasibility Evaluation

Outcomes
Quantitative Data
Response Rate: Calculate the number of completed responses / total of expected responses x 100
Completion Trends Over Time: Calculate if response rates drop at specific time points.
Comparison Across Methods: Calculate the accuracy between remote vs. face-to-face assessments.

4.3.2. Missing Data

Assessing the feasibility of managing missing data in the HBE intervention is essential for ensuring the effectiveness and accuracy of KC@H programme. Missing data can undermine the quality of the evidence produced by the intervention, leading to skewed results and impaired decision-making regarding patient care.**[66]** Addressing potential gaps in data is critical for evaluating patient outcomes and satisfaction during recovery. Table 49 provides a summary of the outcomes of missing data and the proposed feasibility assessment, encompassing quantitative data.

Table 49. Missing Data Outcomes for the Feasibility Evaluation

Outcomes
Quantitative Data
Missing Data Rate: Calculate the number of missing data points / total of expected data points x 100
Completely Random Missing Data: Calculate the number due to no pattern (e.g., skipped due to chance).
Systematic Missing Data: Calculate the number related to a factor (e.g., older participants missing digital data).
Not at Random Missing Data: Calculate the number of specific reasons (e.g., adverse effects causing dropouts).
Item-Level vs. Participant-Level Missingness: Calculate completeness of surveys or just specific questions.

4.3.3. Implementation Issues

Assessing the feasibility of implementation issues is paramount as it directly impacts the effectiveness and acceptance of the KC@H programme. By assessing implementation issues, practitioners can gain valuable insights into the operational challenges and successes of DH solutions, ultimately enhancing the quality of care provided to patients undergoing rehabilitation and facilitating smoother transitions between conventional and DH solution.**[67]** Table 50 provides a summary of the outcomes of implementation issues and the proposed feasibility assessment, encompassing qualitative data.

Table 50. Implementation Issues Outcomes for the Feasibility Evaluation

Outcomes
Qualitative Data
Site-Level Issues: Describe if the research team is following the data collection protocol correctly.
Protocol Adherence Audits: Review case report forms to identify protocol deviations.
Participant Burden Analysis: Describe if long surveys are leading to participant fatigue.

4.3.4.Technical Difficulties

Assessing the feasibility of technical difficulties is crucial for ensuring effective and seamless patient care. Technical barriers, such as connectivity issues, software usability, and device compatibility, can significantly impede the implementation of DH solutions and ultimately affect patient outcomes. The successful integration of DH interventions in managing musculoskeletal conditions depends on overcoming technical difficulties to promote wider accessibility and utilization among patients.**[68]** Table 51 provides a summary of the outcomes of technical difficulties and the proposed feasibility assessment, encompassing both qualitative and quantitative data.

Table 51. Technical Difficulties Outcomes for the Feasibility Evaluation

Outcome
Qualitative Data User Feedback on Digital Tools: Apply questions to participants find if remote sessions are user-friendly. Data Transmission & Security Issues: Describe if confidentiality concerns affect data collection.
Quantitative Data System Error Logs: Calculate the frequency of crashes, login failures, or lost data.

4.4. Acceptability

In a clinical trial, we measure acceptability to confirm if participants view the intervention as suitable, of interest, and helpful. Both qualitative and quantitative methods can measure patient satisfaction and motivation (Table 52), both essential components of acceptability.

Table 52. Acceptability Outcomes and Time Frame of Evaluation

Outcomes
Postoperative appointments (n=7) • Patient Satisfaction • Patient Motivation

4.4.1. Patient Satisfaction

Assessing the feasibility of patient satisfaction plays a pivotal role in adherence to rehabilitation protocols and overall recovery, with research suggesting that higher patient satisfaction is associated with improved clinical outcomes, including functional recovery and pain management.**[69]**

Moreover, factors such as effective communication and personalized care through DH solutions can enhance patient responsibility and engagement, significantly influencing patient satisfaction levels.**[62]**

Patient satisfaction can help understand the extent to which participants feel the intervention, procedures, and overall trial experience meet their expectations. Table 53 provides a summary of the outcomes of patient satisfaction and the proposed feasibility assessment, encompassing both qualitative and quantitative data.

Table 53. Patient Satisfaction Outcomes for the Feasibility Evaluation

Outcomes
Qualitative Data
Interviews or Focus Groups: Apply questions to participants about their experience with remote sessions.
Standardized Surveys: Apply the Patient Satisfaction Scale and the Client Satisfaction Questionnaires.
Promoter Score: Apply questions to assess how likely the patient would recommend the intervention.
Quantitative Data
Retention & Dropout: Calculate the number of dropouts during the intervention
Sessions Adherence Rate: Calculate the number of completed sessions / total prescribed sessions x 100
Doses Adherence Rate: Calculate the number of completed doses / total prescribed doses x 100
Activities Adherence Rate: Calculate the number of completed activities / total prescribed activities x 100

4.4.2. Patient Motivation

Assessing the feasibility of patient motivation is a key determinant for the success of the KC@H intervention, as motivated individuals are more likely to adhere to prescribed interventions and actively participate in their recovery by completing the trial.**[70]**

The KC@H programme can play a significant role in fostering motivation by providing timely feedback, personalized content, and verbal reward for achieving milestones, which can effectively

stimulate patient engagement. Table 54 provides a summary of the outcomes of patient motivation and the proposed feasibility assessment, encompassing both qualitative and quantitative data.

Table 54. Patient Motivation Outcomes for the Feasibility Evaluation

Outcomes
Qualitative Data
Interviews on Motivation Factors: Open-ended questions about their motivation to participate.
Observational Data: Monitoring participant enthusiasm, responsiveness, and engagement during sessions.
Quantitative Data
Motivation Rating Scales: Likert scale questionnaire about the motivation to complete the study
Attendance & Engagement Metrics: Number of attended sessions, completed tasks, and interaction levels
Adherence & Dropout: Number of dropouts during the intervention
Self-Determination Theory Based Assessments: Measure intrinsic vs. extrinsic motivation to participate.

5. Data Usage

5.1. Management

All records are maintained on a secure server, accessible just by the OS and the PI. To comply with data protection laws,**[34]** socio-demographic information will be collected directly from the patient using a patient code to ensure anonymity.

Should any medical or research records require duplication, the participant's name and any further information will be redacted. No personal information, including name, address, or telephone number, will be disseminated from the HME database. All investigative data will be eliminated or obliterated when it is no longer required.

5.2. Presentation

All findings shall be presented in accordance with the Standard Protocol Items: Recommendations for Interventional Trials – SPIRIT.**[71]**

5.3. Analysis

Data will be analysed by employing a mixed-methods approach to evaluate feasibility. There is no scheduled interim analysis. After collecting all outcome data, statistical analyses will be performed. The feasibility objectives and acceptability of intervention outcome measures will be evaluated utilising descriptive analysis, with estimation of confidence intervals taking precedence over formal hypothesis testing. We will evaluate the quality and responsiveness of the intervention outcome measures to determine their suitability.

E. DISCUSSION AND CONCLUSION

This protocol provides a comprehensive description of a feasibility study, aiming to ascertain if it is possible to conduct a clinical trial to evaluate the effectiveness of the KC@H programme. Our findings are projected to contribute to the body of evidence on the use of DH solutions that include HBE to provide a remote orthopaedic care service, employing a synchronous videoconferencing delivery mechanism that does not require face-to-face direct supervision and monitoring of the recovery following ACLR.

As communication technology gets faster and better, healthcare professionals may be able to supervise and monitor patients from a distance if they can get the same results from patient-reported, clinician-reported, and physical performance outcomes.**[47]** In fact, during the COVID-19 pandemic, the need for telehealth services grew due to patients' incapacity to obtain face-to-face rehabilitation services.**[72]**

Furthermore, the KC@H programme employs easily accessible equipment, increasing the chances that this type of DH solution may be easily adopted. Once patients are discharged from the hospital, the KC@H programme can provide continuity of care and improve ACLR recovery beyond what is now accessible to patients. The remote synchronous videoconferencing delivery method could also help patients who live in remote areas where they don't have easy access to CBRE. This would make it easier for them to stick with their recovery pathway and get rehabilitation services. Additionally, it may also be a possible solution for the shortening of the recovery time.

1. Ethical Approval

This protocol of a feasibility study was approved by the Institutional Review Boards of the hosting University (Appendix CIII.01). The study will be carried out in accordance with the Code of Ethics of the World Medical Association – Declaration of Helsinki for experiments involving humans.

2. Funding

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3. Conflict of Interest

The authors declare no conflicts of interest exist with respect to the research, authorship, and/or publication of this article.

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G. APPENDICES

1. Ethics Committee of the University of Évora

Documento	2	2	1	1	9

Comissão de Ética da Universidade de Évora

A Comissão de Ética da Universidade de Évora informa que, com base nas apreciações favoráveis dos seus membros, deliberou dar

Parecer Positivo

para a realização do Projeto: "Barriers and Facilitators for attendance and adherence of the Knee Care @Home Telerehabilitation Program by patients after Anterior Cruciate Ligament Reconstruction: a Mixed Methods Trial", pela mestranda **Daniela Carmelo Pina** sob a supervisão dos Professores Doutores João Paulo Brites de Sousa, Nuno Miguel Prazeres Batalha e José Alberto Frade Martins Parraça (responsáveis académicos).

Universidade de Évora, 22 de janeiro de 2023

O Presidente da Comissão de Ética

(Prof. Doutor Hugo Miguel Cardinho Alexandre Folgado)

2. Participant Information and Consent Form (English)

Title of the Study

Effectiveness of the Knee Care at Home Programme Compared with Clinic-based Rehabilitation in Patients Recovering from Anterior Cruciate Ligament Reconstruction

Registered Protocol Number

NCT05828355

Research Team

João Paulo Brites de Sousa, PhD (lead investigator)

Nuno Miguel Prazeres Batalha, PhD

José Alberto Frade Martins Parraça, PhD

Orlando Jesus Semedo Fernandes, PhD

Ana Maria Rodrigues, PhD

Ana Rita Landroal, PhD

Joana Margarida dos Santos Alegrete, MSc

Daniela Carmelo Pina, Lic

Sponsors

Comprehensive Health Research Centre (CHRC); Escola de Saúde e Desenvolvimento Humano da Universidade de Évora (ESDH-UE); Fundação para a Ciência e Tecnologia do Ministério da Ciência, Tecnologia e Ensino Superior (FCT-MCTES); Hospital da Misericórdia de Évora (HME)

This Informed Consent Form has two parts:

- **Information Sheet (to share information about our research with you)**
- **Certificate of Consent (to provide a signature if you agree to take part)**

You will be given a copy of the full Informed Consent Form

PART I - INFORMATION SHEET

You have been invited to take part in a clinical study. We ask that you carefully review this consent form and discuss any questions you may have with the study team. Before deciding, feel free to consult with your orthopaedic surgeon, as well as friends and family. If there are any terms or language in the consent form that are unclear to you, please ask the orthopaedic surgeon or research team for clarification. It is important to note that our research team is receiving financial support to conduct this study.

Purpose of the Study

Following your anterior cruciate ligament reconstruction surgery, we are interested in evaluating the effectiveness of the Knee Care at Home program in combination with clinic-based rehabilitation sessions, as compared to clinic-based rehabilitation sessions alone. Our goal is to assess the impact on various factors including knee pain, symptoms, function, quality of life, swelling, effusion, range of motion, muscle length, strength, and overall functional performance. Additionally, we will be evaluating your acceptance and adherence to the Knee Care at Home program.

Participants

During the preoperative consultation, we will be inviting all adult men and women in need of anterior cruciate ligament reconstruction surgery at the orthopaedic department of Hospital da Misericórdia de Évora. Following your surgery, two weeks after being discharged from the hospital, your orthopaedic surgeon will determine if you are eligible to take part in this study. We anticipate a total of 56 participants.

Voluntary Participation, Alternatives to Participating, Right to Refuse or Withdraw

It is your decision whether you want to participate. Regardless of your choice, the services provided at Hospital do Misericórdia de Évora will remain unchanged. You will still receive all the services as usual. Even if you initially agreed to participate in the study, you have the option to change your mind and opt-out at any time. Your decision will not impact the care you receive at Hospital da Misericórdia de Évora in any way.

Procedures and Protocol

During their preoperative consultation with the orthopaedic surgeon at the Hospital da Misericórdia de Évora, all adult men and women scheduled for anterior cruciate ligament surgery will receive this document containing the details of the study and informed consent. At this appointment, patients will be asked to carefully read the document and indicate their interest in participating in the study.

During your first postoperative consultation, which takes place two weeks after your surgery and discharge from the hospital, your orthopaedic surgeon will determine if you are eligible to participate in a clinical study. Your participation is contingent upon your consent. You may be asked to take part in the study if you meet the following criteria: (1) are between 18 and 55 years old at the time of your surgery; (2) have had less than 12 months between the injury and your surgery; (3) have undergone a primary anterior cruciate ligament reconstruction, regardless of the surgical method; (4) have a healthy knee on the other side; (5) are fluent in Portuguese; and (6) have access to the internet via a smartphone, tablet, or personal computer.

Patients deemed suitable by the orthopaedic surgeon are randomly assigned to one of two groups. The assignment is made like flipping a coin, ensuring an equal chance of being placed in either the Clinic-Based Rehabilitation group or the Knee Care at Home group.

If you are part of the Clinic-Based Rehabilitation group, you need to attend face-to-face sessions. After anterior cruciate ligament reconstruction, it is recommended by your orthopaedic surgeon that you attend a rehabilitation clinic as soon as possible to receive these sessions. The duration and type of treatments in clinic-based rehabilitation can vary, and it is important to note that the research team does not provide clinic-based rehabilitation sessions with a physiotherapist. You have the freedom to choose where you would like to have your clinic-based rehabilitation sessions based on factors such as availability, cost, and distance. You must prioritize attending these sessions and not neglect them.

If you are part of the Knee Care at Home group, you will receive remote sessions in addition to your clinic-based rehabilitation sessions. The same principles that apply to the clinic-based rehabilitation group also apply to the Knee Care at Home group. Therefore, it is crucial that you attend your clinic-based rehabilitation sessions with a physiotherapist at a rehabilitation clinic and not neglect them.

The Knee Care at Home programme is completely free of charge and is only offered to you as a supplement to your clinic-based rehabilitation sessions. This programme is expected to use fewer resources and give you more control over your knee recovery than clinic-based rehabilitation alone. Internet-based remote programmes can help improve supervision and control your behaviour as you try to improve your clinical outcomes. These programmes can also support you if you find it difficult to access rehabilitation services due to cost, travel time or other inconveniences.

A certified exercise and health professional will guide and supervise 22 weeks of remote sessions that you can do in the comfort of your own home via videoconferencing. The remote sessions, which include therapeutic exercises, will take place three times a week for 40 minutes each. In total, we expect you to attend 66 sessions over 22 weeks. The Knee Care at Home program is based on international guidelines and the expertise of your orthopedic surgeon. Additionally, your orthopedic surgeon can monitor and supervise your progress during the remote sessions. If you are concerned about a particular stage of the knee care at home program, the research team will talk to your orthopedic surgeon and make the necessary changes. We do not know if the Knee Care at

Home program combined with your clinic-based rehabilitation sessions is better for recovery from your surgery than clinic-based rehabilitation alone, so we need to compare the two.

Participants in both groups, Clinic-based Rehabilitation and Knee Care at Home, will be assessed during scheduled consultations at specific intervals (week 2, week 4, week 8, week 12, week 16, week 20, and week 24) after discharge from the hospital. These consultations are covered by your health insurance and are expected to take place during the recovery after your surgery to minimize any additional burden on you. During these consultations, you will be asked to complete questionnaires to help us understand the impact of your anterior cruciate ligament reconstruction on your knee, including pain, symptoms, function, quality of life, and swelling, as well as how you are coping with the situation. Additionally, you will undergo clinical and physical examinations to assess knee effusion, range of motion, muscle length, muscle strength, and functional performance.

During the evaluation sessions, you will be asked not to discuss with the assessor (not the orthopaedic surgeon) about which group you have been placed in. This is crucial to avoid compromising the results of the study. We want to remind you that you will not have any extra expenses related to this study. If it becomes necessary to bring you back for additional consultations outside of the scheduled ones, the Knee Care at Home team will provide financial assistance. The research team will not have access to the assessment records until the study is finished. This is the best way to ensure that the evaluation is not influenced by the desire for positive results.

Duration

Your involvement will be restricted to the postoperative phase. The clinical study intervention will span 22 weeks, commencing in the second week following discharge from the hospital. Throughout this period, you will only need to visit Hospital da Misericórdia de Évora for scheduled postoperative appointments related to the study, unless necessary for reasons unrelated to the study. Please be aware that your orthopaedic surgeon may schedule an extra appointment at week 36 after discharge for a follow-up period.

Side Effects, Risks and Discomfort

Participants in this study are not expected to experience any side effects or risks. However, it is possible that in the second stage of the study, participants may experience increased knee pain, swelling, and muscle pain. There may also be other risks or problems that are currently unknown. If necessary, participants' orthopaedic surgeon will discuss these with them.

If any side effects persist, participants should speak with their orthopaedic surgeon and the study supervisor, who will provide instructions on how to proceed. Participants should ensure they are covered by their personal health insurance, although the study itself is covered by the liability insurance of Universidade de Évora, which is used for all research studies.

Benefits

Participants in the clinic-based rehabilitation group may not receive direct benefits, but their participation will contribute to finding answers to the research question. While there may not be immediate societal benefits at this stage of the research, future generations are likely to benefit. Additionally, participants can request access to published scientific papers and conference abstracts.

Enrolment in the Knee Care at Home group offers several potential benefits, including improved access for those in remote or underserved areas, reduced missed treatments, cost savings, the convenience of performing interventions at home, and continuous supervision for exercise progression and control.

Costs and Payment for Participation

This study does not alter your standard postoperative procedures. All scheduled consultations for evaluation sessions are covered by your health insurance plan and will not result in any extra costs. Participants in the Knee Care at Home group will not be charged for remote sessions. The expenses for clinic-based rehabilitation sessions will be covered by your health insurance or by yourself, as per usual. If it becomes necessary to bring you in for additional consultations outside of your scheduled appointments for any reason, you will receive financial assistance based on the distance between the hospital and your home. You will not receive any other form of compensation or gifts for participating in this study.

Alternative

If you are not enrolled in the Knee Care at Home group and do not participate in the remote sessions alongside your clinic-based rehabilitation, you will still have the option to access remote sessions after the study is finished. Please discuss with your orthopaedic surgeon or the principal investigator for guidance on next steps.

Confidentiality

The information obtained from this study may be utilized in scientific papers or seminars, but your name and other identifying details will not be disclosed. Any study-related documents will only include your patient number and/or initials.

Your identity and medical records will be kept confidential. While we will make every effort to maintain the confidentiality of your personal information, we cannot guarantee that it will not be disclosed if required by law. Organizations with access to research records for quality assurance and data analysis include the Ethics Committee of the Universidade de Évora and the Health Ethics Committee of the Hospital da Misericórdia de Évora.

All records are stored on a secure server, and only the orthopedic surgeon and the principal investigator have access to them. If any of your medical or research records need to be copied, your name and any other identifying information will be removed. No personal information, such as your name, address, or telephone number, will leave the Hospital da Misericórdia de Évora database.

All information collected for this investigation will be deleted or destroyed when it is no longer necessary. If necessary, any pictures taken will be erased or destroyed as soon as they are no longer needed.

Sharing the Results

We will not share any private information. We may update you on the findings of this clinical study before they are publicly available. You will be notified when the results are published in scientific journals or presented at scientific conferences. It is important to publish our research results so that other healthcare professionals can benefit from them.

Who to Contact?

If you have any questions, feel free to ask them now or at any point during the study, even after it has already begun. If you prefer to ask your questions later, you can reach out to us at:

José Alberto Frade Martins Parraça (Research Team Supervisor) / +351 963 341 093 / jparraca@uevora.pt

This document has been reviewed and approved by the Ethics Committee of the Universidade de Évora and the Health Ethics Committee of the Hospital da Misericórdia de Évora. These are committees whose role is to ensure that research participants are not harmed and that all ethical concerns are addressed.

PART II – CERTIFICATE OF CONSENT

Participant

I have read this consent form, or it has been read to me. I was allowed to ask questions about this study, and they were answered to my satisfaction. The risks and benefits were explained to me. I believe that I have not been unduly influenced by any member of the research team to participate in the study by any statement or implication. Any relationship (e.g., as an employee, student, or family member) I have with the research team has not influenced my decision to participate. I understand that I will receive a copy of this consent form after I sign it. I understand that my participation in this study is voluntary and that I may withdraw from the study at any time. I voluntarily agree to participate in this study.

I understand that information about me will be kept confidential, but that confidentiality is not guaranteed. I agree to allow the orthopaedic surgeon and the Knee Care at Home team to view necessary information from my medical records.

By signing this consent form, I do not waive any legal rights I have as a participant in a research study.

I agree to participate on this study. Yes □ No □

Name _____

Signature _____

Date ____/____ /_____

Witness and Illiterate

I witnessed the consent form being read accurately to the potential participant and had the opportunity to ask questions. I confirm that the person gave consent voluntarily.

Name _____ AND Thumb print of participant

Signature_____

Date ____/____ /_____

Researcher

I have read the information sheet carefully to the potential participant and have made sure, to the best of my knowledge, that the participant understands that the following steps will be taken:

		Yes	No
1.		☐	☐
2.		☐	☐
3.		☐	☐
4.		☐	☐
5.		☐	☐
6.		☐	☐
7.		☐	☐
8.		☐	☐
9.		☐	☐
10.		☐	☐

I confirm that the participant has had the opportunity to ask questions about the study and that I have answered all of participant's questions correctly and to the best of my knowledge. I confirm that the subject was not coerced into giving consent and that consent was freely and voluntarily given.

A copy of this informed consent form has been provided to the participant.

Name _____

Signature _____

Date ____/____ /_____

3. Consentimento Informado, Livre e Esclarecido (Portuguese)

Título do Estudo

Comparação da eficácia do Programa de Telereabilitação *Knee Care @ Home* com a Reabilitação Ambulatória Usual após a Reconstrução Cirúrgica do Ligamento Cruzado Anterior

Equipa de Investigação

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Doutor Gabriel Filipe Gonçalves Xavier

Doutoranda Joana Margarida dos Santos Alegrete

Licenciada Daniela Carmelo Pina

Patrocinadores

Comprehensive Health Research Centre (CHRC); Escola de Saúde e Desenvolvimento Humano da Universidade de Évora (ESDH-UE); Fundação para a Ciência e Tecnologia do Ministério da Ciência, Tecnologia e Ensino Superior (FCT-MCTES); Hospital da Misericórdia de Évora (HME)

Este Formulário de Consentimento Livre e Esclarecido tem duas partes:

- **Ficha de Informação (para partilhar informações sobre a nossa investigação).**
- **Certificado de Consentimento Informado, Livre e Esclarecido (para assinatura se concordar em participar).**

Ser-lhe-á entregue uma cópia do Formulário de Consentimento Livre e Esclarecido completo

PARTE I - FICHA DE INFORMAÇÃO

Está a ser-lhe pedido que participe num estudo clínico. Por favor, dedique algum tempo à leitura deste formulário de consentimento e fale com a equipa do estudo sobre quaisquer questões que possa vir a ter. Antes de decidir participar neste estudo pode falar com o seu cirurgião ortopédico, com os seus amigos e com os seus familiares. Este formulário de consentimento pode conter palavras que não entenda. Peça ao cirurgião ortopédico ou à equipa de investigação que lhe explique as palavras que não compreenda totalmente. A nossa equipa de investigação recebe apoio financeiro para levar a cabo este estudo.

Objetivo do Estudo

Após a sua reconstrução cirúrgica do ligamento cruzado anterior, gostaríamos de perceber até que ponto o programa de telerreabilitação *Knee Care @Home,* usado como suplemento a sessões presenciais de reabilitação (reabilitação ambulatória), se compara às sessões presenciais de reabilitação (reabilitação ambulatória) sem este suplemento e quais os seus efeitos nestes fatores relacionados ao seu joelho: dor, sintomas, qualidade de vida, inchaço, derrame, amplitude de movimento, força e comprimento muscular, função e desempenho funcional. Esperamos também avaliar até que ponto recebe e segue, o programa de telerreabilitação *Knee Care @Home*.

Participantes

Na consulta pré-operatória, estamos a convidar todos os adultos, independentemente do sexo, que necessitem de ser operados ao ligamento cruzado anterior do joelho, no departamento de ortopedia do Hospital da Misericórdia de Évora. Após a sua cirurgia e duas semanas após a sua alta do hospital, o seu cirurgião ortopédico avaliará, se é ou não elegível, para participar neste estudo. Contamos com um total de 56 participantes para esta segunda fase.

Participação Voluntária, Alternativas à Participação, Direito de Recusa ou Retirada

Cabe-lhe a si decidir se quer participar ou não. Quer opte por participar ou não, os serviços que irá receber no Hospital da Misericórdia de Évora permanecerão os mesmos. Continuará a receber todos os serviços que normalmente receberia. Mesmo que inicialmente tenha concordado em participar no estudo, poderá mais tarde mudar de ideias e decidir não o fazer. Isto não afetará de forma alguma, os seus cuidados neste Hospital.

Procedimentos e Protocolo

Todos os adultos, independentemente do sexo, com cirurgia programada para o ligamento cruzado anterior do joelho, no departamento ortopédico do Hospital da Misericórdia de Évora, receberão este documento com informação do estudo clínico e o consentimento informado durante a sua consulta pré-operatória com o cirurgião ortopédico. Na consulta, é-lhe pedido que leia atentamente este documento e que indique se está disponível para participar no estudo.

Na sua primeira consulta pós-operatória, duas semanas após a alta da sua cirurgia e do hospital, o seu cirurgião ortopédico avaliará se é elegível para o estudo clínico. A sua participação depende do seu consentimento. Ser-lhe-á pedido que participe no estudo se: (1) tiver entre 18 e 55 anos no momento da sua cirurgia; (2) tiver tido menos de 12 meses entre a lesão e a sua cirurgia; (3) tiver tido uma reconstrução do ligamento cruzado anterior com um enxerto; (4) tiver tido uma reparação primária unilateral e tiver um joelho saudável do outro lado; (5) for fluente em português; e (6) tiver acesso à Internet através de um computador pessoal, tablet ou smartphone.

Os pacientes considerados adequados pelo cirurgião ortopédico serão divididos aleatoriamente em dois grupos. Os grupos serão escolhidos como se estivesse a atirar uma moeda ao ar. O participante tem as mesmas hipóteses de ser colocado num dos dois grupos (grupo de reabilitação ambulatória usual ou grupo *Knee Care @Home*).

Se pertencer ao grupo reabilitação ambulatória usual, deve seguir as suas sessões presenciais de reabilitação (fisioterapia/terapia presencial). A conselho do seu cirurgião ortopédico e como procedimento típico após cirurgia reconstrutiva do ligamento cruzado anterior, deve ir a uma clínica, o mais rapidamente possível, para receber a reabilitação ambulatória. A reabilitação ambulatória (sessões presenciais de reabilitação) após a cirurgia pode demorar muito tempo e o tipo e o número de tratamentos podem variar consideravelmente. Note que a reabilitação ambulatória usual, que geralmente envolve sessões presenciais com um fisioterapeuta, não é fornecida pela equipa de investigação. Decidirá por si próprio, onde gostaria de ter as suas sessões de reabilitação ambulatória usual, dependendo do que lhe for mais conveniente (disponibilidade, custo e distância). A sua participação em sessões de reabilitação ambulatória usual é da maior importância e será aconselhado a não as negligenciar.

Se, por outro lado, pertencer ao grupo *Knee Care @Home*, receberá sessões de telerreabilitação em combinação com sessões presenciais de reabilitação (reabilitação ambulatória). Os mesmos princípios de reabilitação ambulatória descritos para o grupo de reabilitação ambulatória usual também se aplicam ao grupo *Knee Care @Home*. Por conseguinte, a sua participação em sessões presenciais de reabilitação é da maior importância e será aconselhado a não os negligenciar.

O programa de telerreabilitação *Knee Care @Home* é completamente gratuito e ser-lhe-á oferecido apenas como suplemento à reabilitação ambulatória. Espera-se que este programa utilize menos recursos e lhe dê mais controlo sobre a recuperação do joelho do que apenas com a reabilitação ambulatória. Os programas de telerreabilitação podem ajudar a melhorar a supervisão e a monitorizar o seu comportamento, à medida que tenta melhorar os seus resultados clínicos. Estes programas podem também apoiá-lo se tiver dificuldades de acesso aos serviços de reabilitação devido a custos, tempo de viagem ou outros inconvenientes.

Um profissional de exercício e saúde supervisionará, através de videoconferência, um programa de exercícios de 22 semanas que poderá realizar no conforto da sua própria casa. As sessões de telerreabilitação ocorrerão três vezes por semana com duração de 40 minutos cada. No total, esperamos que participe em 66 sessões ao longo de um período de 22 semanas. O programa de

telerreabilitação *Knee Care @Home* baseia-se em diretrizes internacionais e na experiência do seu cirurgião ortopédico. Além disso, o seu cirurgião ortopédico pode acompanhar e supervisionar o seu progresso durante as sessões de telerreabilitação. Se estiver preocupado com alguma fase especifica do programa de telerreabilitação, a equipa de investigação falará com o seu cirurgião ortopédico e procederá às alterações necessárias. Não sabemos se o programa de telerreabilitação *Knee Care @Home* combinado com a reabilitação ambulatória é melhor para a recuperação da sua cirurgia, ou se somente a reabilitação ambulatória basta, pelo que precisamos de comparar as duas.

Para evitar sobrecarregá-lo com tarefas, quer esteja num grupo ou no outro, será avaliado durante as consultas agendadas no período pós-operatório a contar da alta do hospital (semana 2, semana 4, semana 8, semana 12, semana 16, semana 20, e semana 24). Estas consultas estão cobertas pelo seu seguro de saúde e espera-se que tenham lugar durante a recuperação após a sua cirurgia. Nestes momentos, ser-lhe-á pedido que preencha alguns questionários para nos ajudar a compreender o impacto da reconstrução do ligamento cruzado anterior no seu joelho (dor, sintomas, função, qualidade de vida e inchaço) e como está a lidar com a situação. Também terá exames clínicos e físicos para verificar na efusão, amplitude de movimento, força muscular, comprimento muscular e desempenho funcional do joelho.

Ser-lhe-á pedido durante as sessões de avaliação, para não contar aos profissionais da equipa de investigação qual o grupo em que foi colocado. Isto é muito importante para não comprometer os resultados do estudo. Recordamos-lhe que não incorrerá em quaisquer custos adicionais relacionados com este estudo. Se for necessário chamá-lo para outras consultas fora aquelas que estão programadas, a equipa *Knee Care @Home* providenciará apoio financeiro. A equipa de investigação não verá os registos de avaliação até que o estudo esteja concluído. Esta é a melhor maneira de assegurar que a avaliação não é afetada pelas expectativas colocadas no programa de telerreabilitação.

Duração

A a sua participação será limitada ao período pós-operatório e às consultas de acompanhamento marcadas pelo seu cirurgião ortopédico (correspondentes ao procedimento pós-operatório habitual). A intervenção terá uma duração total de 22 semanas (por volta de 6 meses), com início na 2ª semana após a alta hospitalar. Durante este período, não será obrigado a visitar o Hospital da Misericórdia de Évora fora das suas consultas pós-operatórias agendadas, a menos que seja exigido por razões não relacionadas com o estudo. Note que o seu cirurgião ortopédico pode marcar uma consulta adicional na semana 38, após a alta hospitalar, que é o período habitual de seguimento nestas patologias.

Efeitos Secundários, Riscos e Desconforto

Não são esperados efeitos secundários ou riscos para os participantes deste estudo. Contudo, efeitos secundários tais como aumento da dor no joelho, inchaço e dores musculares poderão

ocorrer na segunda fase do estudo. Poderão ainda existir outros riscos ou problemas que ainda não temos conhecimento. Se necessário, o seu cirurgião ortopédico falará consigo sobre os mesmos. Deverá falar com o seu cirurgião ortopédico e com o supervisor da investigação se os efeitos secundários persistirem. Ser-lhe-ão dadas instruções sobre como proceder. Deverá estar coberto pelo seu seguro de saúde pessoal. No entanto, o nosso estudo está coberto pelo seguro de responsabilidade civil para estudos de investigação da Universidade de Évora.

Benefícios

Pode não haver benefícios para os participantes do grupo de reabilitação ambulatória usual, mas é provável que a sua participação nos ajude a encontrar a resposta para a questão da investigação. Nesta fase da investigação, pode não haver benefícios para a sociedade, mas é provável que as gerações futuras venham a beneficiar. Pode também ler quaisquer artigos científicos publicados e resumos de conferências, se assim o solicitar.

Se estiver inscrito no grupo KC@H, poderá beneficiar de:

- Acesso facilitado a serviços de reabilitação (especialmente para participantes que vivem em áreas remotas ou têm acesso limitado a instalações de reabilitação);
- Redução do número de tratamentos falhados;
- Redução de custos;
- Execução das intervenções no conforto da sua própria casa;
- Supervisão contínua (exercício de progresso e controlo).

Custos e Pagamento pela Participação

Este estudo não altera os seus procedimentos pós-operatórios normais. Todas as consultas programadas correspondentes às sessões de avaliação estão incluídas no seu seguro de saúde e não implicarão quaisquer custos adicionais. Os participantes no grupo *Knee Care @Home* não têm de pagar pelas sessões de telerreabilitação. Os custos das sessões presenciais de reabilitação ambulatória são cobertos pelo seu seguro de saúde (dependendo das condições da apólice) e/ou por si próprio, como habitualmente. Se for necessário agendar uma consulta de acompanhamento extraordinária, receberá apoio financeiro calculado com base no custo da consulta. É de salientar que não receberá qualquer outro benefício em dinheiro ou ofertas, se participar neste estudo.

Alternativa

Se não estiver incluído no grupo Knee Care @Home (sessões de telerreabilitação juntamente com as sessões presenciais de reabilitação ambulatória), terá a opção de aceder a sessões de telerreabilitação mais tarde, após a conclusão do estudo. Por favor, fale com o seu cirurgião ortopédico ou o supervisor da investigação sobre como proceder.

Confidencialidade

As informações deste estudo podem ser utilizadas em trabalhos científicos ou em seminários, mas o seu nome e outras informações de identificação não serão utilizadas ou partilhadas. Quaisquer documentos a seu respeito que façam parte do estudo, incluirão apenas o seu número de paciente e/ou iniciais.

Se a sua identidade constar dos seus registos médicos, estes serão também mantidos confidenciais. Embora façamos tudo para podemos manter as suas informações pessoais confidenciais, não podemos garantir que não serão divulgadas, uma vez que as suas informações pessoais serão partilhadas, se exigido por lei. As organizações que podem ver os registos de investigação para garantia de qualidade e análise de dados, incluem o Comité de Ética da Universidade de Évora ou o Comité de Ética da Saúde do Hospital da Misericórdia de Évora.

Todos os registos serão mantidos num servidor seguro e só o cirurgião ortopédico e o investigador principal da equipa terão acesso aos mesmos. Se algum dos seus registos médicos ou de investigação precisar de ser copiado, o seu nome e quaisquer outras informações que possam ser utilizadas para o identificar, serão removidas. Nenhuma informação pessoal, como o seu nome, morada ou número de telefone, deixará a base de dados do Hospital da Misericórdia de Évora. Todas as informações coletadas para esta investigação serão excluídas ou destruídas após a conclusão do estudo. Embora não seja nossa intenção tirar fotos, se necessário, elas serão apagadas ou destruídas após a conclusão do estudo

Partilha dos resultados

Nenhuma informação privada será partilhada. Poderemos informá-lo sobre os resultados obtidos a partir deste estudo clínico antes de os mesmos serem disponibilizados ao público. Será informado quando os resultados forem publicados em revistas científicas ou apresentados em conferências científicas. Os resultados da nossa investigação precisam de ser publicados para que outros profissionais de saúde possam aprender com eles.

Quem contactar?

Se tiver perguntas, pode fazê-las agora ou mais tarde, mesmo depois de o estudo ter começado. Se quiser fazer uma pergunta mais tarde, pode contactar-nos:

José Parraça (Supervisor da Equipa de Investigação) / +351 963 341 093 / jparraca@uevora.pt

Este documento foi revisto e aprovado pelo Comité de Ética da Universidade de Évora e pelo Comité de Ética da Saúde do Hospital da Misericórdia de Évora. Estas são comissões cujo papel é assegurar que os participantes na investigação não sejam prejudicados e que todas as preocupações éticas sejam abordadas.

PARTE II – CERTIFICADO DE CONSENTIMENTO LIVRE E EXCLARECIDO

Participante

Li este formulário de consentimento, ou ele foi-me lido. Foi-me dada a oportunidade de fazer perguntas sobre este estudo e elas foram respondidas a meu contento. Os riscos e benefícios foram-me explicados. Creio não ter sido indevidamente influenciado por nenhum membro da equipa de investigação para participar no estudo por qualquer declaração ou implicação. Qualquer relação que tenha com a equipa de investigação e/ou com a equipa médica (por exemplo, como empregado, estudante ou membro da família) não influenciou a minha decisão de participar. Compreendo que recebo uma cópia deste formulário de consentimento depois de o ter assinado. Compreendo que a minha participação neste estudo é voluntária e que posso retirar-me do estudo em qualquer altura. Concordo voluntariamente em participar neste estudo.

Compreendo que a informação sobre mim será mantida confidencial, mas que a confidencialidade não é garantida. Concordo em permitir que o cirurgião ortopédico e a equipa de *Knee Care @Home* possam consultar informação necessária para o estudo que possa derivar dos meus registos médicos.

Ao assinar este formulário de consentimento, não renuncio a quaisquer direitos legais que tenho como participante num estudo de investigação.

Concordo em participar neste estudo. **SIM •** **NÃO •**

Nome _____

Assinatura _____

Data ____/____ /_____

Testemunhas e Analfabetos

Testemunhei o formulário de consentimento a ser lido corretamente ao potencial participante e tive a oportunidade de fazer perguntas. Confirmo que a pessoa deu o seu consentimento voluntariamente.

Nome _____ e Impressão do polegar do participante

Assinatura_____

Date ____/____ /_____

Investigador

Li cuidadosamente a ficha de informação ao potencial participante e assegurei-me, tanto quanto sei, de que o participante compreende todas as informações prestadas.

	Yes	No
1.	☐	☐
2.	☐	☐
3.	☐	☐
4.	☐	☐
5.	☐	☐
6.	☐	☐
7.	☐	☐
8.	☐	☐
9.	☐	☐
10.	☐	☐

Confirmo que o participante teve a oportunidade de fazer perguntas sobre o estudo e que respondi a todas as perguntas do participante corretamente e com o melhor dos meus conhecimentos. Confirmo que o sujeito não foi coagido a dar o seu consentimento e que o consentimento foi dado livre e voluntariamente.

Foi fornecida uma cópia deste formulário de consentimento informado ao participante.

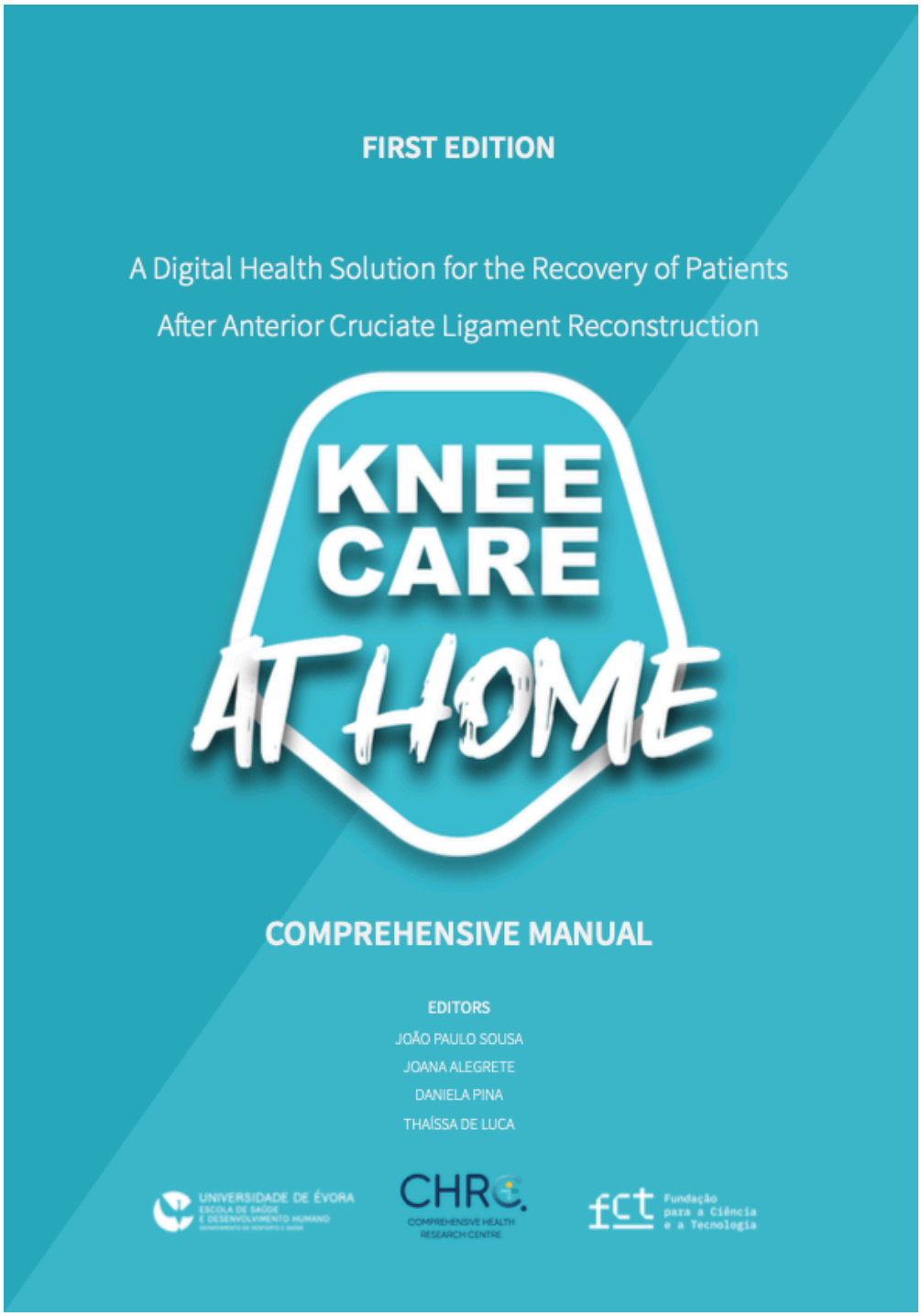
Nome _____

Assinatura _____

Data ____/____ /_____

4. Knee Care at Home Programme Manual (English)

Due to copyrights can be consulted, on demand, but not available as an appendix.



5. Knee Care at Home Programme Manual (Portuguese)

Due to copyrights can be consulted, on demand, but not available as an appendix.

CHAPTER IV – OVERALL SUMMARY

This master's dissertation aimed to explore emerging trends in rehabilitation services following ACLR, with a focus on DH solutions. We also aimed to delineate a feasibility assessment of a new DH solution, so called KC@H. In order to achieve this goal, we have created a protocol to act as a reference for both our team and future researchers.

With this research, we hope to help enlighten researchers on what has been developed so far in DH for ACL problems, but more importantly, we hope to provide new tools for future research and interventions in the field of ACL recovery and DH, as well as a guide on how we can develop a feasibility study.

To develop a home-based exercise program and an accompanying protocol to evaluate its feasibility, it was essential to review existing research in the field of DH related to ACLR.

The identification process initially involved 1174 records, which were then narrowed down to a final sample of 14 records based on eligibility criteria. Recruitment in these 14 records predominantly took place through the public sector, with a single center being utilized in most cases.

In terms of interventions, it is evident that some had already taken place prior to the onset of COVID-19, indicating that the advancement of DH was already underway before the significant rise of telehealth and telemedicine in 2020 and years after, and most of them did not have the purpose of replace CBRE. Among these interventions, mHealth emerged as the most widely used DHT. However, there has been a recent increase in the utilization of wearable devices, which is expected to streamline remote assessments and lower recovery expenses.

Over half of the articles conducted interventions lasting between the 13th and 24th week. We observed that the longer the intervention period, the more assessments were conducted. The assessments utilized various questionnaires to assess the participants' progress. Physical

assessments were conducted in person due to their complexity, suggesting a potential advancement in DH for the optimization of wearable devices capable of performing intricate measurements.

Studying literature about DH for ACL recovery was crucial to build and develop KC@H programme.

KC@H is a DH solution and was designed to enhance clinical rehabilitation by ensuring that the recommended rehabilitation time is completed. Compliance with this is a common challenge. The programme adheres to the recommended rehabilitation schedule and will take place three times a week, with each session lasting forty minutes of effective exercise. Sessions will be supervised by an exercise and healthcare coach via online synchronous session. Participants will need to perform various types of exercises based on their rehabilitation phase, including gait, core, strength, agility, plyometrics, balance, and range of motion exercises.

Evaluations were conducted during eight appointments and at each exercise session. Comprehensive physical assessments will be conducted in person, as sessions will not involve the use of wearable devices. Additionally, participants will be required to complete questionnaires, and perceived physical exertion, pain, adverse events, and technical issues will be assessed at every exercise session. Exercise and healthcare coaches will be responsible for monitoring exercise completion and patients' adherence, reporting adverse events, and addressing any technical issues that may arise during exercise sessions.

To achieve the effectiveness of the KC@H programme, we found it necessary to create a feasibility protocol as a way to evaluate all processes of enrolment, intervention fidelity, data collection, and acceptability. The scoping review was crucial research to identify the topics that require evaluation to achieve effectiveness. Evaluations will be accessible on a website developed by us to systematize

data collection. Surveys and interviews were created on the Limesurvey platform and linked to the KC@H website.

Through feasibility evaluations, we aim to enhance the KC@H intervention programme by offering constructive criticism and conducting detailed analysis to generate new ideas and increase effectiveness of the programme.

Globally, we hoped to have helped to clarify the current landscape of DH use in ACLR.